

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended June 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
(State or Other Jurisdiction of
Incorporation or Organization)

640 Lee Road, Suite 200
Wayne, PA

(Address of principal executive offices)

46-0571712
(I.R.S. Employer
Identification No.)

19087
(Zip Code)

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

N/A

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

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

Table with 3 columns: Title of Each Class, Trading Symbol(s), Name of Each Exchange on which Registered. Row 1: 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... Yes [X] 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... Yes [X] 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 [X]
Non-accelerated filer [ ] Smaller reporting company [X]
Emerging growth company [X]

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. [X]

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 [X]

The number of outstanding shares of the registrant's common stock, par value \$0.00001 per share, as of the close of business on August 5, 2019 was 41,368,224.

**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)

	June 30, 2019	December 31, 2018
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 31,654	\$ 57,019
Marketable securities	83,863	110,953
Accounts receivable, net	19,370	4,861
Inventory	185	791
Prepaid expenses and other current assets	2,822	5,875
Total current assets	137,894	179,499
Property and equipment, net	4,241	4,280
Intangible assets	69,781	72,951
Goodwill	—	18,504
Other assets	5,323	332
Total assets	<u>\$ 217,239</u>	<u>\$ 275,566</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 14,160	\$ 14,755
Accrued expenses	27,597	11,986
Current portion of lease liabilities	991	601
Total current liabilities	42,748	27,342
Other liabilities	5,120	1,703
Long-term debt	29,924	29,914
Contingent consideration	1,668	934
Deferred tax liability	549	549
Total liabilities	80,009	60,442
<b>Stockholders' Equity:</b>		
Preferred stock, \$0.00001 par value; 10,000,000 shares authorized and no shares issued or outstanding at June 30, 2019 and December 31, 2018	—	—
Common stock, \$0.00001 par value; 100,000,000 shares authorized at June 30, 2019 and December 31, 2018; 41,278,570 and 41,210,725 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	—	—
Additional paid-in capital	516,836	507,366
Accumulated other comprehensive loss	8	(69)
Accumulated deficit	(379,614)	(292,173)
Total stockholders' equity	137,230	215,124
Total liabilities and stockholders' equity	<u>\$ 217,239</u>	<u>\$ 275,566</u>

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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
<b>Revenues:</b>				
Product sales, net	\$ 4,979	\$ 1,533	\$ 8,757	\$ 1,533
Contract research	886	1,143	2,149	2,261
Other revenue	—	1,000	—	1,000
<b>Total revenue, net</b>	<b>5,865</b>	<b>3,676</b>	<b>10,906</b>	<b>4,794</b>
<b>Costs and expenses:</b>				
Cost of revenue (excludes amortization)	2,703	1,181	5,480	2,148
Research and development	17,622	13,984	37,541	27,590
Sales and marketing	7,177	12,368	17,008	23,601
General and administrative	7,990	8,121	16,180	14,381
Goodwill impairment	18,504	—	18,504	—
Amortization of definite-lived intangible	1,660	—	3,319	—
<b>Total costs and expenses</b>	<b>55,656</b>	<b>35,654</b>	<b>98,032</b>	<b>67,720</b>
<b>Loss from operations</b>	<b>(49,791)</b>	<b>(31,978)</b>	<b>(87,126)</b>	<b>(62,926)</b>
Other income (expense), net	(85)	760	(315)	1,479
<b>Net loss</b>	<b>\$ (49,876)</b>	<b>\$ (31,218)</b>	<b>\$ (87,441)</b>	<b>\$ (61,447)</b>
Net loss per share, basic and diluted	\$ (1.21)	\$ (1.01)	\$ (2.12)	\$ (1.99)
Weighted average common shares outstanding, basic and diluted	41,274,808	30,944,899	41,261,808	30,915,577
<b>Other comprehensive income (loss):</b>				
Unrealized gain on marketable securities, net of tax of \$0	\$ 30	\$ 111	\$ 64	\$ 46
Foreign currency translation adjustments	27	28	13	12
<b>Total other comprehensive income</b>	<b>57</b>	<b>139</b>	<b>77</b>	<b>58</b>
<b>Comprehensive loss</b>	<b>\$ (49,819)</b>	<b>\$ (31,079)</b>	<b>\$ (87,364)</b>	<b>\$ (61,389)</b>

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 Loss		Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value					
<b>Balance at December 31, 2018</b>	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)	
<b>Balance at March 31, 2019</b>	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)	
<b>Balance at June 30, 2019</b>	41,278,570	\$ —	\$ 516,836	\$ 8	\$ (379,614)	\$ 137,230	

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss		Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value					
<b>Balance at December 31, 2017</b>	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)	
<b>Balance at March 31, 2018</b>	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)	
<b>Balance at June 30, 2018</b>	30,965,296	\$ —	\$ 395,273	\$ (188)	\$ (220,882)	\$ 174,203	

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

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

(In thousands)

	Six Months Ended June 30,	
	2019	2018
<b>Cash flows from operating activities:</b>		
Net loss	\$ (87,441)	\$ (61,447)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,457	537
Stock-based compensation expense	9,676	10,392
Change in fair value of contingent consideration	734	866
Goodwill impairment charge	18,504	—
Changes in operating assets and liabilities:		
Accounts receivable	(14,509)	(1,701)
Inventory	606	(1,026)
Prepaid expenses and other assets	1,973	2,345
Accounts payable	(583)	4,693
Accrued expenses	13,887	1,636
Net cash used in operating activities	<u>(52,696)</u>	<u>(43,705)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(525)	(650)
Purchases of marketable securities	(89,407)	(74,246)
Proceeds from sales and maturities of marketable securities	117,500	144,375
Net cash provided by investing activities	<u>27,568</u>	<u>69,479</u>
<b>Cash flows from financing activities:</b>		
Finance lease payments	(240)	(335)
Proceeds from the exercise of employee stock options	3	394
Net cash (used in) provided by financing activities	<u>(237)</u>	<u>59</u>
Net increase (decrease) in cash and cash equivalents	(25,365)	25,833
Cash and cash equivalents at beginning of period	57,019	20,202
Cash and cash equivalents at end of period	<u>\$ 31,654</u>	<u>\$ 46,035</u>
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Additions to property and equipment included in accounts payable	\$ 392	\$ 442
Property and equipment obtained pursuant to capital lease financing arrangements	\$ —	\$ 1,896
Offering costs included in accounts payable	\$ —	\$ 20

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

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

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

**1. Organization and Nature of Business**

**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 and dermatological diseases. The Company currently has two commercial products and a diverse pipeline of drug candidates. RHOFADÉ (oxymetazoline hydrochloride) cream, 1% (“RHOFADÉ”) was approved by the U.S. Food and Drug Administration (“FDA”) in January 2017 for the topical treatment of persistent facial erythema (redness) associated with rosacea in adults. 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 FDA in December 2017 as an office-based prescription treatment for raised seborrheic keratosis (“SK”), a common non-malignant skin tumor. The Company launched ESKATA in the United States in May 2018. In August 2019, the Company voluntarily discontinued the commercialization of ESKATA in 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, both in the United States and worldwide (excluding Canada).

**Liquidity**

The Company’s condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. At June 30, 2019, the Company had cash, cash equivalents and marketable securities of \$115,517 and an accumulated deficit of \$379,614. Since inception, the Company has incurred net losses and negative cash flows from its operations. Prior to the acquisition of Confluence in August 2017, the Company had never generated any revenue. There can be no assurance that profitable operations will ever be achieved, and, if achieved, will be sustained on a continuing basis. In addition, development activities, clinical and preclinical testing of the Company’s drug candidates, and commercialization of the Company’s marketed product(s) will require significant additional financing. The future viability of the Company is dependent on its ability to generate cash from operating activities or to raise additional capital to finance its operations. The Company’s failure to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

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

### **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 June 30, 2019, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2019 and 2018, the condensed consolidated statement of stockholders' equity for the three and six months ended June 30, 2019 and 2018, and the condensed consolidated statements of cash flows for the six months ended June 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 June 30, 2019, the results of its operations and comprehensive loss for the three and six months ended June 30, 2019 and 2018, its changes in stockholders' equity for the three and six months ended June 30, 2019 and 2018 and its cash flows for the six months ended June 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 six months ended June 30, 2019 and 2018 are unaudited. The results for the three and six months ended June 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 other than those noted below.

### **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 sells RHOFADÉ, and during the three and six months ended June 30, 2019 and 2018 sold ESKATA, to a limited number of wholesalers in the United States (collectively, its “Customers”). These Customers subsequently resell the Company’s products to pharmacies and health care providers. In addition to distribution agreements with Customers, the Company has entered and may continue to enter into arrangements with health care providers, third-party payors, pharmacy benefit managers, and/or group purchasing organizations (“GPOs”) which provide for government mandated or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of the Company’s marketed product(s). The Company discontinued selling ESKATA in August 2019.

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 may provide Customers with trade discounts, rebates, allowances or 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 has contracted and may continue to contract with certain third-party payors, primarily health insurance companies, pharmacy benefit managers and/or government programs, for the payment of rebates with respect to utilization of its marketed product(s). The Company also has agreements with GPOs that provide for administrative fees and discounted pricing in the form of volume-based rebates. The Company is also subject to discount obligations under state Medicaid programs and Medicare. The Company records an estimate for these rebates as a reduction of revenue in the same period the revenue is recognized.

*Other Incentives* - Other incentives includes 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 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 goods 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 estimates 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.

Product sales, net consisted of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
ESKATA	\$ 272	\$ 1,533	\$ 344	\$ 1,533
RHOFADE	4,707	—	8,413	—
Total product sales, net	\$ 4,979	\$ 1,533	\$ 8,757	\$ 1,533

#### *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 six months ended June 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 \$185 and \$791 of inventory as of June 30, 2019 and December 31, 2018, respectively, which was comprised primarily of finished goods.

## **Intangible Assets**

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

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

## **Goodwill**

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

During the three months ended June 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 dermatology 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 three months ended June 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 94% of aggregate gross revenues from product sales and contract research revenue for the six months ended June 30, 2019. The Company's top five customers represented 87% of aggregate gross revenues from product sales and contract research revenue for the six months ended June 30, 2018. The Company currently relies on Allergan Sales, LLC ("Allergan") to distribute RHOFADÉ on its behalf pursuant to the terms of a transition services agreement. Accounts receivable, net as of June 30, 2019 and December 31, 2018 included \$18,532 and \$4,298, respectively, related to amounts invoiced by Allergan for sales of RHOFADÉ pursuant to the terms of the transition services agreement.

The Company is dependent on third-party manufacturers to supply products for commercial distribution, as well as for 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 and 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:

	June 30, 2019			Total
	Level 1	Level 2	Level 3	
<b>Assets:</b>				
Cash equivalents	\$ 20,226	\$ —	\$ —	\$ 20,226
Marketable securities	—	83,863	—	83,863
<b>Total assets</b>	<b>\$ 20,226</b>	<b>\$ 83,863</b>	<b>\$ —</b>	<b>\$ 104,089</b>
<b>Liabilities:</b>				
Acquisition-related contingent consideration	\$ —	\$ —	\$ 1,668	\$ 1,668
<b>Total liabilities</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 1,668</b>	<b>\$ 1,668</b>

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

As of June 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 six months ended June 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 six months ended June 30, 2019.

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

	June 30, 2019			Fair Value
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	
Marketable securities:				
Corporate debt securities	\$ 16,872	\$ 20	\$ —	\$ 16,892
Commercial paper	25,834	—	—	25,834
Asset-backed securities	18,646	9	—	18,655
U.S. government agency debt securities	22,472	10	—	22,482
Total marketable securities	<u>\$ 83,824</u>	<u>\$ 39</u>	<u>\$ —</u>	<u>\$ 83,863</u>

	December 31, 2018			Fair Value
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	
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	<u>\$ 110,978</u>	<u>\$ —</u>	<u>\$ (25)</u>	<u>\$ 110,953</u>

#### 4. Property and Equipment, Net

Property and equipment, net consisted of the following:

	June 30, 2019	December 31, 2018
Computer equipment	\$ 1,360	\$ 1,292
Fleet vehicles	—	2,131
Finance lease right-of-use assets	2,557	—
Manufacturing equipment	607	604
Lab equipment	994	1,068
Furniture and fixtures	852	524
Leasehold improvements	336	332
Property and equipment, gross	<u>6,706</u>	<u>5,951</u>
Accumulated depreciation	<u>(2,465)</u>	<u>(1,671)</u>
Property and equipment, net	<u>\$ 4,241</u>	<u>\$ 4,280</u>

Depreciation expense was \$394 and \$296 for the three months ended June 30, 2019 and 2018, respectively, and was \$795 and \$499 for the six months ended June 30, 2019 and 2018, respectively.

**5. Intangible Assets**

Intangible assets consisted of the following:

	Remaining Life (years)	Gross Cost		Accumulated Amortization	
		June 30, 2019	December 31, 2018	June 30, 2019	December 31, 2018
RHOFADE product rights	9.4	\$ 66,415	\$ 66,229	\$ 3,871	\$ 552
Other intangible assets	8.1	751	751	143	106
Total definite-lived intangible assets		67,166	66,980	4,014	658
IPR&D	na	6,629	6,629	—	—
Total intangible assets, net		\$ 73,795	\$ 73,609	\$ 4,014	\$ 658

Amortization expense was \$1,679 and \$0 for the three months ended June 30, 2019 and 2018, respectively, and was \$3,356 and \$0 for the six months ended June 30, 2019 and 2018, respectively.

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

Year Ending December 31,	
2019	\$ 3,360
2020	6,717
2021	6,718
2022	6,717
2023	6,718
Thereafter	32,922
Total	\$ 63,152

**6. Accrued Expenses**

Accrued expenses consisted of the following:

	June 30, 2019	December 31, 2018
Employee compensation expenses	\$ 3,660	\$ 5,293
Sales discounts and allowances	18,415	2,650
Selling and marketing expenses	741	453
Research and development expenses	2,036	1,437
Professional fees	407	1,123
Other	2,338	1,030
Total accrued expenses	\$ 27,597	\$ 11,986



## **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, all of which was outstanding as of June 30, 2019, and did not draw the remaining \$35,000 that was available until March 31, 2019 under the Loan Agreement.

The Loan Agreement provides 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. All unpaid principal and accrued and unpaid interest will be due and payable on the maturity date. The Loan Agreement provides for an annual interest rate equal to the greater of (i) 8.35% and (ii) the 30-day U.S. LIBOR rate plus 6.25%. The Loan Agreement also provides for a final payment fee equal to 5.75% of the original principal amount of the term loans drawn under the Term Loan Facility, which final payment is due on October 1, 2023 or upon the prepayment of the facility or the acceleration of amounts due under the facility as a result of an event of default.

The Company has 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 Company also has the option to prepay the term loans in part, once in a three-month period, of an amount of \$2,000 or greater, subject to the same prepayment fees and other specified limitations.

The Term Loan Facility is collateralized by substantially all of the Company’s assets, except that the collateral does not include the Company’s intellectual property, and the Company has agreed not to encumber any of its intellectual property. The Loan Agreement contains customary representations, warranties and covenants by the Company. The Loan Agreement also contains specified financial covenants related to minimum consolidated future revenues of the Company.

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

## **8. Stockholders’ Equity**

### **Preferred Stock**

As of June 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 June 30, 2019 or December 31, 2018.

### **Common Stock**

As of June 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 June 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 June 30, 2019, 1,975,820 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 945,200 and 948,761 were outstanding as of June 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:

	Six Months Ended June 30,	
	2019	2018
Risk-free interest rate	2.53 %	2.63 %
Expected term (in years)	6.3	6.3
Expected volatility	101.70 %	95.78 %
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 June 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	28,500	7.66		
Exercised	(1,800)	1.52		
Forfeited and cancelled	(298,358)	24.08		
Outstanding as of June 30, 2019	<u>4,010,423</u>	\$ 20.18	7.23	\$ 345
Options vested and expected to vest as of June 30, 2019	<u>4,010,423</u>	\$ 20.18	7.23	\$ 345
Options exercisable as of June 30, 2019	<u>2,207,189</u> <sup>(1)</sup>	\$ 17.54	6.46	\$ 345

(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 six months ended June 30, 2019 was \$6.22 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 June 30, 2019:

	<u>Number of Shares</u>	<u>Weighted Average Grant Date Fair Value Per Share</u>
Outstanding as of December 31, 2018	626,407	\$ 20.30
Granted	1,517,042	6.27
Vested	(96,252)	22.02
Forfeited and cancelled	(87,610)	13.37
Outstanding as of June 30, 2019	<u>1,959,587</u>	\$ 9.67

**Stock-Based Compensation**

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Cost of revenue	\$ 223	\$ 190	\$ 429	\$ 366
Research and development	1,721	1,756	3,315	3,483
Sales and marketing	216	1,020	806	1,927
General and administrative	2,654	2,283	5,126	4,616
Total stock-based compensation expense	<u>\$ 4,814</u>	<u>\$ 5,249</u>	<u>\$ 9,676</u>	<u>\$ 10,392</u>

As of June 30, 2019, the Company had unrecognized stock-based compensation expense for stock options and RSUs of \$24,719 and \$15,151, respectively, which is expected to be recognized over weighted average periods of 2.15 years and 3.10 years, respectively.

## 10. Net Loss per Share

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
<b>Numerator:</b>				
Net loss	\$ (49,876)	\$ (31,218)	\$ (87,441)	\$ (61,447)
<b>Denominator:</b>				
Weighted average shares of common stock outstanding	41,274,808	30,944,899	41,261,808	30,915,577
Net loss per share, basic and diluted	\$ (1.21)	\$ (1.01)	\$ (2.12)	\$ (1.99)

The Company's potentially dilutive securities, which included stock options and RSUs, have been excluded from the computation of diluted net loss per share since the effect would be to reduce the net loss per share. Therefore, the weighted average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share is the same. The following table presents potential shares of common stock excluded from the calculation of diluted net loss per share for the three and six months ended June 30, 2019 and 2018. All share amounts presented in the table below represent the total number outstanding as of June 30, 2019 and 2018.

	June 30,	
	2019	2018
Options to purchase common stock	4,010,423	4,315,942
Restricted stock unit awards	1,959,587	532,756
Total potential shares of common stock	5,970,010	4,848,698

## 11. Leases

The Company has operating leases for office space and laboratory facilities, and finance leases for fleet vehicles leased for its sales force and laboratory equipment. The components of lease expense were as follows:

	Six Months Ended June 30, 2019
Operating lease expense	\$ 302
<b>Finance Leases:</b>	
Amortization of right-to-use assets	\$ 313
Interest expense	67
Total finance lease expenses	\$ 380

During the three and six months ended June 30, 2018 the Company recorded \$201 and \$478, 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:

	<b>June 30, 2019</b>
<b>Operating Leases:</b>	
Gross cost	\$ 5,207
Accumulated amortization	(177)
Operating lease right-of-use assets	<u>\$ 5,030</u>
Other current liabilities	\$ 488
Other liabilities	3,794
Total operating lease liabilities	<u>\$ 4,282</u>

## 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 leases automobiles for its sales force and other field-based employees under the terms of a master lease agreement with a third party. The lease term for each automobile begins on the date the Company takes delivery and continues for a period of four years.

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

	<b>June 30, 2019</b>
<b>Finance Leases:</b>	
Property and equipment, gross	\$ 2,557
Accumulated depreciation	(763)
Property and equipment, net	<u>\$ 1,794</u>
Other current liabilities	\$ 503
Other liabilities	1,173
Total finance lease liabilities	<u>\$ 1,676</u>

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

	<b>Six Months Ended June 30, 2019</b>
<b>Supplemental Cash Flow Lease Information:</b>	
Operating cash flows from operating leases	\$ 309
Operating cash flows from finance leases	61
Financing cash flows from finance leases	240
Leased assets obtained in exchange for new operating lease liabilities	\$ 3,060
<b>Weighted-Average Remaining Lease Term (in years):</b>	
Operating leases	7.19
Finance leases	2.74
<b>Weighted-Average Discount Rate:</b>	
Operating leases	10.10 %
Finance leases	6.94 %

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

<b>Year Ending December 31,</b>	<b>Operating Leases</b>	<b>Finance Leases</b>
2019	\$ 419	\$ 295
2020	909	567
2021	934	448
2022	959	180
2023	877	—
Thereafter	2,024	—
Total undiscounted lease payments	<u>6,122</u>	<u>1,490</u>
Less: unrecognized interest	(1,840)	(187)
Plus: residual value guarantees	—	373
Total lease liability	<u>\$ 4,282</u>	<u>\$ 1,676</u>

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.

## **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 six months ended June 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 three 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 June 30, 2019 and December 31, 2018.

### **Asset Purchase Agreement with Allergan**

In November 2018, the Company closed the acquisition of RHOFADÉ, which includes an exclusive license to certain intellectual property for RHOFADÉ, as well as additional intellectual property, from 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 has agreed to assume the obligation to pay specified royalties and milestone payments under agreements with Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc. Members of the Company's management team, including Neal Walker, Frank Ruffo and Stuart Shanler, as well as Anand Mehra, a member of the Company's board of directors, are former stockholders of Vicept Therapeutics, Inc., and Dr. Shanler is also a current member of Aspect Pharmaceuticals, LLC. In their capacities as current or former holders of equity interests in these entities, these individuals may be entitled to receive a portion of the potential future payments payable by the Company.

For the six months ended June 30, 2019, the Company incurred an expense of \$379 and \$0 related to royalties and milestones earned by Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc., respectively, under those agreements.

## **13. Agreements Related to Intellectual Property**

### **Asset Purchase Agreement – Allergan Sales, LLC**

In November 2018, the Company closed the acquisition of RHOFADÉ from Allergan pursuant to the Asset Purchase Agreement (see Note 12). The Company is obligated 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 RHOFADÉ have expired or, if later, November 30, 2028. The Company incurred royalties earned by Allergan under the Asset Purchase Agreement of \$471 and \$0 during the three months ended June 30, 2019 and 2018, respectively, and \$842 and \$0 during the six months



ended June 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.

**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 markets under the brand name ESKATA in the United States, in Canada for the treatment of SK. Under the agreement, Cipher is responsible for obtaining marketing approval in Canada for A-101 40% Topical Solution. The Company will supply Cipher with finished product under a supply agreement, and, if regulatory approval is obtained, Cipher will be responsible for distribution and commercialization of A-101 40% Topical Solution in Canada. Additionally, Cipher is responsible for all expenses related to regulatory and commercial activities for A-101 40% Topical Solution in Canada. In April 2018, the Company received an upfront payment of \$1,000 upon signing of the agreement and in October 2018, the Company received \$500 upon the achievement of a specified regulatory milestone. The Company can earn a remaining payment of \$500 upon the achievement of a specified regulatory milestone, and aggregate payments of \$1,750 upon the achievement of specified commercial milestones under the terms of the agreement with Cipher. Cipher will also be required to pay the Company a low double-digit percentage royalty on net sales of A-101 40% Topical Solution in Canada. The term of the agreement expires on the later of the expiration of applicable patents in Canada or the 15<sup>th</sup> anniversary of the first commercial sale of licensed product in Canada. Cipher submitted a New Drug Submission for A-101 40% Topical Solution for the treatment of raised SKs, which was accepted for review by Health Canada in December 2018.

**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 six months ended June 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 six months ended June 30, 2019 and 2018 due to the Company’s conclusion that a valuation allowance was required for those periods.

**15. Segment Information**

The Company has two reportable segments, dermatology therapeutics and contract research. The dermatology therapeutics segment is focused on identifying, developing and commercializing innovative therapies to address significant unmet needs for immuno-inflammatory and dermatological diseases. The Company currently markets and sells RHOFADÉ, which is a topical treatment for persistent facial erythema, or redness, associated with rosacea in adults. The Company sells RHOFADÉ to a limited number of wholesalers in the United States. These wholesalers subsequently resell RHOFADÉ to pharmacies and health care providers. The Company sold and marketed ESKATA in the United States during the six months ended June 30, 2019 and 2018 and subsequently 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 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 six months ended June 30, 2019 and 2018 are summarized in the tables below:

	<b>Dermatology</b>	<b>Contract</b>	<b>Corporate</b>	<b>Total</b>
	<b>Therapeutics</b>	<b>Research</b>	<b>and Other</b>	<b>Company</b>
<b><u>Three Months Ended June 30, 2019</u></b>				
Revenue, net	\$ 4,979	\$ 3,807	\$ (2,921)	\$ 5,865
Cost of revenue (excludes amortization)	1,709	3,819	(2,825)	2,703
Research and development	17,718	—	(96)	17,622
Sales and marketing	7,164	13	—	7,177
General and administrative	—	600	7,390	7,990
Goodwill impairment	18,504	—	—	18,504
Amortization of definite-lived intangible	1,660	—	—	1,660
Loss from operations	\$ (41,776)	\$ (625)	\$ (7,390)	\$ (49,791)

	<b>Dermatology</b>	<b>Contract</b>	<b>Corporate</b>	<b>Total</b>
	<b>Therapeutics</b>	<b>Research</b>	<b>and Other</b>	<b>Company</b>
<b><u>Three Months Ended June 30, 2018</u></b>				
Revenue, net	\$ 2,533	\$ 3,053	\$ (1,910)	\$ 3,676
Cost of revenue	152	2,621	(1,592)	1,181
Research and development	13,984	—	—	13,984
Sales and marketing	12,360	8	—	12,368
General and administrative	—	521	7,600	8,121
Loss from operations	\$ (23,963)	\$ (97)	\$ (7,918)	\$ (31,978)

	Dermatology	Contract	Corporate	Total
<b><u>Six Months Ended June 30, 2019</u></b>	<b><u>Therapeutics</u></b>	<b><u>Research</u></b>	<b><u>and Other</u></b>	<b><u>Company</u></b>
Revenue, net	\$ 8,757	\$ 8,995	\$ (6,846)	\$ 10,906
Cost of revenue (excludes amortization)	3,279	8,856	(6,655)	5,480
Research and development	37,732	—	(191)	37,541
Sales and marketing	16,976	32	—	17,008
General and administrative	—	1,113	15,067	16,180
Goodwill impairment	18,504	—	—	18,504
Amortization of definite-lived intangible	3,319	—	—	3,319
Loss from operations	\$ (71,053)	\$ (1,006)	\$ (15,067)	\$ (87,126)

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

### Intersegment Revenue

Revenue for the contract research segment included \$2,921 and \$1,910 for services performed on behalf of the dermatology therapeutics segment for the three months ended June 30, 2019 and 2018, respectively, and \$6,846 and \$3,293 for the six months ended June 30, 2019 and 2018, respectively. All intersegment revenue has been eliminated in the Company's condensed consolidated statement of operations.

### 16. Subsequent Events

*Linda Rosi v. Aclaris Therapeutics, Inc. et al.* On July 30, 2019, plaintiff Linda Rosi (the "Plaintiff") filed a purported class action complaint in the U.S. District Court for the Southern District of New York against the Company and certain of its executive officers (the "Defendants"), alleging violations by the Defendants of certain federal securities laws. Plaintiff alleges that the Defendants made misleading statements to investors about the Company's business, operations and prospects and failed 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. Plaintiff is seeking unspecified compensatory damages on behalf of herself and all persons and entities that purchased or otherwise acquired the Company's securities between May 8, 2018, and June 20, 2019. Defendants dispute the Plaintiff's claims and intend to defend the matter vigorously. The Company is unable to determine any potential liability or financial exposure which may be associated with this matter at this time.

## 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 and dermatological diseases. We currently have two commercial products and a diverse pipeline of drug candidates. In August 2019, we announced that we are undertaking a strategic business review of our commercial and research and development portfolio of assets to determine how to optimally deploy capital and maximize shareholder return.

RHOFADE (oxymetazoline hydrochloride) cream, 1%, or RHOFADE, was approved by the U.S. Food and Drug Administration, or FDA, in January 2017 for the topical treatment of persistent facial erythema (redness) associated with rosacea in adults. Persistent facial redness is the most common sign of rosacea in most skin types. We acquired RHOFADE, which includes an exclusive license to certain intellectual property for RHOFADE, as well as additional intellectual property, from Allergan Sales, LLC, or Allergan, in November 2018. We currently rely on Allergan to distribute RHOFADE on our behalf pursuant to the terms of a transition services agreement.

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 FDA in December 2017 as an office-based prescription treatment for raised seborrheic keratosis, or SK, a common non-malignant skin tumor. We launched ESKATA in the United States in May 2018. We have also received marketing authorizations for this product in select countries outside of the United States. 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, both in the United States and worldwide (excluding Canada). We made this decision due to the fact that revenues from product sales were insufficient for us to sustain continued commercialization as a result of the product not achieving sufficient market acceptance by physicians and patients, and not for efficacy or safety reasons.

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 our Phase 2 clinical trials, subjects treated

with A-101 45% Topical Solution achieved clinically and statistically significant outcomes for the primary and secondary endpoints of each of the trials. Based on the results from our Phase 2 clinical trials and our end of Phase 2 meeting with the FDA, we are evaluating a twice-weekly dosing regimen in our two Phase 3 pivotal clinical trials, which we refer to as THWART-1 and THWART-2, of A-101 45% Topical Solution as a potential treatment for common warts, which we initiated in September 2018. We completed enrollment of more than 1,000 patients in these two trials. We expect to report data from both of these trials in the second half of 2019. 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.

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, androgenetic alopecia, or AGA, also known as male or female pattern baldness, vitiligo and atopic dermatitis. The following summarizes the status of our Phase 2 clinical trials of ATI-501 and ATI-502:

*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 patients 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. We currently intend to seek a strategic partner to further develop ATI-502 for this indication.

*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. 6-month data were reported in June 2019 and 12-month data are expected in the fourth quarter of 2019. If the 12-month data from this trial are positive, we currently intend to seek a strategic partner to further develop ATI-502 for this indication.

*VITI-201 Topical* – This ongoing Phase 2 open-label uncontrolled clinical trial is evaluating the safety and efficacy of ATI-502 on the repigmentation of facial skin in 34 patients with vitiligo. Although an interim analysis at 6 months demonstrated evidence of repigmentation in some patients, the response rate has been slow and not sufficient to be clinically meaningful. ATI-502 has been observed to be generally well-tolerated and no treatment-related serious adverse events, or SAEs, have been reported to date. Based on this interim analysis, we have decided to discontinue the further development of ATI-502 for this indication.

*AD-201 Topical* – This Phase 2 open-label uncontrolled clinical trial evaluated the safety and efficacy of ATI-502 in 22 adult subjects with moderate-to-severe atopic dermatitis (*i.e.*, subjects who had a Physician's Global Assessment, or PGA, score of 3 or 4 on a 5 point scale). The primary objective was the assessment of safety and tolerability of ATI-502. In this trial, ATI-502 was observed to be generally well-tolerated and no treatment-related SAEs were reported. 7 of the 17 evaluable subjects, or 41%, met the secondary endpoint of achieving a PGA score of less than or equal to 1, with at least a two point change in the PGA score.

*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 SAEs 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. We currently intend to seek a strategic partner to further develop ATI-501 for this indication.

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 compound and oral, novel, small molecule selective MK2 inhibitor, 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 TNF $\alpha$ , IL-1 $\beta$ , 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 patients in August 2019. If we successfully complete the Phase 1 clinical trial, we expect to advance ATI-450 into two Phase 2 clinical trials: one in patients with rheumatoid arthritis and one in an additional inflammatory indication, which may include psoriasis, hidradenitis suppurativa, cryopyrin associated periodic syndrome (CAPS), or pyoderma gangrenosum.

We expect to submit an IND to the FDA for ATI-1777, an investigational compound and soft-JAK inhibitor, for the treatment of atopic dermatitis by the end of the first half of 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 is allowed by the FDA, 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 ITK inhibitors as a potential treatment for psoriasis, inflammatory dermatoses, or inflammatory bowel disease.

Since our inception, we have incurred significant operating losses. Our net loss was \$87.4 million for the six months ended June 30, 2019 and \$132.7 million for the year ended December 31, 2018. As of June 30, 2019, we had an accumulated deficit of \$379.6 million. We expect to incur significant expenses and operating losses related to product manufacturing, marketing, sales and distribution in the near term as we continue to commercialize our marketed product(s). In addition, our marketed product(s), and our drug candidates if approved, may not achieve commercial success. We also expect to incur significant expenses and operating losses for the foreseeable future as we advance our drug candidates from discovery through preclinical development and clinical trials. In addition, if we obtain marketing approval for any of our drug candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, we have incurred and expect to continue to incur significant costs associated with operating as a public company, including legal, accounting, investor relations and other expenses. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy.

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. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter

into such other agreements or arrangements when needed on commercially acceptable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our marketed product(s) or drug candidates.

## **Components of Our Results of Operations**

### **Revenue**

#### *Product Sales, net*

We began commercializing RHOFADÉ in the United States in December 2018. We currently rely on Allergan to distribute RHOFADÉ on our behalf pursuant to the terms of a transition services agreement. We sell RHOFADÉ to wholesalers in the United States, which, in turn, distribute it to pharmacies that will ultimately fill patient prescriptions. We may also enter into arrangements with health care providers, pharmacy benefit managers, third-party payors, and/or group purchasing organizations, or GPOs, which provide for government mandated or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of RHOFADÉ. We have no sales of RHOFADÉ in countries outside of the United States.

We discontinued sales of ESKATA in the United States in August 2019. During the six months ended June 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 have never sold ESKATA outside of the United States.

#### *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 six months ended June 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 cost of manufacturing the finished product forms of ESKATA and RHOFADÉ, as well as costs incurred in connection with the provision of contract research services to our clients through Confluence. Cost of revenue primarily includes:

### *Product sales*

- third-party cost of manufacturing and assembly of finished product forms of ESKATA and RHOFADÉ;
- depreciation of manufacturing equipment;
- product release and stability testing;
- warehousing and insurance costs;
- transition service costs payable to Allergan;
- royalty payments;
- Prescription Drug User Fee Act, or PDUFA, fees;
- non-cash charge to adjust the carrying-value of inventory to net realizable value;
- non-cash charge related to the fair value step-up of acquired RHOFADÉ inventory; and
- non-cash amortization of the intangible asset related to RHOFADÉ intellectual property.

### *Contract research*

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

## **Research and Development Expenses**

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

- expenses incurred under agreements with contract research organizations, or CROs, as well as investigative sites and consultants that conduct our clinical trials and preclinical studies;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials and commercial materials, including manufacturing validation batches;
- outsourced professional scientific development services;
- medical affairs 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 terms and timing of marketing approvals, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. We may never succeed in achieving marketing approval for any of our drug candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some drug candidates or focus on others. A change in the outcome of any of these variables with respect to the development of a drug candidate could mean a significant change in the costs and timing associated with the development of that drug candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

#### **Sales and Marketing Expenses**

Sales and marketing expenses include salaries and related costs for our field sales force, as well as personnel in our marketing and sales operations functions, including stock-based compensation, travel expenses, expenses related to leasing a fleet of vehicles for our field-based sales force, and recruiting expenses. Sales and marketing expenses also include costs of content development, advertising, sponsorships and attendance at dermatology conferences, and costs incurred under the transition services agreement with Allergan.

We anticipate continuing to incur sales and marketing expenses in the near term as we commercialize our marketed product(s) in the United States.

#### **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, costs incurred under the transition services agreement with Allergan, medical affairs activity related to marketed products, as well as payments made under a terminated related party sublease agreement and milestone payments under our finder's services agreement. We anticipate that our general and administrative expenses will continue to increase as a result of increased personnel costs, including

stock-based compensation, expanded infrastructure and higher consulting, legal and tax-related services associated with maintaining compliance with Nasdaq and SEC requirements, accounting and investor relations costs, and director and officer insurance premiums associated with being a public company.

#### **Other Income, Net**

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

#### **Critical Accounting Policies and Significant Judgments and Estimates**

This discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with 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 may provide customers with trade discounts, rebates, allowances or 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 have contracted and may continue to contract with certain third-party payors, primarily health insurance companies, pharmacy benefit managers and/or government programs, for the payment of rebates with respect to utilization of our products. We also have agreements with GPOs that provide for administrative fees and discounted pricing in the form of volume-based rebates. We are also subject to discount obligations under state Medicaid programs and Medicare. We record an estimate for these rebates as a reduction of revenue in the same period the revenue is recognized.

*Other Incentives* - Other incentives includes our co-pay assistance program which is intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by 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 goods 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 finite-lived and indefinite-lived assets. Finite-lived intangible assets are amortized over their estimated useful life based on the pattern over which the intangible assets are consumed or otherwise used up. If that pattern cannot be reliably determined, the straight-line method of amortization is used. Our finite-lived intangible assets consist of a research technology platform acquired through the acquisition of Confluence and the intellectual property rights related to RHOFAD. 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.

Finite-lived intangible assets are tested for impairment when events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. Indefinite-lived intangible assets are tested for impairment at least annually, which 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.

## **Goodwill**

Goodwill is not amortized, but rather is subject to testing for impairment at least annually, which we perform during the fourth quarter, or when indicators of an impairment are present. We consider each of our operating segments, dermatology therapeutics and contract research, to be a reporting unit since this is the lowest level for which discrete financial information is available. We attributed the full amount of the goodwill in connection with the acquisition of Confluence, or \$18.5 million, to our dermatology therapeutics segment. We perform an impairment test annually which is a qualitative assessment based upon current facts and circumstances related to operations of the dermatology 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 three months ended June 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 dermatology 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 three months ended June 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 six months ended June 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 \$2,132 and \$2,317, 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 June 30, 2019 and 2018**

	<u>Three Months Ended June 30,</u>		<u>Change</u>
	<u>2019</u>	<u>2018</u>	
	(In thousands)		
<b>Revenues:</b>			
Product sales, net	\$ 4,979	\$ 1,533	\$ 3,446
Contract research	886	1,143	(257)
Other revenue	—	1,000	(1,000)
Total revenue, net	<u>5,865</u>	<u>3,676</u>	<u>2,189</u>
<b>Costs and expenses:</b>			
Cost of revenue (excludes amortization)	2,703	1,181	1,522
Research and development	17,622	13,984	3,638
Sales and marketing	7,177	12,368	(5,191)
General and administrative	7,990	8,121	(131)
Goodwill impairment	18,504	—	18,504
Amortization of definite-lived intangible	1,660	—	1,660
Total costs and expenses	<u>55,656</u>	<u>35,654</u>	<u>20,002</u>
Loss from operations	<u>(49,791)</u>	<u>(31,978)</u>	<u>(17,813)</u>
Other income (expense), net	(85)	760	(845)
Net loss	<u>\$ (49,876)</u>	<u>\$ (31,218)</u>	<u>\$ (18,658)</u>

**Revenue**

Revenue was \$5.9 million for the three months ended June 30, 2019, compared to \$3.7 million for the three months ended June 30, 2018. Product sales, net included \$4.7 million and \$0.3 million from sales of RHOFADÉ and ESKATA, respectively, during the three months ended June 30, 2019. Product sales, net included \$1.5 million from sales of ESKATA during the three months ended June 30, 2018. We acquired RHOFADÉ in November 2018. Contract research revenue was \$0.9 million and \$1.1 million for the three months ended June 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 up-front payment of \$1.0 million we received upon signing of a license agreement with Cipher in April 2018.

**Cost of Revenue**

Cost of revenue was \$2.7 million for the three months ended June 30, 2019 included \$1.0 million and \$0.7 million of costs related to RHOFADÉ and ESKATA product sales, net, respectively, of which \$0.7 million represented royalties on sales of RHOFADÉ, and \$0.4 million related to a non-cash charge for the write-down of ESKATA finished inventory. We also incurred \$1.0 million of costs related to providing laboratory services to our clients through Confluence. Cost of revenue was \$1.2 million for the three months ended June 30, 2018 and was comprised of \$0.2 million of costs related to ESKATA product sales, net, and \$1.0 million of costs incurred to provide laboratory services to our clients through Confluence.

## Research and Development Expenses

The following table summarizes our research and development expenses:

	Three Months Ended June 30,		Change
	2019	2018	
	(In thousands)		
A-101 45% Topical Solution	\$ 4,403	\$ 507	\$ 3,896
JAK inhibitors	5,418	6,434	(1,016)
MK2 inhibitors	1,184	798	386
ESKATA	102	563	(461)
Personnel expenses	2,363	2,378	(15)
Change in contingent consideration	734	—	734
Other research and development expenses	1,697	1,548	149
Stock-based compensation	1,721	1,756	(35)
Total research and development expenses	<u>\$ 17,622</u>	<u>\$ 13,984</u>	<u>\$ 3,638</u>

Expenses related to A-101 45% Topical Solution increased primarily due to our ongoing Phase 3 clinical trials for the treatment of common warts 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 three months ended June 30, 2019. The increase in expenses for our MK2 inhibitors resulted primarily from preclinical development activities as we prepared to file an IND for ATI-450 and initiate a Phase 1 clinical trial. Other research and development expenses primarily included expenses for medical affairs activities related to RHOFAD and ESKATA as well as drug discovery. The change in contingent consideration during the three months ended June 30, 2019 was the result of updates to our assumptions as a result of the filing of an IND for ATI-450. The increase in other research and development expenses was primarily driven by drug discovery research related to our ITK inhibitors.

## Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses:

	Three Months Ended June 30,		Change
	2019	2018	
	(In thousands)		
Direct marketing and professional fees	\$ 1,604	\$ 4,651	\$ (3,047)
Personnel expenses	3,000	3,786	(786)
Other sales and marketing expenses	2,357	2,911	(554)
Stock-based compensation	216	1,020	(804)
Total sales and marketing expenses	<u>\$ 7,177</u>	<u>\$ 12,368</u>	<u>\$ (5,191)</u>

Direct marketing and professional fees decreased primarily due to expenses we incurred in the three months ended June 30, 2018 preparing for and commercially launching ESKATA which were not present in the current year period. Personnel expenses decreased primarily due to higher recruiting and incentive compensation costs included in the three months ended June 30, 2018 which resulted from the hiring of our field sales force, as well as turnover in our sales force during the three months ended June 30, 2019. Other sales and marketing expenses included sales operations, travel costs, depreciation and other miscellaneous expenses. The decrease in other sales and marketing expenses was primarily the result of costs related to our national sales meeting, employee training and samples fulfillment resulting from our launch



of ESKATA in 2018. The decrease in stock-based compensation was primarily driven by forfeitures of equity awards as the result of turnover in our sales force.

### General and Administrative Expenses

The following table summarizes our general and administrative expenses:

	Three Months Ended June 30,		Change
	2019	2018	
	(In thousands)		
Personnel expenses	\$ 2,136	\$ 1,756	\$ 380
Professional and legal fees	2,077	1,566	511
Facility and support services	652	571	81
Milestone payment	—	1,500	(1,500)
Other general and administrative expenses	471	445	26
Stock-based compensation	2,654	2,283	371
Total general and administrative expenses	<u>\$ 7,990</u>	<u>\$ 8,121</u>	<u>\$ (131)</u>

Personnel and stock-based compensation expenses increased due to increased headcount. Professional and legal fees included accounting, legal, medical affairs, costs incurred under the transition services agreement with Allergan, investor relations costs, as well as legal fees related to patents. The increase in professional and legal fees was primarily related to costs incurred under the transition services agreement with Allergan related to RHOFADÉ, which we acquired in November 2018, as well as medical affairs activities. 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 three months ended June 30, 2018 upon the achievement of a milestone as specified in the finder's services agreement with KPT Consulting, LLC.

### Goodwill Impairment

During the three months ended June 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 dermatology 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

During the three months ended June 30, 2019, we incurred \$1.7 million of non-cash amortization expense related to the intangible asset for RHOFADÉ intellectual property we acquired in November 2018.

### Other Income (Expense), net

The \$0.8 million decrease in other income (expense), net was primarily due to interest expense incurred on our debt which we borrowed in October 2018.

**Comparison of Six Months Ended June 30, 2019 and 2018**

	<u>Six Months Ended June 30,</u>		<u>Change</u>
	<u>2019</u>	<u>2018</u>	
	(In thousands)		
<b>Revenues:</b>			
Product sales, net	\$ 8,757	\$ 1,533	\$ 7,224
Contract research	2,149	2,261	(112)
Other revenue	—	1,000	(1,000)
Total revenue, net	<u>10,906</u>	<u>4,794</u>	<u>6,112</u>
<b>Costs and expenses:</b>			
Cost of revenue (excludes amortization)	5,480	2,148	3,332
Research and development	37,541	27,590	9,951
Sales and marketing	17,008	23,601	(6,593)
General and administrative	16,180	14,381	1,799
Goodwill impairment	18,504	—	18,504
Amortization of definite-lived intangible	3,319	—	3,319
Total costs and expenses	<u>98,032</u>	<u>67,720</u>	<u>30,312</u>
Loss from operations	<u>(87,126)</u>	<u>(62,926)</u>	<u>(24,200)</u>
Other income (expense), net	(315)	1,479	(1,794)
Net loss	<u>\$ (87,441)</u>	<u>\$ (61,447)</u>	<u>\$ (25,994)</u>

**Revenue**

Revenue was \$10.9 million for the six months ended June 30, 2019, compared to \$4.8 million for the six months ended June 30, 2018. Product sales, net included \$8.5 million and \$0.3 million of net revenue from sales of RHOFADÉ and ESKATA, respectively, during the six months ended June 30, 2019. Product sales, net included \$1.5 million from sales of ESKATA during the six months ended June 30, 2018. We acquired RHOFADÉ in November 2018. Contract research revenue was \$2.1 million and \$2.3 million for the six months ended June 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 up-front payment of \$1.0 million we received upon signing of a license agreement with CIPHER in April 2018.

**Cost of Revenue**

Cost of revenue was \$5.5 million for the six months ended June 30, 2019 and included \$2.3 million and \$1.0 million of costs related to RHOFADÉ and ESKATA product sales, net, respectively, of which \$1.2 million represented royalties on sales of RHOFADÉ, and \$0.4 million related to a non-cash charge for the write-down of ESKATA finished inventory. We also incurred \$2.2 million of costs related to providing laboratory services to our clients through Confluence. Cost of revenue was \$2.1 million for the six months ended June 30, 2018 and was comprised of \$0.2 million of costs related to ESKATA product sales, net, and \$1.9 million of costs incurred to provide laboratory services to our clients through Confluence.

## Research and Development Expenses

The following table summarizes our research and development expenses:

	Six Months Ended June 30,		Change
	2019	2018	
	(In thousands)		
A-101 45% Topical Solution	\$ 9,863	\$ 1,526	\$ 8,337
JAK inhibitors	11,063	11,715	(652)
MK2 inhibitors	3,419	1,435	1,984
ESKATA	390	1,248	(858)
Personnel expenses	4,874	4,345	529
Change in contingent consideration	734	866	(132)
Other research and development expenses	3,883	2,972	911
Stock-based compensation	3,315	3,483	(168)
Total research and development expenses	\$ 37,541	\$ 27,590	\$ 9,951

Expenses related to A-101 45% Topical Solution increased primarily due to our ongoing Phase 3 clinical trials for the treatment of common warts 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 six months ended June 30, 2019. The increase in expenses for our MK2 inhibitors resulted primarily from preclinical development activities as we prepared to file an IND for ATI-450 and initiate a Phase 1 clinical trial. Personnel expenses increased due to increased headcount. Other research and development expenses primarily included expenses for medical affairs activities related to RHOFAD and ESKATA as well as drug discovery. The increase in other research and development expenses was primarily driven by drug discovery research related to our ITK inhibitors. The change in contingent consideration during the six months ended June 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 six months ended June 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. The decrease in stock-based compensation was primarily driven by the timing of the issuance of the equity awards during the twelve months preceding June 30, 2019, as well as the relatively lower fair value of those awards.

## Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses:

	Six Months Ended June 30,		Change
	2019	2018	
	(In thousands)		
Direct marketing and professional fees	\$ 4,797	\$ 9,010	\$ (4,213)
Personnel expenses	6,549	7,658	(1,109)
Other sales and marketing expenses	4,856	5,006	(150)
Stock-based compensation	806	1,927	(1,121)
Total sales and marketing expenses	\$ 17,008	\$ 23,601	\$ (6,593)

Direct marketing and professional fees decreased primarily due to expenses we incurred in the six months ended June 30, 2018 preparing for and commercially launching ESKATA which were not present in the current year period. Personnel expenses decreased primarily due to higher recruiting and incentive compensation costs included in the six months ended June 30, 2018 which resulted from the hiring of our field sales force, as well as turnover in our sales force.

during the six months ended June 30, 2019. Other sales and marketing expenses included sales operations, travel costs, depreciation and other miscellaneous expenses. The decrease in stock-based compensation was primarily driven by forfeitures of equity awards as the result of turnover in our sales force.

### General and Administrative Expenses

The following table summarizes our general and administrative expenses:

	Six Months Ended June 30,		Change
	2019	2018	
	(In thousands)		
Personnel expenses	\$ 4,590	\$ 3,553	\$ 1,037
Professional and legal fees	4,179	2,685	1,494
Facility and support services	1,356	1,208	148
Milestone payment	—	1,500	(1,500)
Other general and administrative expenses	928	819	109
Stock-based compensation	5,127	4,616	511
Total general and administrative expenses	<u>\$ 16,180</u>	<u>\$ 14,381</u>	<u>\$ 1,799</u>

Personnel and stock-based compensation expenses increased due to increased headcount. Professional and legal fees included accounting, legal, medical affairs, costs incurred under the transition services agreement with Allergan, investor relations costs, as well as legal fees related to patents. The increase in professional and legal fees was primarily related to costs incurred under the transition services agreement with Allergan related to RHOFADÉ, which we acquired in November 2018, as well as medical affairs activities. 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 six months ended June 30, 2018 upon the achievement of a milestone as specified in the finder's services Agreement with KPT Consulting, LLC.

### Goodwill Impairment

During the six months ended June 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 dermatology 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

During the six months ended June 30, 2019, we incurred \$3.3 million of non-cash amortization expense related to the intangible asset for RHOFADÉ intellectual property we acquired in November 2018.

### Other Income (Expense), net

The \$1.8 million decrease in other income (expense), net was primarily due to interest expense incurred on our debt which we borrowed in October 2018.

## **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. As described below, in October 2018 we also entered into a loan facility with an institutional lender.

As of June 30, 2019, we had cash, cash equivalents and marketable securities of \$115.5 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view towards liquidity and capital preservation.

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

### **Loan and Security Agreement with Oxford**

In October 2018, we entered into a loan and security agreement, or the Loan and Security Agreement, with Oxford Finance LLC, or 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, and did not draw the remaining \$35.0 million that was available until March 31, 2019 under the agreement. The Loan and Security Agreement provides for interest only payments through the payment date immediately prior to November 1, 2021, followed by 24 consecutive equal monthly payments of principal and interest in arrears starting on November 1, 2021 and continuing through the maturity date of October 1, 2023. All unpaid principal and accrued and unpaid interest will be due and payable on the maturity date. The Loan and Security Agreement provides for an annual interest rate equal to the greater of (i) 8.35% and (ii) the 30-day U.S. LIBOR rate reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue plus 6.25%. The Loan and Security Agreement also provides for a final payment equal to 5.75% of the original principal amount of the term loans drawn, which final payment is due on October 1, 2023 or upon the prepayment of the facility or the acceleration of amounts due under the facility as a result of an event of default.

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

**Cash Flows**

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

	<b>Six Months Ended June 30,</b>	
	<b>2019</b>	<b>2018</b>
	<b>(In thousands)</b>	
Net cash used in operating activities	\$ (52,696)	\$ (43,705)
Net cash provided by investing activities	27,568	69,479
Net cash provided by (used in) financing activities	(237)	59
Net increase (decrease) in cash and cash equivalents	<u>\$ (25,365)</u>	<u>\$ 25,833</u>

**Operating Activities**

During the six months ended June 30, 2019, operating activities used \$52.7 million of cash primarily resulting from our net loss of \$87.4 million, partially offset by non-cash adjustments of \$33.4 million. Net cash provided by changes in our operating assets and liabilities during the six months ended June 30, 2019 consisted of a \$13.3 million increase in accounts payable and accrued expenses and a \$2.9 million decrease in prepaid expenses and other current assets, which were partially offset by a \$14.5 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 June 30, 2019, as well as the timing of vendor invoicing and payments. Expenses incurred, but not yet paid, as of June 30, 2019 primarily included sales discounts and allowances related to sales of RHOFADÉ, 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 pre-clinical development activities for ATI-450. The decrease in prepaid expenses and other current assets was due to research and development activities primarily related to pre-clinical development activities for ATI-450 and ATI-502 which concluded during the six months ended June 30, 2019 and sales and marketing expenses related to our national sales meeting which was held during the six months ended June 30, 2019. The increase in accounts receivable was primarily the result of sales of RHOFADÉ. Non-cash expenses of \$33.4 million were composed of a goodwill impairment charge of \$18.5 million, stock-based compensation expense of \$9.7 million, a charge of \$0.7 million related to the change in contingent consideration and depreciation and amortization expense of \$4.5 million.

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

### **Investing Activities**

During the six months ended June 30, 2019, investing activities provided \$27.6 million of cash, consisting of proceeds from sales and maturities of marketable securities of \$117.5 million, partially offset by purchases of marketable securities of \$89.4 million, and purchases of equipment of \$0.5 million.

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

### **Financing Activities**

During the six months ended June 30, 2019, financing activities used \$0.2 million of cash primarily related to finance lease payments.

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

### **Funding Requirements**

We anticipate we will incur net losses in the near term as we continue to commercialize our marketed product(s), 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 complete the development and initiate commercialization of these programs if, among other things, our clinical trials are not successful or if the FDA does not approve our drug candidates currently in clinical trials when we expect, or at all.

Our primary uses of capital are, and we expect will continue in the near term to be, compensation and related expenses, clinical costs, external research and development services, laboratory and related supplies, sales, marketing and advertising costs, legal and other regulatory expenses, and administrative and overhead costs. In addition, we are investing in a new research facility for our drug discovery operations. Our future funding requirements will be heavily determined by the resources needed to support the commercialization of our marketed product(s), as well as 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.

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 commercialize A-101 45% Topical Solution for the treatment of common warts, if approved, 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 may need to substantially curtail our planned operations and the pursuit of our growth strategy.

We may raise additional capital through the sale of equity or debt securities. In such an event, your ownership will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of a holder of our common stock.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical drugs, we are unable to estimate the exact amount of our working capital requirements. Our 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 pre-clinical and clinical trials for our drug candidates;
- the costs, timing and outcome of regulatory review of our drug candidates;
- the cost of commercializing our marketed product(s) and the costs and timing of future commercialization activities, including drug manufacturing, marketing, sales and distribution, for any of our drug candidates for which we receive marketing approval;
- the revenue received from commercial sales of our marketed product(s) and any of our drug candidates for which we receive marketing approval;
- our ability to establish collaborations to commercialize our products within and outside the United States;
- 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; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future products or drug candidates, if any, as a result of licenses to, or partnership or collaborations 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 terminated our lease for office space in Malvern, Pennsylvania in June 2019. 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.

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

In October 2018, we borrowed \$30.0 million under the Loan and Security Agreement with Oxford. Amounts borrowed under the Loan and Security Agreement are subject to interest only through October 2021, after which we will be required to make principal and interest payments through the maturity date of October 2023.

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 aggregate payments of up to \$80.0 million upon the achievement of specified pre-commercialization milestones, such as clinical trials and regulatory approvals. Further, we have agreed to pay up to an additional \$10.0 million to Rigel upon the achievement of a second set of development milestones. With respect to any products we commercialize under the agreement, we will pay Rigel quarterly tiered royalties on our annual net sales of each product developed using the licensed JAK inhibitors at a high single digit percentage of annual net sales, subject to specified reductions.

Under a stock purchase agreement with the selling stockholders of Vixen, we are obligated to make aggregate payments of up to \$18.0 million upon the achievement of specified pre-commercialization milestones for three products covered by the Vixen patent rights in the United States, the European Union and Japan, and aggregate payments of up to \$22.5 million upon the achievement of specified commercial milestones for products covered by the Vixen patent rights. We are also obligated to make 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.

Under the Asset Purchase Agreement with Allergan pursuant to which we acquired intellectual property, we have agreed to pay Allergan royalties on net sales of RHOFAD E ranging from a mid-single digit percentage to a mid-teen percentage of net sales, subject to specified reductions, limitations and other adjustments, on a country-by-country basis until the date that the patent rights related to a particular product, such as RHOFAD E, have expired or, if later, November 30, 2028. In addition, we have agreed to assume the obligation to pay specified royalties and milestone payments under agreements with Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc. We have also agreed to pay Allergan a one-time payment of \$5.0 million upon the achievement of a specified development milestone related to the potential development of an additional dermatology product.

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.

The Loan and Security Agreement with Oxford provides 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%. To the extent that any present or future credit facilities that we enter into are based on a floating interest rate, we will be subject to risks relating to changes in market interest rates. In periods of rising interest rates when we have such debt outstanding, our interest expense would increase. Based upon our debt outstanding under the Loan and Security Agreement of \$30.0 million as of June 30, 2019, a 100 basis-point increase in the interest rate on our loan with Oxford would result in approximately \$304,000 of additional interest expense on an annualized basis.

### **Item 4. Controls and Procedures**

#### *(a) Evaluation of Disclosure Controls and Procedures*

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

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

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of June 30, 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 RHOFADÉ, 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 RHOFADÉ were \$4.7 million and \$8.4 million during the three and six months ended June 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 June 30, 2019 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. In connection with the acquisition of RHOFADÉ, management is in the process of analyzing and evaluating our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

*Linda Rosi v. Aclaris Therapeutics, Inc. et al.* On July 30, 2019, plaintiff Linda Rosi (the "Plaintiff") filed a purported class action complaint in the U.S. District Court for the Southern District of New York against us and certain of our executive officers (the "Defendants"), alleging violations by the Defendants of certain federal securities laws. Plaintiff alleges that the Defendants made misleading statements to investors about our business, operations and prospects and failed 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. Plaintiff is seeking unspecified compensatory damages on behalf of herself and all persons and entities that purchased or otherwise acquired our securities between May 8, 2018, and June 20, 2019. Defendants dispute the Plaintiff's claims and intend to defend the matter vigorously.

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 risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. Except as noted below, our risk factors have not changed materially from those described in “Part I, Item 1A. Risk Factors” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on March 18, 2019.

***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. Further, our obligations under the Loan and Security Agreement with Oxford are subject to acceleration upon the occurrence of specified events of default, including the delisting of our common stock on The Nasdaq Global Market.

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

Since our initial public offering, 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 to receive marketing approval of our drug candidates;
- unanticipated serious safety concerns related to the use of ESKATA, RHOFADÉ or any drug candidate;
- 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 addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical companies following periods of volatility in the market prices of these companies' stock. On July 30, 2019, one purported class action complaint was filed against us and certain of our executive officers alleging violations of certain federal securities laws. Defendants dispute the plaintiff's claims and intend to defend the matter vigorously. This case, and additional litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

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

None.

## Item 6. Exhibits

<b>Exhibit No.</b>	<b>Document</b>
3.1	<a href="#">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).</a>
3.2	<a href="#">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).</a>
31.1*	<a href="#">Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act.</a>
31.2*	<a href="#">Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act.</a>
32.1**	<a href="#">Certifications of Principal Executive Officer and Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act.</a>
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

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\* 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.

### SIGNATURES

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

ACLARIS THERAPEUTICS, INC.

Date: August 8, 2019

By: /s/ Neal Walker

Neal Walker  
President and Chief Executive Officer  
*(On behalf of the Registrant)*

Date: August 8, 2019

By: /s/ Frank Ruffo

Frank Ruffo  
Chief Financial Officer  
*(Principal Financial Officer)*

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

I, Neal Walker, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 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: August 8, 2019

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

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

I, Frank Ruffo, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 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: August 8, 2019

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

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

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

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 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 8<sup>th</sup> day of August, 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.

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