Dermira, Inc.
Form 10-Q
November 07, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2018

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number 001-36668

DERMIRA, INC.

(Exact name of registrant as specified in its charter)

Delaware	27-3267680
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

275 Middlefield Road, Suite 150

Menlo Park, CA 94025

(Address of principal executive offices) (Zip Code)

(650) 421-7200

(Registrant's telephone number, including area code)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 Exchange Act.

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

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

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

As of October 31, 2018, the registrant had 42,120,870 shares of common stock outstanding.

Dermira, Inc.

Quarterly Report on Form 10-Q

Index

PART I. FINANCIAL INFORMATION

ITEM 1. Financial Statements
DERMIRA, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	September 30, 2018 (unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 144,976	$295,923
Short-term investments	233,923	255,070
Trade and other receivables, net	2,114	52
Inventory	2,919	—
Prepaid expenses and other current assets	9,252	5,569
Total current assets	393,184	556,614
Property and equipment, net	1,300	1,433
Long-term investments	10,829	—
Intangible assets	976	1,126
Goodwill	771	771
Restricted cash	801	800
Other assets	2,061	50
Total assets	$ 409,922	$560,794
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 13,465	$15,094
Accrued liabilities	31,084	25,115
Refund liability	—	10,000
Accrued payments related to acquired in-process research and development	29,727	50,161
Deferred revenue, current	—	4,988
Total current liabilities	74,276	105,358
Long-term liabilities:		
Deferred revenue, non-current	—	25,286
Convertible notes, net	280,764	279,389
Deferred tax liability	—	194
Other long-term liabilities	1,035	918
Total liabilities	356,075	411,145
Stockholders' equity:		
Common stock	42	42
Additional paid-in capital	727,184	703,215
Accumulated other comprehensive loss	(151)	(215)
Accumulated deficit	(673,228)	(553,393)

Total stockholders' equity	53,847	149,649
Total liabilities and stockholders' equity	$ 409,922	$560,794

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

DERMIRA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue:				
Product sales	$717	$—	$717	$—
Collaboration and license revenue	—	1,066	39,379	3,198
Total revenue	717	1,066	40,096	3,198
Costs and operating expenses:				
Cost of sales	237	—	237	—
Research and development	16,292	30,788	61,428	76,626
Acquired in-process research and development	—	128,555	—	128,555
Selling, general and administrative	49,510	19,754	120,790	44,667
Impairment of intangible assets	—	—	1,126	—
Total costs and operating expenses	66,039	179,097	183,581	249,848
Loss from operations	(65,322)	(178,031)	(143,485)	(246,650)
Interest and other income, net	2,198	1,721	5,969	3,585
Interest expense	(3,420)	(2,864)	(12,408)	(4,184)
Loss before taxes	(66,544)	(179,174)	(149,924)	(247,249)
Benefit for income taxes	—	—	194	—
Net loss	$(66,544)	$(179,174)	$(149,730)	$(247,249)
Net loss per share, basic and diluted	$(1.58)	$(4.30)	$(3.57)	$(6.15)
Weighted-average common shares used to compute net loss per share, basic and diluted	42,066	41,625	41,939	40,172

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

DERMIRA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss	$(66,544)	$(179,174)	$(149,730)	$(247,249)
Other comprehensive income:				
Unrealized gain on available-for-sale securities	19	125	64	166
Total comprehensive loss	$(66,525)	$(179,049)	$(149,666)	$(247,083)

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

DERMIRA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities		
Net loss	$(149,730)	$(247,249)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	398	252
Stock-based compensation	22,709	15,220
Acquired in-process research and development	—	128,555
Amortization of discount for payments related to acquired in-process research and development	4,566	252
Net amortization of premiums on available-for-sale securities	44	1,939
Amortization of convertible note discount and issuance costs	1,375	686
Impairment of intangible assets	1,126	—
Changes in assets and liabilities:		
Trade and other receivables, net	(2,062)	21,400
Inventory	(1,973)	—
Prepaid expenses and other current assets	(2,614)	3,818
Other assets	(2,011)	63
Accounts payable	(2,053)	(3,759)
Accrued liabilities	5,881	9,507
Refund liability	(10,000)	—
Other long-term liabilities	117	191
Deferred revenue	(379)	(3,198)
Deferred taxes	(194)	—
Net cash used in operating activities	(134,800)	(72,323)
Cash flows from investing activities		
Purchases of available-for-sale securities	(258,116)	(225,924)
Maturities of available-for-sale securities	267,385	188,662
Payments pursuant to in-license agreements	(26,000)	—
Purchase of property and equipment	(595)	(49)
Net cash used in investing activities	(17,326)	(37,311)
Cash flows from financing activities		
Net proceeds from issuance of common stock in connection with equity financings	—	181,538
Net proceeds from issuance of convertible notes	—	278,252
Net proceeds from issuance of common stock in connection with equity awards	1,180	1,682
Net cash provided by financing activities	1,180	461,472
Net increase (decrease) in cash and cash equivalents and restricted cash	(150,946)	351,838
Cash and cash equivalents and restricted cash at beginning of year	296,723	42,293

Cash and cash equivalents and restricted cash at end of period	$145,777	$394,131
Supplemental disclosure of noncash investing activities		
Acquisition of in-process research and development	$—	$128,555

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

DERMIRA, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

1. Organization

We are a biopharmaceutical company dedicated to bringing biotech ingenuity to medical dermatology by delivering differentiated, new therapies to the millions of patients living with chronic skin conditions. We are committed to understanding the needs of both patients and physicians and using our insight to identify, develop and commercialize leading-edge medical dermatology clinical programs. Our approved treatment, QBREXZA™ (glycopyrronium) cloth ("QBREXZA"), is indicated for pediatric and adult patients (ages nine and older) with primary axillary hyperhidrosis (excessive underarm sweating). We are also evaluating lebrikizumab in a Phase 2b clinical trial for the treatment of moderate-to-severe atopic dermatitis (a severe form of eczema) and have early-stage research programs in other areas of dermatology. We are headquartered in Menlo Park, California.

2. Summary of Significant Accounting Policies

Basis of Presentation

Our condensed consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("U.S. GAAP") and applicable rules and regulations of the U.S. Securities and Exchange Commission ("SEC") for interim reporting. As permitted under those rules and regulations, certain footnotes or other financial information normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These condensed consolidated financial statements have been prepared on the same basis as our annual consolidated financial statements and, in the opinion of our management, reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair presentation of our financial information. The results of operations for the three- and nine-month periods ended September 30, 2018 are not necessarily indicative of the results to be expected for the full year ending December 31, 2018 or any other future period. The condensed consolidated balance sheet as of December 31, 2017 has been derived from audited consolidated financial statements at that date but does not include all of the information required by U.S. GAAP for complete financial statements. See "Recent Accounting Pronouncements" below for discussion of our adoption of the new revenue recognition guidance.

The accompanying condensed consolidated financial statements include the accounts of our wholly owned subsidiary, Dermira Canada. All intercompany accounts and transactions have been eliminated in consolidation.

The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with our audited consolidated financial statements and the related notes thereto for the year ended December 31, 2017 included in our Annual Report on Form 10-K, filed with the SEC on February 22, 2018.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets

and liabilities at the date of the condensed consolidated financial statements and reported amounts of revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition and variable consideration, inventory, acquired in-process research and development, investments, accrued research and development expenses, goodwill, intangible assets, other long-lived assets, stock-based compensation and the valuation of deferred tax assets. We base our estimates on our historical experience and also on assumptions that we believe are reasonable; however, actual results could significantly differ from those estimates.

Restricted Cash

Restricted cash primarily consists of letters of credit collateralized by a money market account pursuant to certain lease and sublease agreements. Cash and cash equivalents and restricted cash as reported within the condensed consolidated statements of cash flows for the nine months ended September 30, 2018 and 2017 consisted of the following (in thousands):

	Nine Months Ended September 30, 2018		Nine Months Ended September 30, 2017	
	Beginning of Period	End of Period	Beginning of Period	End of Period
Cash and cash equivalents	$295,923	$144,976	$41,793	$393,631
Restricted cash	800	801	500	500
Cash and cash equivalents and restricted cash as reported per statement of cash flows	$296,723	$145,777	$42,293	$394,131

Inventory

Inventory consists of raw materials, work-in-process and finished goods. Inventory costs are determined using the lower of standard cost, which approximates the actual costs determined using the first-in, first-out basis, or net realizable value. Standard costs are reviewed and updated annually or as needed. We expense costs associated with the manufacture of our products prior to regulatory approval and capitalize the cost of inventory when there is a high probability of future economic benefit. We began capitalizing the cost of inventory related to QBREXZA in the second quarter of 2018, the period in which we received regulatory approval to market the product. We are expensing costs associated with the manufacture of our lebrikizumab product candidate.

We review all inventory balances on a quarterly basis for impairment and recognize any reduction in value as a current period expense with a reserve provision on the consolidated balance sheets. If the conditions that caused the impairment were to be resolved in a subsequent period, the reserve provision would not be reversed until the related inventory was sold or otherwise disposed.

Revenue Recognition

Effective January 1, 2018, we adopted Accounting Standards Update (“ASU”) 2014-09, Revenue from Contracts with Customers (Topic 606) (“Topic 606” or “ASU 2014-09”) using the modified retrospective method which consisted of applying and recognizing the cumulative effect of Topic 606 at the date of initial application. Topic 606 supersedes the revenue recognition requirements in Accounting Standards Codification (“ASC”) Topic 605, Revenue Recognition (“Topic 605”), including most industry-specific revenue recognition guidance throughout the Industry Topics of the ASC. All periods prior to the adoption date of Topic 606 have not been restated to reflect the impact of the adoption of Topic 606, but continue to be accounted for and presented under Topic 605.

The following paragraphs in this section describe our revenue recognition accounting polices under Topic 606 upon adoption on January 1, 2018. Refer to Note 2 to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2017 for revenue recognition accounting policies under Topic 605.

We recognize revenue when we transfer promised goods or services to customers 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 for contracts with customers 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) we satisfy the performance obligations. At contract inception, we assess the goods or services promised within each contract and assess whether each promised good or service is distinct and determine those that are performance obligations. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Sales

Our product sales consist of sales of QBREXZA within the United States. Following the approval of QBREXZA by the U.S. Food and Drug Administration (“FDA”) in June 2018 and, in advance of the availability of QBREXZA in pharmacies on October 1, 2018, we commenced shipments of QBREXZA in September 2018 to wholesalers and a preferred dispensing partner (together, “Customers”) for distribution to pharmacies and patients. We recognize revenue from product sales when our Customers obtain control of our product, which is generally upon delivery.

Product sales are recognized at the transaction price, net of estimates of variable consideration, including commercial rebates, discounts related to a patient savings card program, distribution fees, trade discounts, government rebates and chargebacks and product returns. Variable consideration amounts are estimated at contract inception using the expected-value method and updated at the end of each reporting period as additional information becomes available. The amounts of variable consideration are included in the transaction price only to the extent it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved. Estimates and assumptions are updated quarterly and if actual future results vary materially from estimates, we will record an adjustment, which could impact product sales and earnings in the period of adjustment.

The following items of variable consideration are recorded at the time of revenue recognition and require significant estimates and judgment.

Commercial rebates and savings card program. We contract with certain third-party payers for the payment of rebates with respect to the utilization of QBREXZA. Rebates to these payers are based on contractual percentages applied to the amount of QBREXZA prescribed to patients who are covered by the plan or the organization with which we have contracts. We estimate and record rebates as a reduction to the transaction price in the same period the related product sales are recognized. We estimate commercial rebates based on contractual terms, estimated payer mix, industry information and other third-party data. We also have a savings card program to provide assistance to eligible patients with out-of-pocket costs, such as deductibles, co-insurance and co-payments, for the patient's usage of QBREXZA. Reductions to product sales for the savings card program are estimated based on actual and expected program utilization.

Distribution fees and trade discounts. We pay our Customers certain fees for distribution services for QBREXZA. We determined that such distribution services are not distinct from our sales of QBREXZA and the related fees are recorded as a reduction to the transaction price in the period the related product sales are recognized. Distribution fees are recorded based on contractual terms. We also incentivize prompt payment from our Customers by providing a discount for payments made within a certain number of days.

Government rebates and chargebacks. We are subject to discount obligations under state Medicaid programs, Medicare and other government programs. Reserves for these rebates and chargebacks are recorded as a reduction to the transaction price in the period the related product sales are recognized. Chargeback amounts represent credit we expect to issue to our Customers and are recorded as a reduction to trade and other receivables, net. Reductions to product sales for government managed programs are estimated based on statutorily-defined discounts, estimated payer mix, expected sales to qualified healthcare providers and expected utilization.

Product returns. Our product return policy provides our Customers the right to return QBREXZA, generally based on its expiration date. The reserve for product returns is recorded as a reduction to the transaction price in the period the related product sales are recognized. We estimate product returns using third-party input and market data for products with characteristics similar to QBREXZA.

Collaborative Arrangements

We enter into collaborative arrangements with partners that typically include payment to us of one of more of the following: (i) license fees; (ii) milestone payments related to the achievement of developmental, regulatory, or commercial goals; and (iii) royalties on net sales of licensed products. Where a portion of non refundable up-front fees or other payments received are allocated to continuing performance obligations under the terms of a collaborative arrangement, they are recorded as deferred revenue and recognized as revenue when (or as) the underlying performance obligation is satisfied.

As part of the accounting for these arrangements, we must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligation. The stand-alone selling price may include items such as forecasted revenues, development timelines, discount rates, and probabilities of technical and regulatory success. We evaluate each performance obligation to determine if it can be satisfied at a point in time or over time. In addition, variable consideration must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

License Fees

If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone Payments

At the inception of each arrangement that includes milestone payments (variable consideration), we evaluate whether the milestones are considered probable of being reached and estimate 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 transaction price. Milestone payments that are not within our or our collaboration partner's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration or other revenues and earnings in the period of adjustment.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any royalty revenue resulting from any of our collaborative arrangements.

Under certain collaborative arrangements, we have been reimbursed for a portion of our research and development ("R&D") expenses, including costs of drug supplies. When these R&D services are performed under a reimbursement or cost sharing model with our collaboration partner, we record these reimbursements as a reduction of R&D expense in our consolidated statements of operations.

Advertising Expenses

We expense the costs of advertising as incurred. Advertising expenses were $15.0 million and $36.5 million for the three and nine months ended September 30, 2018, respectively. Advertising expenses were immaterial for the three and nine months ended September 30, 2017.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration for dilutive potential shares of common stock. Diluted net loss per share is the same as basic net loss per share, since the effects of potentially dilutive securities are antidilutive for all periods presented.

The following common stock equivalent shares were not included in the computations of diluted net loss per share for the periods presented because their effect was antidilutive (in thousands):

	Outstanding as of September 30,	
	2018	2017
Stock options to purchase common stock	7,078	5,824
Shares subject to outstanding restricted stock units	1,650	301
Estimated shares issuable under the employee stock purchase plan	448	140
Shares issuable upon conversion of convertible notes	8,110	8,110
	17,286	14,375

Recent Accounting Pronouncements

In August 2018, the Financial Accounting Standards Board ("FASB") issued ASU 2018-13, Fair Value Measurement Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement ("ASU 2018-13"), which amends certain disclosure requirements over Level 1, Level 2 and Level 3 fair value measurements. ASU 2018-13 is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. Early adoption is permitted. We are currently evaluating the impact of adopting ASU 2018-13, but do not anticipate it will have a material impact on our disclosures.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash ("ASU 2016-18"), which requires that the statement of cash flows explain the change in the total amount of restricted cash during the period and other additional disclosures. We adopted ASU 2016-18 in the first quarter of 2018 using the retrospective transition method by restating our condensed consolidated statements of cash flows to include restricted cash balances. Net cash flows for the nine months ended September 30, 2018 and 2017 did not change as a result of adopting ASU 2016-18.

In February 2016, the FASB issued ASU 2016-02, Leases ("ASU 2016-02"). ASU 2016-02 is aimed at making leasing activities more transparent and comparable, and requires lessees to recognize substantially all leases on their balance sheet as a right-of-use asset and a corresponding lease liability, including leases currently accounted for as operating leases. We will adopt ASU 2016-02 on January 1, 2019. We anticipate recognizing a right-of-use asset and a lease liability on our consolidated balance sheet for the discounted value of future lease payments from the adoption of this ASU. As of September 30, 2018, we had aggregate future minimum lease payments of approximately $20.4 million. We are currently evaluating the full impact that the adoption of ASU 2016-02 will have on our consolidated financial statements and related disclosures.

As noted above, effective January 1, 2018, we adopted Topic 606. Since ASU 2014-09 was issued, several additional ASUs have been issued and incorporated within Topic 606 to clarify various elements of the guidance. As part of our adoption efforts, we completed the assessment of our collaboration and license agreements under Topic 606. We adopted Topic 606 in the first quarter of 2018 using the modified retrospective method which consists of applying and recognizing the cumulative effect of Topic 606 at the date of initial application and providing certain additional disclosures as defined per Topic 606. On January 1, 2018, we recorded a cumulative adjustment to decrease deferred revenue and accumulated deficit by approximately $29.9 million, to reflect the impact of the adoption of Topic 606. The cumulative adjustment related primarily to our agreements with Maruho Co., Ltd. ("Maruho") which are described further in Note 7 Collaboration and License Agreements.

Below is a summary of the affected line items of the condensed consolidated balance sheets upon adoption of Topic 606 (in thousands):

	Balance at December 31, 2017	Adjustments Due to Topic 606	Balance at January 1, 2018
Balance Sheet			
Deferred revenue, current	$4,988	$ (4,609)	$379
Deferred revenue, non-current	25,286	(25,286)	—
Accumulated deficit	$(553,393)	$ 29,895	$(523,498)

As a result of adopting Topic 606 on January 1, 2018 under the modified retrospective method, we did not revise the comparative financial statements for the prior years as if Topic 606 had been effective for those periods. Below is disclosure of what our collaboration and license revenue would have been in the three and nine months ended September 30, 2018 under Topic 605 (in thousands):

	Three Months Ended September 30, 2018			Nine Months Ended September 30, 2018		
	As Reported	Balances Without Adoption of ASU 2014-09	Effect of Change	As Reported	Balances Without Adoption of ASU 2014-09	Effect of Change
Statement of Operations						
Collaboration and license revenue	$—	$ 1,066	$ (1,066)	$ 39,379	$ 42,922	$ (3,543)

Our product sales revenue under Topic 606 would not have been materially different under Topic 605.

3. Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value should maximize the use of observable inputs and minimize the use of unobservable inputs. The accounting guidance for fair value establishes a three-level hierarchy for disclosure of fair value measurements, as follows:

Level 1—Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Inputs (other than quoted market prices included in Level 1) that are either directly or indirectly observable, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the instrument's anticipated life.

Level 3—Unobservable inputs that are supported by little or no market activity and reflect our best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Where quoted prices are available in an active market, securities are classified as Level 1. When quoted market prices are not available for the specific security, then we estimate fair value by using quoted prices for identical or similar instruments in markets that are not active and model based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Where applicable, these models project future cash flows and discount the future amounts to a present value using market based observable inputs obtained from various third party data providers, including but not limited to benchmark yields, reported trades and broker/dealer quotes. There were no transfers between Level 1 and Level 2 during the periods presented.

The following tables set forth the fair value of our financial assets, which consists of investments classified as available-for-sale securities, that were measured on a recurring basis (in thousands):

		As of September 30, 2018			
			Gross	Gross	
		Amortized	Unrealized	Unrealized	Fair
	Fair Value Hierarchy Level	Cost	Gains	Losses	Value
Financial assets:					
Money market funds	Level 1	$31,903	$ —	$ —	$31,903
U.S. Treasury securities	Level 1	118,953	—	(96)	118,857
Corporate debt	Level 2	115,556	5	(55)	115,506
Repurchase agreements	Level 2	32,000	—	—	32,000
U.S. Government agency securities	Level 2	8,973	—	(5)	8,968
Commercial paper	Level 2	75,975	—	—	75,975

Total investments		$383,360	$ 5	$ (156)	$383,209

		As of December 31, 2017			
		Amortized	Gross Unrealized	Gross Unrealized	Fair
	Fair Value Hierarchy Level	Cost	Gains	Losses	Value
Financial assets:					
Money market funds	Level 1	$187,649	$ —	$ —	$187,649
U.S. Treasury securities	Level 1	13,968	—	(5)	13,963
Corporate debt	Level 2	189,287	2	(194)	189,095
Repurchase agreements	Level 2	60,500	—	—	60,500
U.S. Government agency securities	Level 2	25,466	—	(18)	25,448
Commercial paper	Level 2	71,864	—	—	71,864
Total investments		$548,734	$ 2	$ (217)	$548,519

As of September 30, 2018, we did not hold any investments with a maturity exceeding two years or that have been in a continuous loss position for 12 months or more. We do not intend to sell the securities that are in an unrealized loss position and we believe it is more likely than not that the investments will be held until recovery of the amortized cost bases. We have determined that the gross unrealized losses on our securities as of September 30, 2018 were temporary in nature.

The estimated fair value of our convertible notes was $238.6 million as of September 30, 2018 and was based upon observable, Level 2 inputs, including pricing information from recent trades of the convertible notes as of September 30, 2018.

See Note 7 for information relating to payments which were measured using unobservable, Level 3 inputs, including a discount rate.

4. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Accrued outside research and development services	$ 7,848	$ 9,065
Accrued compensation	9,887	9,427
Accrued professional and consulting services	5,650	4,411
Accrued interest	3,258	1,102
Other	4,441	1,110
Total accrued liabilities	$ 31,084	$ 25,115

5. Impairment of in-process research and development

In connection with the acquisition of Valocor Therapeutics, Inc. (“Valocor”) in 2011, we acquired intangible assets that were associated with in-process research and development (“IPR&D”) projects relating to preclinical product candidates. These assets are considered to be indefinite lived and are not amortized, but are tested for impairment on an annual basis, as well as between annual tests if there are changes in circumstances that would indicate a reduction in the fair value of the IPR&D projects below their respective carrying amounts. If and when development is complete, the associated assets would be deemed finite lived and would then be amortized based on their respective estimated useful lives. In March 2018, we received results that the investigational treatment olumacostat glasaretil (formerly DRM01) did not meet the co-primary endpoints in its two Phase 3 pivotal trials (CLAREOS-1 and CLAREOS-2) in patients ages nine years and older with moderate-to-severe acne vulgaris. We determined that the intangible assets related to this product candidate were considered to be impaired and recorded an impairment charge of $1.1 million to IPR&D in the condensed consolidated statements of operations during the first quarter of 2018.

6. Convertible Notes

In May 2017, we sold $287.5 million aggregate principal amount of 3.00% Convertible Senior Notes due 2022 (“Notes”) in a private placement. We received net proceeds of $278.3 million, after deducting the initial purchasers’ discounts of $8.6 million and issuance costs of $0.6 million. The Notes were issued pursuant to an Indenture, dated as of May 16, 2017 (the “Indenture”), between us and U.S. Bank National Association, as trustee. The Notes are senior, unsecured obligations and bear interest at a rate of 3.00% per year, payable in cash semi-annually in arrears on May 15 and November 15 of each year, beginning on November 15, 2017. The Notes mature on May 15, 2022, unless earlier converted or repurchased in accordance with their terms.

The Notes are convertible into shares of our common stock, par value $0.001 per share, at an initial conversion rate of 28.2079 shares of common stock per $1,000 principal amount of the Notes, which is equivalent to an initial conversion price of approximately $35.45 per share of common stock. The conversion rate and the corresponding conversion price are subject to adjustment upon the occurrence of certain events, but will not be adjusted for any accrued and unpaid interest. Holders of the Notes who convert their Notes in connection with a make-whole fundamental change (as defined in the Indenture) are, under certain circumstances, entitled to an increase in the conversion rate. Additionally, in the event of a fundamental change, holders of the Notes may require us to repurchase all or a portion of their Notes at a price equal to 100% of the principal amount of Notes, plus any accrued and unpaid interest, including any additional interest to, but excluding, the repurchase date. Holders of the Notes may convert all or a portion of their Notes at their option at any time prior to the close of business on the business day immediately prior to May 15, 2022, in multiples of $1,000 principal amount.

As of September 30, 2018, there were unamortized issuance costs and debt discounts of $6.7 million, which were recorded as a direct deduction from the Notes on the condensed consolidated balance sheets.

7. Collaboration and License Agreements

Maruho Agreements

In March 2013, we entered into a Right of First Negotiation Agreement with Maruho Co., Ltd. ("Maruho Right of First Negotiation Agreement"), pursuant to which we provided Maruho with certain information and the right to negotiate an exclusive license to develop and commercialize certain of our products in specified territories. In connection with the entry into this agreement, Maruho paid us $10.0 million ("Maruho Payment"), which would be credited against certain payments payable by Maruho to us if we were to enter into a license agreement for any of our products. Maruho's right of first negotiation expired in December 2016 but the right to credit the Maruho Payment against certain payments under any future license agreement for our products remains. We concluded that there are no remaining performance obligations under Topic 606 as of the date of the adoption. As a result, a cumulative adjustment to reduce deferred revenue of $10.0 million was recorded upon the adoption of Topic 606 on January 1, 2018. As of September 30, 2018, we do not have a deferred revenue balance related to the Maruho Right of First Negotiation Agreement on the condensed consolidated balance sheets.

In September 2016, we entered into an Exclusive License Agreement with Maruho, which grants Maruho an exclusive license to develop and commercialize glycopyrronium tosylate for the treatment of hyperhidrosis in Japan ("Maruho G.T. Agreement"). Pursuant to the terms of the Maruho G.T. Agreement, we received an upfront payment of $25.0 million from Maruho in October 2016 and are eligible to receive additional payments totaling up to $70.0 million, contingent upon the achievement of certain milestones associated with submission and approval of a marketing application in Japan and certain sales thresholds, as well as royalty payments based on a percentage of net product sales in Japan. The Maruho G.T. Agreement further provides that Maruho will be responsible for funding all development and commercial costs for the program in Japan and, until such time, if any, as Maruho elects to establish its own source of supply of drug product, Maruho will purchase product supply from us for development and, if applicable, commercial purposes at cost. The Maruho G.T. Agreement is unrelated to, and the exclusive license of glycopyrronium tosylate in Japan to Maruho was not subject to the terms of, the existing Maruho Right of First Negotiation Agreement.

Under Topic 606, we evaluated the terms of the Maruho G.T. Agreement and the transfer of intellectual property rights (the "license") was identified as the only performance obligation as of the inception of the agreement. We concluded that the license for the intellectual property was distinct from our ongoing manufacturing obligations. We further determined that the transaction price under the arrangement was comprised of the $25.0 million upfront payment. The future potential milestone amounts were not included in the transaction price, as they were all determined to be fully constrained. As part of our evaluation of the development and regulatory milestones constraint, we determined that the achievement of such milestones is contingent upon success in future clinical trials and regulatory approvals, each of which is uncertain at this time. We will re-evaluate the transaction price each quarter and as uncertain events are resolved or other changes in circumstances occur. Future potential milestone amounts would be recognized as revenue from collaboration arrangements, if unconstrained. Reimbursable program costs are recognized proportionately with the performance of the underlying services or delivery of drug substance and are accounted for as reductions to R&D expense and are excluded from the transaction price.

Unless earlier terminated, the Maruho G.T. Agreement will remain in effect until the later of: (1) expiration or abandonment of the last valid claim of the applicable patent rights in Japan; (2) expiration of any market exclusivity in Japan granted by the applicable regulatory authority; and (3) 15 years following the date of the first commercial sale of the drug product in Japan.

Under Topic 606, the entire transaction price of $25.0 million was allocated to the license performance obligation. The license was deemed to be delivered in 2016 in connection with the execution of the agreement and the

performance obligation was fully satisfied. As a result, a cumulative adjustment to reduce deferred revenue of $19.6 million was recorded upon the adoption of Topic 606 on January 1, 2018. As of September 30, 2018, we do not have a deferred revenue balance related to the Maruho G.T. Agreement on the condensed consolidated balance sheet.

UCB Agreements

In March 2014, we and UCB Pharma S.A. (“UCB”), entered into a Development and Commercialisation Agreement, dated March 21, 2014 (“UCB Agreement”), which provided that we would (a) develop Cimzia (certolizumab pegol) for the treatment of psoriasis in order for UCB to seek regulatory approval from the U.S. Food and Drug Administration (“FDA”), the European Medicines Agency and the Canadian federal department for health, and (b) upon the grant of regulatory approval in the United States and Canada, promote sales of Cimzia to dermatologists and conduct related medical affairs activities in the United States and Canada. The UCB Agreement also provided either party with the right to terminate the agreement under certain terms. We expressed our intent to terminate the UCB Agreement in accordance with its terms.

As a result, we and UCB entered into an agreement on November 6, 2017 to effect the termination of the UCB Agreement and an orderly transition of the development and commercialization activities under the UCB Agreement from us to UCB ("Transition Agreement"). The Transition Agreement, among other things, (a) terminated the UCB Agreement on February 15, 2018, (b) provided for the repurchase by UCB of all product rights, licenses and intellectual property relating to Cimzia, (c) specified the responsibilities and obligations of us and UCB in connection with the transition of certain activities under the UCB Agreement from us to UCB as a result of the termination of the UCB Agreement, (d) terminated UCB's right to designate a director nominee to our board of directors and (e) provided for the resignation of UCB's designee from our board of directors.

Pursuant to the UCB Agreement, there were no termination or penalty payments required by either party. In consideration for the repurchase of all product rights, licenses and intellectual property relating to Cimzia, UCB paid us $11.0 million in November 2017 and an additional $39.0 million in June 2018 upon FDA approval of Cimzia for the treatment of psoriasis. We were obligated to reimburse UCB for up to $10.0 million of development costs incurred by UCB in connection with the development of Cimzia between January 1, 2018 and June 30, 2018. If the aggregate development costs reimbursed by us to UCB during this six-month period were less than $10.0 million, we were obligated to pay UCB the difference between such aggregate costs and $10.0 million. These terms replaced the provisions of the UCB Agreement pursuant to which we would have been eligible to recoup our external development costs incurred related to the Cimzia program, net of milestones received, through a royalty on future net sales of Cimzia. As of September 30, 2018, we have fully reimbursed UCB the $10.0 million for development costs incurred by UCB.

Under Topic 606, we evaluated the terms of the Transition Agreement and the transition services were identified as the only performance obligation as of the inception of the agreement. We further determined that the transaction price under the arrangement was comprised of $1.0 million, representing the net consideration from the $11.0 million payment received from UCB and the $10.0 million refund liability due to UCB. The $1.0 million transaction price was fully recognized as revenue as of June 30, 2018. The $39.0 million milestone amount payable upon the approval of Cimzia for the treatment of psoriasis in the United States was initially not included in the transaction price, as it was determined to be fully constrained. Upon UCB's receipt of FDA approval of Cimzia for the treatment of psoriasis in June 2018, the $39.0 million milestone payment was included in the transaction price and fully recognized during the three months ended June 30, 2018 as all performance obligations were satisfied. For the nine months ended September 30, 2018, we recognized $39.4 million in revenue in our condensed consolidated statement of operations related to UCB. No other revenue will be recognized from UCB in future periods pursuant to the Transition Agreement as all performance obligations have been satisfied and the entire transaction price has been recognized.

In-license Agreements

Roche Agreement

In August 2017, we entered into a licensing agreement ("Roche Agreement") with F. Hoffmann-La Roche Ltd and Genentech, Inc. (together, "Roche"), pursuant to which we obtained exclusive, worldwide rights to develop and commercialize lebrikizumab, an injectable, humanized antibody targeting interleukin 13, for atopic dermatitis and all other indications, except Roche retained certain rights, including exclusive rights to develop and promote lebrikizumab for interstitial lung diseases, such as idiopathic pulmonary fibrosis ("Retained Field"), and rights to use lebrikizumab for internal research purposes and for in vitro diagnostic purposes. The Roche Agreement became effective in September 2017 upon the early termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. Pursuant to the terms of the Roche Agreement, Roche relinquished its rights in the Retained Field effective July 13, 2018 and all of Roche's rights and all of our obligations with respect to the Retained Field expired. Accordingly, we have exclusive, worldwide rights to develop and commercialize lebrikizumab for all indications. Roche's rights to use lebrikizumab for internal research purposes and for in vitro

diagnostic purposes remain.

Under the terms of the Roche Agreement, we made an initial payment of $80.0 million to Roche in October 2017 and a $25.0 million payment to Roche in July 2018 upon the achievement of 50% enrollment in our Phase 2 clinical study of lebrikizumab, which was achieved in June 2018, and will make an additional payment to Roche in the fourth quarter of 2018 for $30.0 million related to the achievement of 100% enrollment in our Phase 2 clinical study of lebrikizumab in October 2018. We will also be obligated to make payments upon the achievement of certain milestones, comprising $40.0 million upon the initiation of the first Phase 3 clinical study, up to $210.0 million upon the achievement of regulatory and first commercial sale milestones in certain territories and up to $1.0 billion based on the achievement of certain thresholds for net sales of lebrikizumab for all indications. Upon regulatory approval, if obtained, we will make royalty payments representing percentages of net sales that range from the high single-digits to the high teens. Royalty payments will be made from the first commercial sale date in such country and end on the later of the date that is (a) ten years after the date of the first commercial sale of lebrikizumab in such country, (b) the expiration of the last to expire valid claim of the applicable licensed compound patent rights, our patent rights or joint patent rights in such country covering the use, manufacturing, import, offering for sale, or sale of lebrikizumab in such country, (c) the expiration of the last to expire valid claim of the applicable licensed non-compound patent rights in such country covering the use, import, offering for sale, or sale of the product in such country, or (d) the expiration of the last to expire regulatory exclusivity conferred by the applicable regulatory authority in such country for lebrikizumab.

We determined that the acquired IPR&D related to the Roche Agreement had no alternative future use and recorded an expense of $128.6 million during the year ended December 31, 2017 in the consolidated statements of operations as acquired in-process research and development expense. This expense was comprised of the initial payment of $80.0 million, which was made in October 2017, a $25.0 million milestone payment, which was made in July 2018, and an additional payment due in 2018 of $30.0 million. The payments due in 2018 were measured on a non-recurring basis using unobservable, Level 3 inputs, including a discount rate used to value the payments at present value as of the effective date of the Roche Agreement. As of September 30, 2018, on the condensed consolidated balance sheets, we recorded $29.7 million in accrued liabilities related to acquired in-process research and development for the $30.0 million payment which will be paid in the fourth quarter of 2018. The remaining milestone payments will be recognized when the contingency related to each milestone is resolved and the consideration is paid or becomes payable.

Rose U Agreement

In April 2013, we entered into an exclusive license agreement with Rose U LLC (“Rose U”) pursuant to which we obtained a worldwide exclusive license within a field of use including hyperhidrosis to practice, enforce and otherwise exploit certain patent rights, know how and data related to our hyperhidrosis program. The license agreement includes a sublicense of certain data and an assignment of certain regulatory filings which Rose U had obtained from Stiefel Laboratories, Inc., a GSK company (“Stiefel”). In connection with the license agreement, we also entered into a letter agreement with Stiefel pursuant to which we assumed Rose U’s obligation to pay Stiefel $2.5 million in connection with the commercialization of products developed using the licensed data and to indemnify Stiefel for claims arising from the use, development or commercialization of products developed using the Stiefel data.

As of September 30, 2018, we have paid or accrued license and other fees of $4.3 million to Rose U and Stiefel, including a $2.5 million accrual in connection with the first commercial sale of QBREXZA to be paid in the fourth quarter of 2018, and are required to pay Rose U additional amounts totaling up to $0.6 million upon the achievement of certain milestones. In addition, we are also obligated to pay Rose U low-to-mid single-digit royalties on net product sales and low double-digit royalties on sublicense fees and certain milestone, royalty and other contingent payments received from sublicensees, to the extent such amounts are in excess of the milestone and royalty payments we are obligated to pay Rose U directly upon the events or sales triggering such payments. We are entitled to credit the $2.5 million milestone against current and future royalty payments owed to Rose U in accordance with the terms of the

license agreement.

8. Inventory

Inventory consists of the following (in thousands):

	September 30, 2018	December 31, 2017
Raw materials	$ 1,144	$ —
Work-in process	781	—
Finished goods	994	—
Total inventory	$ 2,919	$ —

9. Stock-Based Compensation

The following table reflects a summary of stock option activity under our 2010 Equity Incentive Plan ("2010 Plan"), 2014 Equity Incentive Plan ("2014 EIP") and 2018 Equity Inducement Plan ("2018 Inducement Plan") and related information for the period from December 31, 2017 through September 30, 2018:

	Shares Subject to Outstanding Stock Options	Weighted-Average Exercise Price Per Share
Stock options outstanding at December 31, 2017	6,022	$ 19.15
Stock options granted	2,189	$ 22.14
Stock options exercised	(104)	$ 3.62
Stock options forfeited	(1,029)	$ 25.91
Stock options outstanding at September 30, 2018	7,078	$ 19.32

The following table reflects a summary of restricted stock unit ("RSU") activity under our 2014 EIP and 2018 Inducement Plan and related information for the period from December 31, 2017 through September 30, 2018:

	Shares Subject to Outstanding RSUs	Weighted-Average Grant Date Fair Value Per Share
RSUs outstanding at December 31, 2017	296	$ 30.81
RSUs granted	1,662	$ 12.65
RSUs vested and settled	(131)	$ 29.67
RSUs forfeited	(177)	$ 23.25
RSUs outstanding at September 30, 2018	1,650	$ 13.42

Total stock-based compensation expense related to the 2010 Plan, the 2014 EIP, the 2018 Inducement Plan and the 2014 Employee Stock Purchase Plan was allocated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	$2,511	$2,104	$7,772	$5,918
Selling, general and administrative	5,371	3,397	14,930	9,302
Total stock-based compensation expense	$7,882	$5,501	$22,702	$15,220

Total stock-based compensation expense capitalized to inventory was not material for any of the periods presented.

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

The interim financial statements included in this Quarterly Report on Form 10-Q and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the consolidated financial statements and notes thereto for the year ended December 31, 2017, included as part of our Annual Report on Form 10-K for the year ended December 31, 2017, and our unaudited Condensed Consolidated Financial Statements for the three- and nine-month periods ended September 30, 2018 and other disclosures (including the disclosures under "Part II — Other Information, Item 1A. Risk Factors") included in this Quarterly Report on Form 10-Q. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended ("Exchange Act"). These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "pote "predict," "project," "estimate," or "continue," and similar expressions or variations. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Factors that could cause or contribute to these differences include those set forth elsewhere in this Quarterly Report on Form 10-Q, particularly in Part II — Other Information, Item 1A. Risk Factors below, that could cause actual results to differ materially from historical results or anticipated results. Except as may be required by law, we disclaim any obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

We are a biopharmaceutical company dedicated to bringing biotech ingenuity to medical dermatology by delivering differentiated, new therapies to the millions of patients living with chronic skin conditions. We are committed to understanding the needs of both patients and physicians and using our insight to identify, develop and commercialize leading-edge medical dermatology clinical programs. Our management team has extensive experience in product development and commercialization, having served in leadership roles at several leading dermatology companies. Our approved treatment, QBREXZA™ (glycopyrronium) cloth ("QBREXZA"), is indicated for pediatric and adult patients (ages nine and older) with primary axillary hyperhidrosis (excessive underarm sweating). We are also evaluating lebrikizumab in a Phase 2b clinical trial for the treatment of moderate-to-severe atopic dermatitis (a severe form of eczema) and have early-stage research programs in other areas of dermatology.

Our portfolio consists of:

- QBREXZA, a topical, once-daily anticholinergic wipe that was approved by the U.S. Food and Drug Administration ("FDA") in June 2018 for the treatment of primary axillary hyperhidrosis in adult and pediatric patients nine years of age and older. Primary axillary hyperhidrosis is a medical condition with no known cause that results in sweating beyond what is needed for normal body temperature regulation. Anticholinergics are a class of pharmaceutical products that exert their effect by blocking the action of acetylcholine, a neurotransmitter that transmits signals within the nervous system that are responsible for a range of bodily functions, including the activation of sweat glands. QBREXZA is applied directly to the skin and is designed to block sweat production by inhibiting sweat gland activation. We began shipping QBREXZA to wholesalers and a preferred dispensing partner (together, "Customers") in September 2018, and QBREXZA became commercially available in pharmacies nationwide on October 1, 2018.
- Lebrikizumab, a novel, injectable, humanized monoclonal antibody targeting interleukin 13 ("IL-13") that we are developing for the treatment of moderate-to-severe atopic dermatitis. IL-13 is a naturally occurring cytokine that is thought to play an important role in mediating effects of inflammation on bodily tissues, including in patients with atopic dermatitis. Lebrikizumab is designed to bind to IL-13 with high affinity, specifically preventing formation of the IL-13 receptor/interleukin 4 ("IL-4") receptor complex and subsequent signaling. In August 2017, we entered into a license agreement (the "Roche Agreement") with F. Hoffmann-La Roche Ltd and Genentech, Inc. (together, "Roche") pursuant to which we obtained exclusive, worldwide rights to develop and commercialize lebrikizumab for atopic dermatitis and all other indications, except Roche retained certain rights, including exclusive rights to develop and promote lebrikizumab for interstitial lung diseases, such as idiopathic pulmonary fibrosis (the "Retained Field"), and rights to use lebrikizumab for internal research purposes and for in vitro diagnostic purposes. The Roche Agreement became effective in September 2017 upon the early termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. Pursuant to the terms of the Roche Agreement, Roche relinquished its rights in the Retained Field effective July 13, 2018 and all of Roche's rights and all of our obligations with respect to the Retained Field expired. Accordingly, we have exclusive, worldwide rights to develop and commercialize lebrikizumab for all indications. Roche's rights to use lebrikizumab for internal research purposes and for in vitro diagnostic purposes remain. Based on the results of two exploratory Phase 2 clinical trials conducted by Roche in atopic dermatitis patients, we initiated a Phase 2b clinical trial in January 2018 to evaluate the safety and efficacy of lebrikizumab as a monotherapy compared with placebo and to establish the dosing regimen for a potential Phase 3 program in patients with moderate-to-severe atopic dermatitis. We completed enrollment of a total of 280 patients ages 18 years and older in the Phase 2b clinical trial in October 2018 and expect to announce topline results by early April 2019.

Key Developments

Below is a summary of selected key developments affecting our business that have occurred since June 30, 2018:

QBREXZA

- Launched QBREXZA on October 1, 2018 in pharmacies nationwide for the treatment of primary axillary hyperhidrosis in adult and pediatric patients nine years of age and older. QBREXZA was approved by the FDA in June 2018 and began shipping to Customers in September 2018.
- Announced in September 2018 that two of the largest pharmacy benefit managers in the United States, Express Scripts, Inc. and OptumRx, had agreed to provide immediate coverage of QBREXZA through their national formularies, effective October 1, 2018. As of October 1, 2018, we had secured coverage for approximately 53% of the total U.S. commercial lives.
- Announced in September 2018 the hiring of 112 therapeutic sales specialists, 14 division business managers and two regional business directors.
- Presented new pediatric efficacy and safety data for glycopyrronium tosylate in patients with primary axillary hyperhidrosis in September 2018 at the European Academy of Dermatology and Venereology Congress.

- Results from the pivotal Phase 3 studies were published online in July 2018 in the Journal of the American Academy of Dermatology.

Lebrikizumab

- Completed patient enrollment in the Phase 2b clinical study of lebrikizumab in October 2018.

Financial Overview

For the three months ended September 30, 2018, net loss decreased 63% to $66.5 million from $179.2 million for the same period in 2017. The decrease is primarily due to our recognition in 2017 of acquired in-process research and development expenses of $128.6 million related to the Roche Agreement. We recognized revenue of $0.7 million for the three months ended September 30, 2018, comprised exclusively of net product sales of QBREXZA. We did not recognize any collaboration and license revenue for the three months ended September 30, 2018. Research and development expenses decreased 47% to $16.3 million for the three months ended September 30, 2018 compared to the same period in 2017, driven primarily by a reduction in clinical trial activities. Selling, general and administrative expenses increased 151% to $49.5 million for the three months ended September 30, 2018 compared to the same period in 2017, driven primarily by expenses related to the commercial launch of QBREXZA, as well as headcount growth and associated expenses.

For the nine months ended September 30, 2018, net loss decreased 39% to $149.7 million from $247.2 million for the same period in 2017. The decrease is primarily due to our recognition in 2017 of acquired in-process research and development expenses of $128.6 million related to the Roche Agreement. Product sales for QBREXZA were $0.7 million for the nine months ended September 30, 2018, related to the commencement of shipments of QBREXZA to our Customers in September 2018. Collaboration and license revenue was $39.4 million for the nine months ended September 30, 2018, an increase of $36.2 million compared to the same period in 2017, driven primarily by the $39.0 million revenue recognized pursuant to a transition agreement (“Transition Agreement”) that provided for an orderly transition of activities under the development and commercialisation agreement between us and UCB Pharma S.A. (“UCB”), dated March 21, 2014 (“UCB Agreement”), which provided for the development and commercialization of Cimzia, an injectable biologic tumor necrosis factor-alpha inhibitor for the treatment of psoriasis. Research and development expenses decreased 20% to $61.4 million for the nine months ended September 30, 2018 compared to the same period in 2017, driven primarily by a reduction in clinical trial activities. Selling, general and administrative expenses increased 170% to $120.8 million for the nine months ended September 30, 2018 compared to the same period in 2017, driven primarily by expenses related to the commercial launch of QBREXZA, as well as headcount growth and associated expenses. We also recorded an impairment charge of $1.1 million against intangible assets for the nine months ended September 30, 2018 related to our olumacostat glasaretil development program.

As of September 30, 2018, we had cash and investments of $389.7 million.

Since our inception, we have devoted substantially all of our efforts to developing our product candidates, including conducting preclinical and clinical trials and manufacturing activities, to commercializing QBREXZA, and to providing general and administrative support for our operations. We have financed our operations primarily through the sale of equity securities and convertible debt securities.

We have never been profitable and may never be profitable. As of September 30, 2018, we had an accumulated deficit of $673.2 million. We expect to incur significant costs to continue to commercialize QBREXZA and advance our lebrikizumab product candidate through clinical development. As a result, we will need substantial additional funding to support our operating activities. The timing and the amount of future funding we will require and the success of our business will be based in large part on the successful commercialization of QBREXZA and the outcome of the lebrikizumab Phase 2b clinical study. Adequate funding may not be available to us on acceptable terms, or at all. We currently anticipate that we will seek to fund our operations through public or private equity or debt financings or other sources, such as potential collaboration or license agreements. Our failure to obtain sufficient funds on acceptable terms as and when needed could have a material adverse effect on our business, results of operations and financial condition.

Critical Accounting Policies and Significant Estimates

Our management's discussion and analysis of financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions.

While our significant accounting policies are described in the notes to our condensed consolidated financial statements, we believe that the following changes to our critical accounting policies are most important to understanding and evaluating our reported condensed consolidated financial results, as these policies relate to the more significant areas involving management's judgments and estimates.

Inventory

Inventory consists of raw materials, work-in-process and finished goods. Inventory costs are determined using the lower of standard cost, which approximates the actual costs determined using the first-in, first-out basis, or net realizable value. Standard costs are reviewed and updated annually or as needed. We expense costs associated with the manufacture of our products prior to regulatory approval and capitalize the cost of inventory when there is a high probability of future economic benefit. We began capitalizing the cost of inventory related to QBREXZA in the second quarter of 2018, the period in which we received regulatory approval to market the product. We are expensing costs associated with the manufacture of our lebrikizumab product candidate.

We review all inventory balances on a quarterly basis for impairment and recognize any reduction in value as a current period expense with a reserve provision on the consolidated balance sheets. If the conditions that caused the impairment were to be resolved in a subsequent period, the reserve provision would not be reversed until the related inventory was sold or otherwise disposed.

Revenue Recognition

Effective January 1, 2018, we adopted Accounting Standards Update (“ASU”) 2014-09, Revenue from Contracts with Customers (Topic 606) (“Topic 606”) using the modified retrospective method which consisted of applying and recognizing the cumulative effect of Topic 606 at the date of initial application. Topic 606 supersedes the revenue recognition requirements in Accounting Standards Codification (“ASC”) Topic 605, Revenue Recognition (“Topic 605”), including most industry-specific revenue recognition guidance throughout the Industry Topics of the ASC. All periods prior to the adoption date of Topic 606 have not been restated to reflect the impact of the adoption of Topic 606, but continue to be accounted for and presented under Topic 605.

The following paragraphs in this section describe our revenue recognition accounting polices under Topic 606 upon adoption on January 1, 2018. Refer to Note 2 to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2017 for revenue recognition accounting policies under Topic 605.

We recognize revenue when we transfer promised goods or services to customers 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 for contracts with customers 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) we satisfy the performance obligations. At contract inception, we assess the goods or services promised within each contract and assess whether each promised good or service is distinct and determine those that are performance obligations. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Sales

Our product sales consist of sales of QBREXZA within the United States. Following the approval of QBREXZA by the FDA in June 2018 and, in advance of the availability of QBREXZA in pharmacies on October 1, 2018, we commenced shipments of QBREXZA in September 2018 to our Customers for distribution to pharmacies and patients. We recognize revenue from product sales when our Customers obtain control of our product, which is generally upon delivery.

Product sales are recognized at the transaction price, net of estimates of variable consideration, including commercial rebates, discounts related to a patient savings card program, distribution fees, trade discounts, government rebates and

chargebacks and product returns. Variable consideration amounts are estimated at contract inception using the expected-value method and updated at the end of each reporting period as additional information becomes available. The amounts of variable consideration are included in the transaction price only to the extent it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved. Estimates and assumptions are updated quarterly and if actual future results vary materially from estimates, we will record an adjustment, which could impact product sales and earnings in the period of adjustment.

The following items of variable consideration are recorded at the time of revenue recognition and require significant estimates and judgment.

Commercial rebates and savings card program. We contract with certain third-party payers for the payment of rebates with respect to the utilization of QBREXZA. Rebates to these payers are based on contractual percentages applied to the amount of QBREXZA prescribed to patients who are covered by the plan or the organization with which we have contracts. We estimate and record rebates as a reduction to the transaction price in the same period the related product sales are recognized. We estimate commercial rebates based on contractual terms, estimated payer mix, industry information and other third-party data. We also have a savings card program to provide assistance to eligible patients with out-of-pocket costs, such as deductibles, co-insurance and co-payments, for the patient's usage of QBREXZA. Reductions to product sales for the savings card program are estimated based on actual and expected program utilization.

Distribution fees and trade discounts. We pay our Customers certain fees for distribution services for QBREXZA. We determined that such distribution services are not distinct from our sales of QBREXZA and the related fees are recorded as a reduction to the transaction price in the period the related product sales are recognized. Distribution fees are recorded based on contractual terms. We also incentivize prompt payment from our Customers by providing a discount for payments made within a certain number of days.

Government rebates and chargebacks. We are subject to discount obligations under state Medicaid programs, Medicare and other government programs. Reserves for these rebates and chargebacks are recorded as a reduction to the transaction price in the period the related product sales are recognized. Chargeback amounts represent credit we expect to issue to our Customers and are recorded as a reduction to trade and other receivables, net. Reductions to product sales for government managed programs are estimated based on statutorily-defined discounts, estimated payer mix, expected sales to qualified healthcare providers and expected utilization.

Product returns. Our product return policy provides our Customers the right to return QBREXZA, generally based on its expiration date. The reserve for product returns is recorded as a reduction to the transaction price in the period the related product sales are recognized. We estimate product returns using third-party input and market data for products with characteristics similar to QBREXZA.

Collaborative Arrangements

We enter into collaborative arrangements with partners that typically include payment to us of one of more of the following: (i) license fees; (ii) milestone payments related to the achievement of developmental, regulatory, or commercial goals; and (iii) royalties on net sales of licensed products. Where a portion of non refundable up-front fees or other payments received are allocated to continuing performance obligations under the terms of a collaborative arrangement, they are recorded as deferred revenue and recognized as revenue when (or as) the underlying performance obligation is satisfied.

As part of the accounting for these arrangements, we must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligation. The stand-alone selling price may include items such as forecasted revenues, development timelines, discount rates, and probabilities of technical and regulatory success. We evaluate each performance obligation to determine if it can be satisfied at a point in time or over time. In addition, variable consideration must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

License Fees

If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, up-front fees allocated to the license when the license is

transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone Payments

At the inception of each arrangement that includes milestone payments (variable consideration), we evaluate whether the milestones are considered probable of being reached and estimate 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 transaction price. Milestone payments that are not within our or our collaboration partner's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration or other revenues and earnings in the period of adjustment.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any royalty revenue resulting from any of our collaborative arrangements.

Under certain collaborative arrangements, we have been reimbursed for a portion of our research and development ("R&D") expenses, including costs of drug supplies. When these R&D services are performed under a reimbursement or cost sharing model with our collaboration partner, we record these reimbursements as a reduction of R&D expense in our consolidated statements of operations.

Results of Operations

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2018	2017	$	%	2018	2017	$	%
	(in thousands, except percentages)							
Revenue:								
Product sales	$717	$—	$717	*	$717	$—	$717	*
Collaboration and license revenue	—	1,066	(1,066)	(100)%	39,379	3,198	36,181	*
Total revenue	717	1,066	(349)	(33)	40,096	3,198	36,898	*
Costs and operating expenses:								
Cost of sales	237	—	237	*	237	—	237	*
Research and development	16,292	30,788	(14,496)	(47)	61,428	76,626	(15,198)	(20)%
Acquired in-process research and development	—	128,555	(128,555)	(100)	—	128,555	(128,555)	(100)
Selling, general and administrative	49,510	19,754	29,756	151	120,790	44,667	76,123	170
	—	—	—	*	1,126	—	1,126	*

Impairment of intangible assets								
Total costs and operating expenses	66,039	179,097	(113,058)	(63)%	183,581	249,848	(66,267)	(27)%
Loss from operations	(65,322)	(178,031)	112,709	(63)%	(143,485)	(246,650)	103,165	(42)%
Interest and other income, net	2,198	1,721	477	28%	5,969	3,585	2,384	66%
Interest expense	(3,420)	(2,864)	(556)	19%	(12,408)	(4,184)	(8,224)	197%
Loss before taxes	(66,544)	(179,174)	112,630	(63)%	(149,924)	(247,249)	97,325	(39)%
Benefit for income taxes	—	—	—	*	194	—	194	*
Net loss	$(66,544)	$(179,174)	$112,630	(63)%	$(149,730)	$(247,249)	$97,519	(39)%

*Percentage not meaningful

Revenue. Our revenue during the periods presented has been comprised of QBREXZA product sales and collaboration and license revenue. The collaboration and license revenue relates to (i) payments received in connection with the Transition Agreement with UCB and (ii) our exclusive license agreement with Maruho, which grants Maruho an exclusive license to develop and commercialize glycopyrronium tosylate for the treatment of hyperhidrosis in Japan ("Maruho G.T. Agreement").

We recognized $0.7 million in net product sales for the three and nine months ended September 30, 2018, related to sales of QBREXZA. We commenced shipments of QBREXZA to our Customers in September 2018, in advance of the availability of QBREXZA in pharmacies on October 1, 2018.

We did not recognize any collaboration and license revenue for the three months ended September 30, 2018. We recognized $39.4 million in collaboration and license revenue for the nine months ended September 30, 2018 pursuant to the Transition Agreement with UCB, consisting primarily of the $39.0 million revenue recognized in connection with the FDA's approval of Cimzia for the treatment of moderate-to-severe chronic plaque psoriasis in May 2018. No collaboration and license revenue from UCB will be recognized in future periods pursuant to the Transition Agreement as all performance obligations have been satisfied and the entire transaction price has been recognized. We recognized $1.1 million and $3.2 million in collaboration and license revenue for the three and nine months ended September 30, 2017, respectively, related to the ratable recognition of the $25.0 million upfront payment received pursuant to the Maruho G.T. Agreement in accordance with Topic 605. Collaboration and license revenue for the three and nine months ended September 30, 2018 under Topic 605 would have been $1.1 million and $42.9 million, respectively.

Cost of sales. Cost of sales was $0.2 million for the three and nine months ended September 30, 2018. In periods prior to receiving FDA approval for QBREXZA, we expensed all inventory and related costs associated with the manufacture of QBREXZA to research and development expense. Cost of sales for the three and nine months ended September 30, 2018 would have been $0.4 million if we had not used inventory that was previously expensed.

Research and Development. Research and development expenses include external costs incurred for the development of our product candidates, including third-party expenses necessary for clinical studies and manufacturing, and internal expenses consisting primarily of salaries and related costs, including stock-based compensation expense, for personnel in our research and development functions. We track external research and development costs incurred for each of our product candidates. We do not track our internal research and development costs by product candidate, as these costs are typically spread across multiple product candidates. We expense research and development costs as they are incurred.

The following table summarizes our research and development expenses incurred during the respective periods:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	$ Change	2018	2017	$ Change
	(in thousands)					
External costs:						
QBREXZA[1]	$1,174	$5,337	$(4,163)	$3,718	$11,211	$(7,493)
Lebrikizumab[2]	6,348	89	6,259	12,951	89	12,862
Cimzia[3]	—	5,591	(5,591)	75	13,997	(13,922)
Olumacostat glasaretil[4]	(324)	10,189	(10,513)	10,186	25,836	(15,650)
Other external research and development expenses	1,407	689	718	4,384	1,341	3,043
Internal costs	7,687	8,893	(1,206)	30,114	24,152	5,962
Total research and development expenses	$16,292	$30,788	$(14,496)	$61,428	$76,626	$(15,198)

1. In June 2018, we received FDA approval of QBREXZA for the treatment of primary axillary hyperhidrosis in adult and pediatric patients nine years of age and older. QBREXZA became commercially available in pharmacies nationwide on October 1, 2018.
2. We initiated a Phase 2b dose-ranging study assessing lebrikizumab in adult patients with moderate-to-severe atopic dermatitis in January 2018 and completed enrollment in October 2018.
3. In November 2017, we entered into the Transition Agreement with UCB, which provided for an orderly transition of the development and commercialization activities through June 2018 under the UCB Agreement and terminated the collaboration on February 15, 2018. Cimzia was approved by the FDA for the treatment of moderate-to-severe

chronic plaque psoriasis in May 2018.

4. In March 2018, we announced that olumacostat glasaretil did not meet the co-primary endpoints in its two Phase 3 pivotal trials (CLAREOS-1 and CLAREOS-2) in patients ages nine years and older with moderate-to-severe acne vulgaris. Based on these results, we expect to discontinue the program. We have made and will continue to make additional adjustments to previously recognized expenses.

Research and development expenses decreased $14.5 million, or 47%, for the three months ended September 30, 2018 compared to the three months ended September 30, 2017. This decrease was primarily due to reductions in clinical trial activities totaling $16.1 million related to our olumacostat glasaretil and Cimzia development programs and $4.2 million related to QBREXZA, which were partially offset by an increase of $6.3 million related to our lebrikizumab product candidate.

Research and development expenses decreased $15.2 million, or 20%, for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017. This decrease was primarily due to reductions in clinical trial activities totaling $29.6 million related to our olumacostat glasaretil and Cimzia development programs and $7.5 million related to QBREXZA, which were partially offset by increases of $12.9 million related to our lebrikizumab product candidate and $6.0 million in internal costs related to headcount growth and associated expenses. The $7.5 million reduction in expenses related to QBREXZA was inclusive of a $2.0 million small business waiver fee refund from the FDA recorded in the second quarter of 2018.

Manufacturing costs related to QBREXZA are capitalized as inventory and subsequently expensed as cost of sales when that inventory is sold. The timing and amount of research and development expenses incurred in future years will depend upon the timing and outcomes of current or future clinical studies and associated manufacturing activities for our lebrikizumab product candidate and new product candidates resulting from our early-stage research programs or business development activities.

Selling, General and Administrative. Selling, general and administrative expenses consist of salaries and related costs, including stock-based compensation, for personnel in our selling, general and administrative functions, including our sales and marketing and medical affairs functions, and costs for advertising and promotion, market research and commercial planning services and professional fees for audit, tax and legal services.

Selling, general and administrative expenses increased $29.8 million, or 151%, for the three months ended September 30, 2018 compared to the three months ended September 30, 2017. This increase was primarily due to a $16.2 million increase in external costs to prepare for the commercial launch of QBREXZA, inclusive of advertising and promotion expenses, and a $13.6 million increase in internal costs related to headcount growth and associated expenses.

Selling, general and administrative expenses increased $76.1 million, or 170%, for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017. This increase was primarily due to a $45.3 million increase in external costs to prepare for the commercial launch of QBREXZA, inclusive of advertising and promotion expenses, and a $30.8 million increase in internal costs related to headcount growth and associated expenses.

We expect our selling, general and administrative expenses to increase in 2019 due primarily to the annualization of costs incurred in 2018 as we expanded our operating activities, increased our headcount and built out our infrastructure to support commercialization of QBREXZA, as well as an increase in promotional activities.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through the issuance and sale of equity securities and convertible debt securities.

In May 2017, we sold $287.5 million aggregate principal amount of 3.00% Convertible Senior Notes due 2022 (“Notes”) in a private placement to qualified institutional buyers and received net proceeds of $278.3 million, after deducting the initial purchasers’ discounts of $8.6 million and issuance costs of $0.6 million. As of September 30, 2018, we had $287.5 million in aggregate principal amount of Notes outstanding.

Additionally, in February 2017, we filed an automatic shelf registration statement on Form S-3 for the potential offering, issuance and sale by us of shares of our common stock. In March 2017, we sold 5,750,000 shares of our common stock pursuant to the automatic shelf registration statement (“2017 Public Offering”) and received gross proceeds of $193.8 million and net proceeds of $181.5 million, after deducting underwriting discounts and

commissions of $11.6 million and offering expenses of $0.7 million.

In November 2015, we filed a shelf registration on Form S-3 with the SEC for the issuance and sale of up to an aggregate offering of $300.0 million of shares of our common stock, preferred stock, debt securities, warrants to purchase our common stock, preferred stock or debt securities, subscription rights to purchase our common stock, preferred stock or debt securities and/or units consisting of some or all of these securities. In June 2016, we sold 5,175,000 shares of our common stock in a shelf offering pursuant to the shelf registration statement and received gross proceeds of $144.9 million and net proceeds of $135.6 million, after deducting underwriting discounts and commissions of $8.7 million and offering expenses of $0.6 million. The shelf registration statement expired on November 2, 2018.

As of September 30, 2018, we had $389.7 million of cash and investments. Our cash and investments are held in a variety of interest-bearing instruments, including money market funds, U.S. Treasury securities, corporate debt, repurchase agreements, U.S. Government agency securities and commercial paper. Cash in excess of immediate requirements is invested with a view toward liquidity and capital preservation, and we seek to minimize the potential effects of concentration and degrees of risk.

Our primary use of cash is to fund our operating expenses, including costs to acquire in-process research and development projects. As of September 30, 2018, we had an accumulated deficit of $673.2 million. We expect to incur additional losses and expend substantial cash resources for the foreseeable future for commercialization of QBREXZA, the clinical development and potential commercialization of our current and any future product candidates we may choose to pursue and to support the administrative and reporting requirements of a public company.

Cash Flows

The following table shows a summary of our cash flows for the nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,	
	2018	2017
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$(134,800)	$(72,323)
Investing activities	(17,326)	(37,311)
Financing activities	1,180	461,472
Net increase (decrease) in cash and cash equivalents and restricted cash	$(150,946)	$351,838

Operating Activities. Net cash used in operating activities was $134.8 million for the nine months ended September 30, 2018 and consisted of a net loss of $149.7 million and a $15.3 million increase in net operating assets, offset by $30.2 million in non-cash charges. The increase in net operating assets consisted primarily of a $10.0 million decrease in refund liability, a $2.6 million increase in prepaid expenses and other current assets, a $2.1 million increase in trade and other receivables, net, a $2.1 million decrease in accounts payable, a $2.0 million increase in other assets and a $2.0 million increase in inventory. These changes were partially offset by a $5.9 million increase in accrued liabilities. Non-cash charges included $22.7 million of stock-based compensation, $4.6 million of amortization of discount for payments related to acquired in-process research and development, $1.4 million of amortization of convertible note discount and issuance costs and $1.1 million of impairment of intangible assets related to olumacostat glasaretil. Net cash used in operating activities was $72.3 million for the nine months ended September 30, 2017 and consisted of a net loss of $247.2 million, offset by $146.9 million in non-cash charges and a $28.0 million decrease in net operating assets. Non-cash charges included $128.6 million in acquired in-process research and development expense related to the Roche Agreement, $15.2 million of stock-based compensation expense and $1.9 million of net amortization of premiums on available-for-sale securities. The decrease in net operating assets consisted primarily of a $21.4 million decrease in trade and other receivables, net, attributable to the receipt of the third and fourth milestone payments from UCB, which were recognized in the fourth quarter of 2016, a $9.5 million increase in accrued liabilities and a $3.8 million decrease in prepaid expenses and other current assets. These changes were partially offset by a $3.8 million decrease in accounts payable and a $3.2 million decrease in deferred revenue.

Investing Activities. Net cash used in investing activities for the nine months ended September 30, 2018 was $17.3 million, which resulted primarily from purchases of investments of $258.1 million and from payments made pursuant to in-license agreements with Roche and Rose U LLC of $26.0 million, partially offset by proceeds from maturities of investments of $267.4 million. Net cash used in investing activities for the nine months ended September 30, 2017 was $37.3 million, which resulted primarily from purchases of investments of $225.9 million, partially offset by proceeds from maturities of investments of $188.7 million.

Financing Activities. Net cash provided by financing activities for the nine months ended September 30, 2018 was $1.2 million, which resulted from net proceeds from the issuance of common stock in connection with equity awards.

Net cash provided by financing activities for the nine months ended September 30, 2017 was $461.5 million, which resulted primarily from net proceeds of $181.5 million from our 2017 Public Offering and net proceeds of $278.3 million from the sale of the Notes.

Operating and Capital Expenditure Requirements

We have incurred losses since inception and anticipate that we will continue to generate losses for the foreseeable future. We expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and prepare for potential commercialization of and commercialize any approved products. We believe that existing cash and investments on hand as of September 30, 2018 are sufficient to meet our anticipated cash requirements, excluding costs to complete a potential Phase 3 program for lebrikizumab, to mid-2020 and to: commercialize QBREXZA; complete and generate topline results from our ongoing Phase 2b dose-ranging study for lebrikizumab; and continue potential lifecycle management activities related to our product candidates. However, we expect we will need to raise substantial additional financing in the future to fund our operations. In order to meet these additional cash requirements, we may seek to raise debt or sell additional equity or convertible debt securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of debt or convertible debt securities, these instruments could have rights senior to those of our common stock and could contain covenants that restrict our operations. We cannot ensure that additional financing will be available to us in the amounts we need or that such financing will be available on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, scale back or discontinue one or more of our product development programs or other aspects of our business plan or relinquish, license or otherwise dispose of rights to products or product candidates that we would otherwise seek to commercialize or develop ourselves on terms that are less favorable than might otherwise be available, any of which could have a material adverse effect on our business, results of operations and financial condition. Please see “Part II — Other Information, Item 1A, Risk Factors” below for additional risks associated with our substantial capital requirements.

Contractual Obligations and Other Commitments

There were no material changes in our commitments under contractual obligations, as disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” contained in our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on February 22, 2018.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements, as defined in Item 303(a)(4) of Regulation S-K promulgated under the Exchange Act, and do not have any holdings in variable interest entities.

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

During the nine months ended September 30, 2018, there have been no significant changes in market risks as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017.

ITEM 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended ("Exchange Act"), and the rules and regulations thereunder, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, or persons performing similar functions, as appropriate, to allow for timely decisions regarding required or necessary disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired control objectives, and we are required to apply judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2018, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the fiscal quarter ended September 30, 2018, we added additional controls related to the commercialization of QBREXZA™ (glycopyrronium) cloth, including controls related to the recording of product sales. There were no other changes in our internal controls over financial reporting identified in connection with the evaluation required by Rules 13a 15(d) and 15d 15(d) of the Exchange Act that occurred during the fiscal quarter ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION.

ITEM 1. LEGAL PROCEEDINGS

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, financial condition or cash flows.

ITEM 1A. RISK FACTORS

Our operations and financial results are subject to numerous risks and uncertainties, including those described below, which may have a material and adverse effect on our business, results of operations, cash flows, financial conditions, and the trading price of our common stock. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. You should consider these risks and uncertainties carefully, together with all of the other information included or incorporated by reference in this Quarterly Report on Form 10-Q. If any of the following risks actually occur, our business, financial condition, results of operations and future prospects could be materially and adversely affected. In that event, the market price of our stock could decline, and you could lose part or all of your investment.

Risks Related to Commercialization of QBREXZA™ (glycopyrronium) Cloth

QBREXZA™ (glycopyrronium) cloth is our only approved product and the success of our business is dependent on its successful commercialization.

Our product, QBREXZA™ (glycopyrronium) cloth ("QBREXZA"), was recently approved by the U.S. Food and Drug Administration ("FDA") for the topical treatment of primary axillary hyperhidrosis in adult and pediatric patients nine years of age and older and became available in pharmacies nationwide on October 1, 2018. The success of our business will depend on the successful commercialization of QBREXZA. The commercial success of QBREXZA will depend on a number of factors, including the following:

- the effectiveness of our sales team and our ability to scale our distribution capabilities (see also "—We recently built a team of sales representatives and our distribution capabilities. If we are unable to establish effective sales and distribution capabilities on our own or through third parties, we will be unable to successfully commercialize QBREXZA or generate product sales.");
- the availability of formulary coverage and adequate reimbursement for QBREXZA (see also "—Our commercial success may be severely hindered if patients do not have access to our approved product from their insurers without undue restriction.");
- acceptance by physicians, payers and patients of the benefits, safety and efficacy of QBREXZA, including relative to alternative and competing treatments (see also "—QBREXZA may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.");
- a continued acceptable safety profile of QBREXZA (see also "—QBREXZA may cause undesirable side effects or have other unexpected properties that could limit its commercial profile, result in post-approval regulatory action or expose us to product liability claims, any of which may adversely impact our business, financial condition, operating results and prospects.");
- our ability to successfully obtain the substances and materials used in QBREXZA from third parties and to have finished product manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for sale (see also "—Risks Related to Our Dependence on Third Parties");
-

our ability to ensure compliance with federal and state healthcare laws and regulations (see also "—Our employees, independent contractors, principal investigators, consultants, vendors, CROs, distributors, prescribers and any partners with which we may collaborate may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our business." and "—We may also be subject to healthcare laws, regulation and enforcement and our failure to comply with those laws could adversely affect our business, operations and financial condition."); and

- our ability to establish and enforce intellectual property rights in and to QBREXZA and avoid third-party patent interference or intellectual property infringement claims (see also "—Risks Related to Our Intellectual Property").

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to commercialize our product, which would harm our business, financial condition, operating results and prospects.

We recently built a team of sales representatives and our distribution capabilities. If we are unable to establish effective sales and distribution capabilities on our own or through third parties, we will be unable to successfully commercialize QBREXZA or generate product sales.

To achieve commercial success, we must effectively maintain our commercial infrastructure, including our sales and distribution capabilities, as well as continue to expand our organization cross-functionally to enable us to execute on our commercialization goals. Factors that may inhibit our efforts to successfully commercialize QBREXZA through our own sales organization include:

- our inability to train and retain adequate numbers of effective sales personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe QBREXZA;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with maintaining an independent sales organization.

There are significant risks involved in managing a sales organization, including our ability to retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales personnel and effectively manage a geographically dispersed sales team. We may also choose to collaborate with third parties that have direct sales forces and established distribution systems to augment our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize QBREXZA. Even if we are able to enter into such arrangements, we will likely have little control over these third parties, and any such third party may fail to devote the necessary resources and attention to sell and market our product effectively. Any failure in our ability to maintain our commercial infrastructure and sales and distribution capabilities would adversely impact the commercialization of our product. The inability to successfully commercialize our product, either on our own or through collaborations with one or more third parties, would harm our business, financial condition, operating results and prospects.

We have contracted with a third-party logistics company to warehouse QBREXZA and distribute it to wholesalers, distributors, pharmacies, hospitals and other drug suppliers that will ultimately distribute our product directly to patients. Our third-party logistics company also provides billing, collection and returns services. This distribution network requires significant coordination with our market access, finance, quality and technical operations teams. Failure to maintain our contracts with our third-party logistics company, wholesalers, distributors, pharmacies, hospitals or other drug suppliers, or the inability or failure of any of them to adequately perform under the contracts, could negatively impact the distribution of our product. Failure to coordinate financial systems could also negatively impact our ability to accurately report and forecast product sales. If we are unable to effectively manage the distribution process, sales of QBREXZA could be severely compromised and our business, financial condition, operating results and prospects would be harmed.

Our commercial success may be severely hindered if patients do not have access to QBREXZA from their insurers without undue restriction.

The availability of formulary coverage and adequate reimbursement from private third-party payers such as pharmacy benefit managers and commercial insurers, and to a lesser degree, governmental healthcare programs, such as

Medicare and Medicaid, is critical to market acceptance and commercial success of QBREXZA, which is available only by prescription. Timely coverage and acceptable patient cost-sharing tiers for our product may be adversely affected by a number of factors, including but not limited to, increasing and intense pressure from political, social, competitive and other sources to reduce drug unit costs or limit changes in list price; changes in federal, state or foreign government regulations or private third-party payers' reimbursement policies; consolidation and increasing assertiveness of commercial payers seeking net price reduction via drug rebates and other forms of discounts linked to the placement of QBREXZA on their formularies; and the imposition of restrictions on access or coverage of particular drugs or pricing determined based on perceived pharmacoeconomic value.

A trend in the healthcare industry is cost containment. Third-party payers are developing increasingly sophisticated methods of controlling healthcare costs by, among other methods, limiting or preventing (via formulary exclusion) coverage for particular medications, requiring drug companies to provide them with varying levels of discounts from list prices and challenging the value of list prices charged for medical products. Coverage decisions may depend upon the size of a patient population, perceptions of clinical efficacy and economic standards that may disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

Although private third-party payers in the United States tend to follow Medicare reimbursement policies for products which are administered in a hospital or physician office setting, no uniform policy of pharmacy benefit coverage and reimbursement for drug products exists among third-party payers. Therefore, coverage and reimbursement for drug products adjudicated in a pharmacy benefit setting can differ significantly across payers. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product to each third-party payer separately, with no assurance that coverage will be obtained.

In addition, the market for QBREXZA will depend significantly on access to third-party payers' drug formularies, or lists of medications for which third-party payers provide coverage and impose patient out-of-pocket cost sharing limits. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payers may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other therapeutically similar alternative is available.

Third-party payers may also seek additional evidence, beyond the data required to obtain regulatory approval, demonstrating clinical benefits and value in specific patient populations before covering our product for those patients. This increased requirement is seen in particular with dermatology products that are perceived by payers to treat so-called lifestyle conditions. If third-party payers believe QBREXZA does not demonstrate sufficient value, they may not cover QBREXZA or may limit access to QBREXZA.

Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payers to reimburse all or part of the costs of their prescription drugs. Even if we obtain favorable coverage for our product, the patient may be required to pay co-payments or co-insurance they find unacceptably high. Patients may be unlikely to use QBREXZA unless coverage is established and reimbursement for their medicine from their insurer adequately covers a significant portion of the cost of our product.

Our inability to promptly obtain insurance coverage, profitable reimbursement rates or access to third-party payers' drug formularies from private payers and, to a smaller degree, government-funded health insurance for our product, could have a material adverse effect on our business, financial condition, operating results and prospects.

QBREXZA may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.

The commercial success of QBREXZA will depend significantly on the broad adoption and use of the product by physicians and patients for the approved indication. The degree and rate of physician and patient adoption of our product will depend on a number of factors, including:

- patient demand for an approved product that treats primary axillary hyperhidrosis;
- our ability to successfully compete with existing therapies, some of which are widely known and accepted by physicians and patients, including demonstrating that the relative cost, safety and efficacy of QBREXZA provides an

attractive alternative to the existing therapies;
- the availability of formulary coverage and adequate reimbursement from private third-party payers for QBREXZA;
- the cost of treatment with QBREXZA in relation to alternative treatments and patients' willingness to pay for the product;
- acceptance by physicians, major operators of clinics and patients of QBREXZA as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy over other available therapies to treat primary axillary hyperhidrosis;
- patients' perception of primary axillary hyperhidrosis as a condition for which medical treatment may be appropriate and a prescription therapy may be available;
- overcoming any biases physicians or patients may have toward particular therapies for the treatment of primary axillary hyperhidrosis;
- proper training and administration of QBREXZA by physicians and medical staff;

- patients properly using QBREXZA as instructed;
- patient satisfaction with the results and administration of QBREXZA and overall treatment experience;
- the willingness of patients to pay for QBREXZA relative to other discretionary items, especially during economically challenging times;
- the revenue and profitability that QBREXZA may offer a physician as compared to alternative therapies;
- the prevalence and severity of side effects from the use or potential misuse of QBREXZA;
- limitations or warnings contained in the FDA-approved labeling of QBREXZA;
- the effectiveness of our sales, marketing and distribution efforts;
- adverse publicity about QBREXZA or favorable publicity about competitive products;
- potential product liability claims;
- our ability to effectively manage our third-party supply and manufacturing operations while increasing production capabilities for QBREXZA to commercial levels; and
- our ability to manage our operations to effectively support our commercialization activities.

If QBREXZA fails to achieve the broad degree of physician, patient and payer adoption necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our business.

QBREXZA may cause undesirable side effects or have other unexpected properties that could limit its commercial profile, result in post-approval regulatory action or expose us to product liability claims, any of which may adversely impact our business, financial condition, operating results and prospects.

If we or others identify undesirable side effects or other previously unknown problems caused by QBREXZA or other products with the same or related active ingredients, a number of potentially negative consequences could result, including:

- regulatory authorities may withdraw their approval of QBREXZA;
- we could be sued and held liable for harm caused to patients (see also "—We may face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.");
- regulatory authorities may require a recall of QBREXZA or we or our potential partners may voluntarily recall the product (see also "—We or our current and prospective partners may be subject to product recalls in the future that could harm our brand and reputation and could negatively affect our business.");
- regulatory authorities may require the addition of warnings or contraindications in the product labeling, narrowing of the indication in the QBREXZA label or field alerts to physicians and pharmacies;
- we may be required to institute a risk evaluation and mitigation strategy;
- we may have limitations on how we promote QBREXZA;
- we may be required to change the way QBREXZA is administered or modify the product in some other way;
- the FDA or applicable foreign regulatory authority may require additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of QBREXZA;
- sales of QBREXZA may decrease significantly; and
- our brand and reputation may suffer.

Any of the above events resulting from undesirable side effects or other previously unknown problems could prevent us or our potential partners from achieving or maintaining market acceptance of QBREXZA and could substantially increase our costs, which may adversely affect our business, financial condition, operating results and prospects.

We may face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and the commercialization of QBREXZA. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. QBREXZA and our past and current product candidates were designed to affect important bodily functions and processes. Any side effects, manufacturing defects, failure to follow instructions, misuse or abuse associated with our product or product candidates could result in injury to a patient or even death. We cannot offer any assurance that we will not face product liability suits in the future, nor can we provide assurances that our insurance coverage will be sufficient to cover our liability under any such cases.

In addition, a liability claim may be brought against us even if our product or product candidates merely appear to have caused an injury. Product liability claims may be brought against us by, among others, consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product or product candidates. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- the inability to commercialize our product or product candidates;
- decreased demand for our product or product candidates;
- product recall or withdrawal from the market or labeling, marketing or promotional restrictions;
- withdrawal of clinical trial participants;
- decreased enrollment rates of clinical trial participants;
- termination of clinical trial sites or entire clinical trial programs;
- impairment of our business reputation;
- substantial costs of any related litigation or similar disputes;
    - distraction of management's attention and other resources from our primary business;
- substantial monetary awards to patients or other claimants against us that may not be covered by insurance; or
- loss of revenue.

Large judgments have been awarded in class action or individual lawsuits based on drugs that had anticipated or unanticipated side effects. Although we have obtained product liability insurance coverage, our insurance coverage may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and could harm our business, financial condition, operating results and prospects.

If we are found to have improperly promoted off-label uses of QBREXZA, or if physicians misuse our product or use our product off-label, we may become subject to prohibitions on the sale or marketing of our product, product liability claims and significant fines, penalties and sanctions, and our brand and reputation could be harmed.

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about drug and biologic products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling and comparative safety or efficacy claims cannot be made without direct comparative clinical data. For example, although QBREXZA may appeal to individuals who have not been diagnosed with primary axillary hyperhidrosis or suffer from other forms of

hyperhidrosis, we are able to promote it only for primary axillary hyperhidrosis. If we are found to have promoted off-label uses of our product, we may receive warning or untitled letters and become subject to significant criminal and civil liability, which would materially harm our business. Both federal and state governments have levied large civil and criminal fines against companies for alleged improper off-label promotion and have enjoined several companies from engaging in off-label promotion.

If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred and our brand and reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our product for off-label uses, we could be subject to FDA regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations.

We cannot, however, prevent a physician from prescribing our product outside of its approved indication when in the physician's independent professional medical judgment he or she deems appropriate. Physicians or patients may also misuse our product or use improper techniques, potentially leading to adverse results, side effects or injury, which may lead to product liability claims. If our product is misused or used with improper technique, we may become subject to costly litigation by physicians or their patients. See also "—We may face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate." Furthermore, the use of our product for indications other than those approved by the FDA may not effectively treat such conditions, which could harm our reputation among physicians and patients.

We rely completely on third parties to supply, manufacture and distribute drug supplies for QBREXZA, including certain sole-source suppliers and manufacturers.

We do not currently have, nor do we plan to acquire, the infrastructure or capability to supply, manufacture or distribute commercial quantities of QBREXZA. Our ability to commercially supply QBREXZA depends, in part, on our ability to successfully manufacture drug substance and other substances and materials used in QBREXZA from third parties and to have the finished product manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for sale. If we fail to develop and maintain supply relationships with these third parties, we may be unable to successfully commercialize QBREXZA.

We rely and will continue to rely on certain third parties as the sole source of the materials they supply or the finished products they manufacture. For example, we are dependent on our current suppliers of the nonwoven material and pouchstock in QBREXZA. Any of our existing suppliers or manufacturers may:

- fail to supply us with product on a timely basis or in the requested amount due to unexpected damage to or destruction of facilities or equipment or otherwise;
- fail to increase manufacturing capacity and produce drug product and components in larger quantities and at higher yields in a timely or cost-effective manner, or at all, to sufficiently meet our commercial needs;
- be unable to meet our production demands due to issues related to their reliance on sole-source suppliers and manufacturers;
- supply us with product that fails to meet regulatory requirements;
- become unavailable through business interruption or financial insolvency;
- lose regulatory status as an approved source;
- be unable or unwilling to renew current supply agreements when such agreements expire on a timely basis, on acceptable terms or at all; or
- discontinue production or manufacturing of necessary drug substances or products.

In the event of any of the foregoing, if we do not have an alternative supplier or manufacturer in place, we would be required to expend substantial management time and expense to identify, qualify and transfer processes to alternative suppliers or manufacturers. Transferring technology to other sites may require additional processes, technologies and validation studies, which are costly, may take considerable amounts of time, may not be successful and, in most cases, require review and approval by the FDA and foreign regulatory authorities. Any need to find and qualify new suppliers or manufacturers could delay production of QBREXZA indefinitely, adversely impact our ability to market QBREXZA and adversely affect our business. There can be no assurance that replacements would be available to us on a timely basis, on acceptable terms or at all. Additionally, we and our manufacturers do not currently maintain significant inventory of drug substances and other materials. Any interruption in the supply of a drug substance or other material or in the manufacture of QBREXZA could have a material adverse effect on our business, financial condition, operating results and prospects.

Additionally, although we are ultimately responsible for ensuring compliance with regulatory requirements such as current good manufacturing practices ("cGMPs"), we are dependent on our contract suppliers and manufacturers for day-to-day compliance with cGMP for production of both drug substances and finished products. Facilities used by our contract suppliers and manufacturers to produce the drug substances and materials or finished products for commercial sale must pass inspection and be approved by the FDA and other relevant regulatory authorities. A number of our contract suppliers and manufacturers must comply with cGMP requirements enforced by the FDA through its facilities inspection program and review of submitted technical information. If the safety of QBREXZA is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize our product and we may be held liable for injuries sustained as a result. In addition, the manufacturing facilities of certain of our suppliers are located outside of the United States. This may give rise to difficulties in importing our product into the United States or other countries as a result of, among other things, regulatory agency approval requirements, taxes, tariffs, local import requirements such as import duties or inspections, incomplete or inaccurate import documentation or defective packaging. Any of these factors could adversely impact our ability to effectively commercialize QBREXZA.

QBREXZA will be subject to ongoing and continued regulatory review. Failure to comply with applicable regulatory requirements could have a material adverse impact on our business.

We are subject to ongoing FDA obligations and continued regulatory review with respect to, among other things, the manufacturing, processing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for QBREXZA. These requirements include submissions of safety and other post-marketing information and reports and registration, as well as continued compliance with cGMP requirements and with the FDA's good clinical practice ("GCP").

In addition, manufacturers of drug and biologic products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where, or processes by which, the product is manufactured, a regulatory agency may impose restrictions on that product or us, including requesting that we initiate a product recall, or requiring notice to physicians, withdrawal of the product from the market or suspension of manufacturing.

If we, our product or product candidates or the manufacturing facilities for our product or product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- impose restrictions on the marketing or manufacturing of the product, suspend or withdraw product approvals or revoke necessary licenses;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us or our partners to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- issue warning letters, show cause notices or untitled letters describing alleged violations, which may be publicly available;
- commence criminal investigations and prosecutions;
- impose injunctions, suspensions or revocations of necessary approvals or other licenses;
- impose other civil or criminal penalties;
- suspend any ongoing clinical trials;
- delay or refuse to approve pending applications or supplements to approved applications filed by us or our potential partners;
- refuse to permit drugs or precursor chemicals to be imported or exported to or from the United States;

- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require us or our partners to initiate a product recall.

The regulations, policies or guidance of the FDA and other applicable government agencies may change and new or additional statutes or government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulations that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

We or our current and prospective partners may be subject to product recalls in the future that could harm our brand and reputation and could negatively affect our business.

We or our current and prospective partners may be subject to product recalls, withdrawals or seizures if QBREXZA fails to meet specifications or is believed to cause injury or illness or if we are alleged to have violated governmental regulations including those related to manufacturing, labeling, promotion, sale or distribution. Any recall, withdrawal or seizure in the future could materially and adversely affect consumer confidence in our brand and lead to decreased demand for our product. In addition, a recall, withdrawal or seizure of QBREXZA would require significant management attention, would likely result in substantial and unexpected expenditures and would harm our business, financial condition, operating results and prospects.

Risks Related to Development and Regulatory Approval of Our Product Candidates

Our business is dependent on the successful development and regulatory approval of our current and any future product candidates.

Our product candidate, lebrikizumab, is currently in Phase 2b development for the treatment of moderate-to-severe atopic dermatitis. We also have early-stage research programs in other areas of dermatology. The success of our business, including our ability to finance our company and generate additional revenue in the future, will depend on the successful development and regulatory approval of our current product candidate and any future product candidates we may in-license, acquire or develop. The clinical success of our current and any future product candidates will depend on a number of factors, including the following:

- the ability to raise additional capital on acceptable terms, or at all;
- timely completion of our clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors as well as our ability to timely recruit and enroll patients in our clinical trials, which may be delayed due to numerous factors, including the prevalence of other companies' clinical trials for their product candidates for the same or similar indications;
- whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our current or any future product candidates;
    - acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our current or any future product candidates by the FDA and similar foreign regulatory authorities;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, efficacy and acceptable risk to benefit profile of our current or any future product candidates;
- the prevalence, duration and severity of potential side effects experienced with our current or any future product candidates;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our current or any future product candidates;
- our ability to successfully obtain the substances and materials used in our current or any future product candidates from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for preclinical and clinical testing;
- the ability of third parties with whom we contract to manufacture clinical trial supplies of our current or any future product candidates, remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with cGMP; and
- a continued acceptable safety profile during clinical development of our current or any future product candidates.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to successfully complete and obtain regulatory approvals of our current or any future product candidates.

Clinical drug development is very expensive, time-consuming and uncertain. Our clinical trials may fail to adequately demonstrate the safety and efficacy of our current or any future product candidates, which could prevent or delay regulatory approval and commercialization.

Clinical drug development is very expensive, time-consuming and difficult to design and implement, and its outcome is inherently uncertain. Before obtaining regulatory approval for the commercial sale of a product candidate, we must demonstrate through clinical trials that a product candidate is both safe and effective for use in the target indication. Most product candidates that commence clinical trials are never approved by regulatory authorities for commercialization. The clinical trials for these product candidates may take significantly longer than expected to complete. In addition, we, any partner with which we currently or may in the future collaborate, the FDA, an institutional review board ("IRB") or other regulatory authorities, including state and local agencies and counterpart agencies in foreign countries, may suspend, delay, require modifications to or terminate our clinical trials at any time, for various reasons, including:

- discovery of serious or unexpected toxicities or side effects experienced by study participants or other safety issues;
- lack of effectiveness of any product candidate during clinical trials or the failure of a product candidate to meet specified endpoints;
- slower than expected rates of subject recruitment and patient enrollment in clinical trials resulting from numerous factors, including the prevalence of other companies' clinical trials for their product candidates for the same indication, such as atopic dermatitis;
- difficulty in retaining subjects who have initiated participation in a clinical trial but may withdraw at any time due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason;
- difficulty in obtaining IRB approval for studies to be conducted at each site;
- delays in manufacturing or obtaining, or inability to manufacture or obtain, sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or the product formulation or method of delivery;
- changes in applicable laws, regulations and regulatory policies;
- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective contract research organizations ("CROs"), clinical trial sites and other third-party contractors;
- inability to add a sufficient number of clinical trial sites;
- uncertainty regarding proper dosing;
- failure of our CROs or other third-party contractors to comply with contractual and regulatory requirements or to perform their services in a timely or acceptable manner;
- failure by us, our employees, our CROs or their employees or any partner with which we may collaborate or their employees to comply with applicable FDA or other regulatory requirements relating to the conduct of clinical trials or the handling, storage, security and recordkeeping for drug and biologic products;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or
- insufficient data to support regulatory approval.

We or any partner with which we may collaborate may suffer significant setbacks in our clinical trials similar to the experience of a number of other companies in the pharmaceutical and biotechnology industries, even after receiving promising results in earlier trials. In the event that we or our potential partners abandon or are delayed in the clinical development efforts related to our current or any future product candidates, we may not be able to execute on our business plan effectively and our business, financial condition, operating results and prospects would be harmed. For example, in March 2018, we received results that the investigational treatment olumacostat glasaretil (formerly DRM01) for moderate-to-severe acne vulgaris did not meet the co-primary endpoints in its two Phase 3 pivotal trials (CLAREOS-1 and CLAREOS-2) in patients ages nine years and older notwithstanding earlier clinical trials. Based on these results, we expect to discontinue the development program. Furthermore, if we experience delays in the completion of, or if we terminate, any of our current or future clinical trials, our business, financial condition, operating results and prospects would be adversely affected.

We have in the past relied and expect to continue to rely on third-party CROs and other third parties to conduct and oversee our clinical trials, other aspects of our product development and our regulatory submission process. If these third parties do not meet our requirements, conduct the trials as required or otherwise provide services as anticipated, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or successfully commercialize, our current or any future product candidates when expected or at all.

We have in the past relied and expect to continue to rely on third-party CROs and other third parties to conduct and oversee our clinical trials, other aspects of our product development and our regulatory submission process. We also rely upon various medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA's regulations and GCPs, which are an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, and state regulations governing the handling, storage, security and recordkeeping for drug and biologic products. These CROs and other third parties play a significant role in the conduct of our clinical trials, the subsequent collection and analysis of data from the clinical trials, the preparation for and submission of our filings with the FDA and comparable foreign regulatory authorities and the successful commercialization of our product.

We rely heavily on third parties for the execution of our clinical trials and preclinical studies, and control only certain aspects of their activities. We and our CROs and other third-party contractors are required to comply with GCP and good laboratory practice ("GLP") requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCP and GLP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP and GLP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authorities may require us to perform additional clinical trials before approving our or our partners' marketing applications. We cannot provide assurances that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials or preclinical studies complies with applicable GCP and GLP requirements. In addition, our clinical trials must generally be conducted with products produced under cGMP regulations. Our failure to comply with these regulations and policies may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our CROs or clinical trial sites terminate their involvement in our clinical trials for any reason, we may not be able to enter into arrangements with alternative CROs or clinical trial sites in a timely manner, or do so on commercially reasonable terms or at all. In addition, if our relationship with clinical trial sites is terminated, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trial unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and could receive cash compensation in connection with such services. If these relationships and any related compensation result in perceived

or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be questioned by the FDA and comparable foreign regulatory authorities.

Additionally, the regulatory submission process for a product candidate is complex. We expect to rely on a third-party service provider for the preparation and submission of filings with the FDA and comparable foreign regulatory authorities for approval of our current and any future product candidates. If our relationship with such service provider is terminated prior to completion of our regulatory submission process, we may not be able to enter into an arrangement with an alternative service provider in a timely manner, or do so on commercially reasonable terms, and our submission may be substantially delayed.

We are dependent on F. Hoffmann-La Roche Ltd and Genentech, Inc. (together, "Roche") for the manufacture and supply of lebrikizumab drug substance. If Roche elects to transfer its manufacture and supply responsibilities to us, we may not be able to engage a qualified contract manufacturer to manufacture and supply the drug substance in a timely manner, if at all. Any interruption in our supply may cause serious delays in the timing of our clinical trials, increase our costs and adversely impact our financial results.

Pursuant to the terms of our license agreement with Roche for the exclusive, worldwide rights to develop and commercialize lebrikizumab for, among other indications, atopic dermatitis (the "Roche Agreement"), Roche is responsible for the manufacture and supply to us of lebrikizumab drug substance and we are completely reliant upon Roche to provide us with adequate supply for our use. We may experience an interruption in supply if, among other reasons, we incorrectly forecast our supply requirements, Roche allocates supply to its own development programs, Roche incorrectly plans its manufacturing production or Roche is unable to manufacture lebrikizumab drug substance in a timely manner to match our development or commercial needs.

Additionally, the Roche Agreement provides that, subject to certain requirements, Roche has the right to transfer its drug substance manufacture and supply responsibilities to us at any time. We do not currently have, nor do we plan to acquire, the infrastructure or capability to supply, manufacture or distribute clinical or commercial quantities of lebrikizumab drug substance. If Roche elects to transfer its manufacture and supply responsibilities to us, we will incur added costs in qualifying a contract manufacturer to manufacture and supply the lebrikizumab drug substance. There can be no assurance that a qualified contract manufacturer would be available to us on a timely basis, on acceptable terms or at all, or that a seamless transfer of technology would occur from Roche to the contract manufacturer.

If we experience any interruption in the supply of lebrikizumab drug substance, our ability to timely supply our clinical sites would be adversely impacted, causing potentially serious delays in the timing of our clinical trials and substantially increased costs if trials need to be adjusted or re-performed.

We may be unable to obtain regulatory approval for our current or any of our future product candidates under applicable regulatory requirements. The FDA and foreign regulatory bodies have substantial discretion in the approval process, including the ability to delay, limit or deny approval of product candidates. The delay, limitation or denial of any regulatory approval would adversely impact our business and our operating results.

We may never obtain regulatory approval to commercialize our current or any future product candidates. The research, testing, manufacturing, safety surveillance, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, sale, marketing, distribution, import, export and reporting of safety and other post-market information related to our current and any future product candidates are subject to extensive regulation by the FDA and other regulatory authorities in the United States and in foreign countries, and such regulations differ from country to country. We are not permitted to market any of our current or any future product candidates in the United States until we receive approval of an NDA, biologics license application ("BLA") or other applicable regulatory filing from the FDA. We are also not permitted to market our product or our current or any future product candidates in any foreign countries until we receive the requisite approval from the applicable regulatory authorities of such countries.

To gain approval to market a new drug, the FDA and foreign regulatory authorities must receive preclinical, clinical and chemistry, manufacturing and controls data that adequately demonstrate the safety, purity, potency, efficacy and compliant manufacturing of the product for the intended indication applied for in an NDA, BLA or other applicable regulatory filing. The development and approval of new drug products and biologic products involves a long, expensive and uncertain process. A delay or failure can occur at any stage in the process. A number of companies in the pharmaceutical and biopharmaceutical industry have suffered significant setbacks in clinical trials, including in Phase 3 clinical development, even after promising results in earlier preclinical studies or clinical trials. These

setbacks have been caused by, among other things, findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of clinical trials by other parties may not be indicative of the results in trials we or our partners may conduct.

The FDA and foreign regulatory bodies have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of product candidates for many reasons, including:

- the FDA or the applicable foreign regulatory body may disagree with the design, implementation, choice of dose, analysis plans or interpretation of the outcome of one or more clinical trials;
- the FDA or the applicable foreign regulatory body may not deem a product candidate safe and effective for its proposed indication, or may deem a product candidate’s safety or other perceived risks to outweigh its clinical or other benefits;

- the FDA or the applicable foreign regulatory body may not find the data from preclinical studies and clinical trials, including the number of subjects in the safety database, sufficient to support approval, or the results of clinical trials may not meet the level of statistical or clinical significance required by the FDA or the applicable foreign regulatory body for approval;
- the FDA or the applicable foreign regulatory body may disagree with our interpretation of data from preclinical studies or clinical trials performed by us or third parties, or with the interpretation of any partner with which we may collaborate;
- the data collected from clinical trials may not be sufficient to support the submission and approval of an NDA, BLA or other applicable regulatory filing;
- the FDA or the applicable foreign regulatory body may require additional preclinical studies or clinical trials;
- the FDA or the applicable foreign regulatory agency may identify deficiencies in the formulation, manufacturing, quality control, labeling or specifications of our current or any future product candidates;
    - the FDA or the applicable foreign regulatory agency may require clinical trials in pediatric patients in order to establish pharmacokinetics or safety for this more drug-sensitive population;
- the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional post-approval clinical trials;
- the FDA or the applicable foreign regulatory agency may grant approval but impose substantial and costly post-approval requirements;
- the FDA or the applicable foreign regulatory agency may approve our current or any future product candidates for a more limited indication or a narrower patient population than we originally requested;
    - the FDA or applicable foreign regulatory agency may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our current or any future product candidates;
- the FDA or the applicable foreign regulatory body may not approve of the manufacturing processes, controls or facilities of third-party manufacturers or testing labs with which we contract; or
- the FDA or the applicable foreign regulatory body may change its approval policies or adopt new regulations in a manner rendering our clinical data or regulatory filings insufficient for approval.

Of the large number of drugs, including biologics, in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized. For example, our current and any future product candidates may not be approved by the FDA or applicable foreign regulatory agencies even though they meet specified endpoints in our clinical trials. The FDA or applicable foreign regulatory agencies may ask us to conduct additional costly and time-consuming clinical trials in order to obtain marketing approval or approval to enter into an advanced phase of development, or may change the requirements for approval even after such agency has reviewed and commented on the design for the clinical trials. Any delay in obtaining, or inability to obtain, applicable regulatory approval for any of our product candidates would delay or prevent commercialization of our current and any future product candidates and would harm our business, financial condition, operating results and prospects.

We have never obtained approval of a BLA submission or equivalent foreign filing, and we may be unable to successfully do so for any of our current or any future product candidates. Failure to successfully prepare or obtain approval of a BLA or equivalent foreign filing in a timely manner for our current or any future product candidates could have a material adverse impact on our business and financial performance.

Obtaining approval of a BLA submission or equivalent foreign filing involves complicated processes. Although our employees have obtained approvals for BLAs in the past while employed at other companies, we as a company have not obtained approvals of BLAs or equivalent foreign filings. As a result, such activities may require more time and cost more than we anticipate. Failure to complete or obtain, or delays in completing or obtaining, approval of our BLA submission for our current or any future product candidates would prevent us from or delay us in commercializing the product candidate in the United States. The occurrence of any of the foregoing could have a material adverse impact on our business and financial performance.

39

We may conduct clinical trials for our current and any future product candidates outside the United States and the FDA and applicable foreign regulatory authorities may not accept data from such trials, which would likely result in additional costs to us and delay our business plan.

We have conducted, and may in the future choose to conduct, one or more of our clinical trials outside the United States. For example, our Phase 3 clinical program for glycopyrronium tosylate was conducted in multiple countries. Although the FDA or applicable foreign regulatory authority may accept data from clinical trials conducted outside the United States or the applicable jurisdiction, acceptance of such study data by the FDA or applicable foreign regulatory authority may be subject to certain conditions. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay aspects of our business plan.

Other Risks Related to Our Business and Financial Operations

We have had significant and increasing operating expenses and we will require substantial additional financing to achieve our goals, which we may not be able to obtain when needed and on acceptable terms, or at all. We have a history of losses, we have not generated any significant revenue from product sales and we may not be able to achieve or maintain profitability, which could cause our business and operating results to suffer.

We are a biopharmaceutical company with a limited operating history upon which investors can evaluate our business and prospects. QBREXZA, which became available in pharmacies nationwide on October 1, 2018, is our only product approved for commercialization. We have not generated any significant revenue from product sales. We are not profitable and have incurred losses in each year since we commenced operations in August 2010. We have incurred net losses of $149.7 million and $247.2 million for the nine months ended September 30, 2018 and 2017, respectively, and of $303.3 million and $89.1 million for the fiscal years ended December 31, 2017 and 2016, respectively. As of September 30, 2018, we had an accumulated deficit of $673.2 million.

We have financed our operations primarily through the sale of equity securities and convertible debt securities. Since our inception, most of our resources have been dedicated to the development of our product candidates and, more recently, preparation for the commercial launch of QBREXZA. The size of our future net losses will depend, in part, on our future expenses and our ability to generate revenue through future sales of QBREXZA, any future products and our current and potential future collaborations. Revenue from our current and potential future collaborations is uncertain because milestones or other contingent payments under our agreements may not be achieved or received.

As of September 30, 2018, we had capital resources consisting of cash and investments of $389.7 million. We will continue to expend substantial cash resources for the foreseeable future for the commercialization of QBREXZA and the clinical development of our current product candidate and development of any other indications and product candidates we may choose to pursue. These expenditures will include costs associated with any acquisition or in-license of products and product candidates, technologies or businesses, research and development, conducting preclinical studies, non-clinical studies and clinical trials, manufacturing and supply, regulatory submissions, preparing for potential commercial approvals and product launches, as well as marketing and selling any products

approved for sale. In addition, other unanticipated costs may arise. Because the conduct and results of any clinical trial are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our current and any future product candidates.

We believe that existing cash and investments on hand as of September 30, 2018 are sufficient to meet our anticipated cash requirements, excluding costs to complete a potential Phase 3 program for lebrikizumab, to mid-2020 and to: commercialize QBREXZA; complete and generate topline results from our ongoing Phase 2b dose-ranging study for lebrikizumab; and continue potential lifecycle management activities related to our product candidates. We have based these estimates, however, on assumptions that may prove to be wrong, and we could spend our available capital resources much faster than we currently expect or require more capital to fund our operations than we currently expect. See also "—Our future operating results are difficult to predict and may fluctuate significantly. Our gross-to-net estimates related to revenue recognition from product sales are difficult to estimate and if our estimates differ significantly from actual product sales, we will be required to record an adjustment in a subsequent period." We will need to raise additional capital to fund our operations and continue to support our planned research and development and commercialization activities.

The amount and timing of our future funding requirements will depend on many factors, including:

- costs to maintain our infrastructure to continue our commercialization of QBREXZA;
- the cost of commercialization activities, including manufacturing, marketing, sales and distribution costs;
- the degree and rate of market acceptance of QBREXZA;
- the amount of revenue generated from future sales of QBREXZA;
- the timing, rate of progress and cost of any preclinical and clinical trials and other product development activities for our current and any future product candidates that we develop, in-license or acquire;
- the results of the clinical trials for our current and any future product candidates in the United States and any foreign countries;
- the timing of, and the costs involved in, FDA approval and any foreign regulatory approval of our current and any future product candidates, if at all;
- the number and characteristics of any additional future product candidates we develop or acquire;
- our ability to establish and maintain strategic collaborations, licensing, co-promotion or other arrangements and the terms and timing of such arrangements;
- costs under our third-party manufacturing and supply arrangements for QBREXZA and our current and any future product candidates we commercialize;
- costs and timing of completion of any additional outsourced commercial manufacturing or supply arrangements that we may establish;
- whether we are required to assume manufacture and supply responsibilities for lebrikizumab drug substance (see "—We are dependent on Roche for the manufacture and supply of lebrikizumab drug substance. If Roche elects to transfer its manufacture and supply responsibilities to us, we may not be able to engage a qualified contract manufacturer to manufacture and supply the drug substance in a timely manner, if at all. Any interruption in our supply may cause serious delays in the timing of our clinical studies, increase our costs and adversely impact our financial results.");
- costs of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights associated with QBREXZA and our current and any future product candidates, including post-grant challenges or opposition to third-party patent claims;
- costs associated with prosecuting or defending any litigation that we may become involved in and any damages payable by us that result from such litigation;
- costs associated with defending any government investigations or enforcement actions including legal costs and fines;
- costs associated with any product recall that could occur;
- costs of operating as a public company;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing products or treatments;
- costs associated with any acquisition or in-license of products and product candidates, technologies or businesses; and
- personnel, facilities and equipment requirements.

We cannot be certain that additional funding will be available on acceptable terms, or at all. Any future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe that we have sufficient funds for our current or future operating plans.

In order to fund the development and potential commercialization of our current and any future product candidates, we may also need to enter into collaboration agreements with pharmaceutical and biotechnology companies. Our ability to establish and maintain these collaborations is highly uncertain and subject to a number of variables. Under these arrangements, we may be responsible for substantial costs in connection with the clinical development, regulatory approval or the commercialization of a partnered product candidate. Furthermore, the payments we could receive from our potential collaboration partners may be subject to numerous conditions and may ultimately be insufficient to cover the cost of this development and commercialization.

If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, scale back or discontinue one or more of our product development programs or our commercialization efforts, or other aspects of our business plan. In addition, our ability to achieve profitability or to respond to competitive pressures would be significantly limited.

We need to effectively manage the increased size and complexity of our organization to execute our business strategy.

We recently experienced significant growth in the number of our employees and the scope of our operations as we prepared for commercialization of QBREXZA. Our need to manage our operations, growth and various projects effectively requires that we:

- continue to improve our operational, financial, management and regulatory compliance controls and reporting systems and procedures;
- identify, recruit, maintain, motivate and integrate additional talented employees;
- further develop our marketing, sales and distribution capabilities;
- manage our commercialization activities for QBREXZA effectively and in a cost-effective manner;
- establish and maintain relationships with development and commercialization partners;
- manage our preclinical and clinical trials effectively;
- manage our third-party supply and manufacturing operations effectively and in a cost-effective manner, while increasing production capabilities for QBREXZA to commercial levels; and
- manage our development efforts effectively while carrying out our contractual obligations to partners and other third parties.

In addition, historically, we have utilized and continue to utilize the services of part-time outside consultants to perform a number of tasks for us, including tasks related to preclinical and clinical testing. Our growth strategy may also entail expanding our use of consultants to implement these and other tasks going forward. We rely on consultants for certain functions of our business and will need to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. There can be no assurance that we will be able to manage our existing consultants or find other competent outside consultants, as needed, on economically reasonable terms, or at all.

To effectively manage the increased size and complexity of our organization, we may incur significant costs and our management and business development resources may be diverted. If we are unable to successfully implement the tasks necessary to effectively manage the increased size and complexity of our organization and execute our business strategy, our ability to achieve our research, development and commercialization goals may be materially adversely impacted.

If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop our current and any future product candidates, commercialize QBREXZA or otherwise implement our business plan.

Our ability to compete in the highly competitive pharmaceuticals industry depends upon our ability to attract and retain highly qualified managerial, scientific, medical, sales and marketing and other personnel. We are highly dependent on our management and scientific personnel, including: our Chief Executive Officer and Chairman of our board of directors, Thomas G. Wiggans; our Chief Medical Officer and a member of our board of directors, Eugene A. Bauer, M.D.; our Chief Technical Operations Officer, Christopher Horan; our Chief Financial Officer, Andrew L. Guggenhime; our Chief Development Officer, Luis C. Peña; our Chief Commercial Officer, Lori Lyons-Williams; and our Chief Business and Strategy Officer, Christopher M. Griffith. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our products or in-licensing or acquisition of new assets and could negatively impact our ability to successfully implement our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. We employ all of our executive officers and key personnel on an at-will basis and their employment can be terminated by us or them at any time, for any reason and without notice. In order to retain valuable employees at our company, in addition to salary and cash incentives, we provide stock options and restricted stock units that vest over time. The value to employees of stock options and restricted stock units that vest over time will be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract offers from other companies. For example, following our announcement that the investigational treatment olumacostat glasaretil (formerly DRM01) for moderate-to-severe acne vulgaris did not meet the co-primary endpoints in its two Phase 3 pivotal trials (CLAREOS-1 and CLAREOS-2) in patients ages nine years and older, the value of our common stock decreased significantly, which may adversely impact our ability to attract and retain employees.

We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Francisco Bay Area where we are headquartered. We could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many of the other pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives.

In addition, we have scientific and clinical advisors who assist us in formulating our development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

Our failure to successfully in-license, acquire, develop and market additional product candidates or approved products would impair our ability to grow our business.

We intend to in-license, acquire, develop and market additional products and product candidates. Because our internal research and development capabilities are limited, we may be dependent upon pharmaceutical companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify and select promising pharmaceutical product candidates and products, negotiate licensing or acquisition agreements with their current owners and finance these arrangements.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales and other resources, may compete with us for the license or acquisition of product candidates and approved

products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. Additionally, we may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including preclinical or clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any approved products that we acquire will be manufactured or sold profitably or achieve market acceptance.

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

The development of product candidates and commercialization of products require substantial additional cash to fund expenses. In order to fund further development of our current and any future product candidates, we may collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. We face significant competition in seeking appropriate partners. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the partner's resources and experience, the terms and conditions of the proposed collaboration and the proposed partner's evaluation of a number of factors. Those factors may include the design or results of clinical trials; the likelihood of approval by the FDA or other regulatory authorities; the potential market for the subject product candidate; the costs and complexities of manufacturing and delivering such product candidate to patients; the potential of competing products; any uncertainty with respect to our ownership of our intellectual property; and industry and market conditions generally. The partner may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential partners. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future partners.

Collaborations typically impose detailed obligations on each party, such as those required under the Roche Agreement. If we were to breach our obligations, we may face substantial consequences, including potential termination of the collaboration, and our rights to product candidates, in which we have invested substantial time and money, would be lost.

We may not be successful in our efforts to implement collaborations or other alternative arrangements for the development of our current or any future product candidates. When we partner with a third party for development and commercialization of a product candidate, we can expect to relinquish to the third party some of the control over the future success of that product candidate. Our collaboration partner may not devote sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization. The terms of any collaboration or other arrangement that we establish may not be favorable to us. In addition, any collaboration that we enter into may be unsuccessful in the development and commercialization of our product candidates. In some cases, we may be responsible for continuing preclinical and initial clinical development of a partnered product candidate or research program, and the payment we receive from our collaboration partner may be insufficient to cover the cost of this development.

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

We face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. Numerous companies are engaged in the development, patenting,

manufacturing and marketing of healthcare products competitive with those that we are developing and commercializing. We face competition from a number of sources, such as pharmaceutical companies, generic drug companies, biotechnology companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, clinical trial expertise, intellectual property portfolios, experience in obtaining patents and regulatory approvals for product candidates and other resources than we do. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. In addition, QBREXZA and any of our current or future product candidates, if approved, may compete with other dermatological products, including over-the-counter ("OTC") treatments, for a share of some patients' discretionary budgets and for physicians' attention within their clinical practices.

Many pharmaceutical companies currently offer products or are developing alternative product candidates and technologies, for indications similar to those targeted by our product or product candidate, including: AbbVie Inc., Akaal Pharma Pty Ltd., Allergan plc, Almirall, S.A., Amgen Inc., AnaptysBio, Inc., Asana BioSciences, LLC, Aslan Pharmaceuticals Pte Ltd., Astellas Pharma US, Inc., Bayer HealthCare AG (formerly Intendis, Inc.), BioPharmX Corporation, Boehringer Ingelheim Pharmaceuticals, Inc., Brickell Biotech, Inc., Bristol-Myers Squibb Co., Concert Pharmaceuticals, Inc., Can-Fite BioPharma Ltd., Cassiopea S.p.A., a subsidiary of Cosmo Pharmaceuticals S.A., Celgene Corporation, Dermavant Sciences Ltd. (a subsidiary of Roivant Sciences), Chugai Pharmaceutical Co., DS Biopharma Limited, Eirion Therapeutics, Inc., Eli Lilly and Company, Foamix Pharmaceuticals Ltd., Galapagos NV, Galderma S.A., Galectin Therapeutics, Inc., Genentech, Inc., Gilead Sciences, Inc., GlaxoSmithKline LLC, Glenmark Pharmaceuticals Limited, Janssen Pharmaceuticals, Inc. (a division of Johnson & Johnson), Johnson & Johnson, LEO Pharma A/S, Maruho Co., Ltd., Medimetriks Pharmaceuticals, Inc., MedImmune, LLC (a wholly-owned subsidiary of AstraZeneca plc), Menlo Therapeutics Inc., Miramar Labs, Inc., Momenta Pharmaceuticals, Inc., MorphoSys AG, Mylan Inc., Novan, Inc., Novartis AG, Pfizer Inc., Qurient Co., Ltd., Ralexar Therapeutics, Inc., Ranbaxy Laboratories Limited, a division of Sun Pharmaceutical Industries Ltd., Regeneron Pharmaceuticals, Inc., Sandoz International GmbH (a division of Novartis), Sanofi-Aventis Groupe S.A., Shire plc, Teva Pharmaceutical Industries Ltd., TheraVida, Inc., Torii Pharmaceutical Co. Ltd., Ulthera, Inc. (a subsidiary of Merz Pharma GmbH & Co. KGaA),Valeant Pharmaceuticals International, Inc., Vanda Pharmaceuticals Inc. and XBiotech Inc.

The markets for dermatological therapies are competitive and are characterized by significant technological development and new product introduction. We anticipate that QBREXZA and any of our current or future product candidates, if approved, will face significant competition from other approved therapies as well as unregulated, unapproved and off-label treatments. QBREXZA and any of our current or future product candidates, if approved, would present novel therapeutic approaches for the approved indications and would have to compete with existing therapies, some of which are widely known and accepted by physicians and patients. To compete successfully in this market, we will have to demonstrate that the relative cost, safety and efficacy of our approved product provide an attractive alternative to existing and other new therapies. The competition we face could lead to reduced market share for QBREXZA and any of our current or future product candidates that are approved and contribute to downward pressure on the pricing of our products, which could harm our business, financial condition, operating results and prospects.

Due to less stringent regulatory requirements in certain foreign countries, there are many more dermatological products and procedures available for use in those international markets than are approved for use in the United States. In certain international markets, there are also fewer limitations on the claims that our competitors can make about the effectiveness of their products and the manner in which they can market their products. As a result, we expect to face more competition in these markets than in the United States.

We expect to face generic competition and may face competition from biosimilars, which could adversely affect our business, financial condition, operating results and prospects.

Upon the expiration or loss of any patent protection for QBREXZA and our current and any future product candidates that are approved, or upon the “at-risk” launch by a generic competitor of a generic version of QBREXZA or our current and any future product candidates that are approved, which may be sold at significantly lower prices than our approved product candidates, we could lose a significant portion of sales of that product in a short period of time, which would adversely affect our business, financial condition, operating results and prospects. In particular, QBREXZA faces competition from currently marketed generic oral and compounded topical anticholinergic agents. In addition, we may be subject to additional competition from third parties pursuing topical formulations of other anticholinergic agents for hyperhidrosis.

We may also face competition from biosimilars. In the United States, the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar," or "biosimilar," to or "interchangeable" with an FDA-approved biological product. This pathway allows competitors to reference the FDA's prior determinations regarding innovative biological products and to obtain approval of a biosimilar application 12 years after the time of approval of the innovative biological product. The 12-year exclusivity period runs from the initial approval of the innovator product and not from approval of a new indication. In addition, the 12-year exclusivity period does not prevent another company from developing a product that is highly similar to the innovative product, generating all the data necessary for a full BLA and seeking approval. Exclusivity only assures that another company cannot rely on the FDA's prior determinations in approving a BLA for an innovator's biological product to support the biosimilar product's approval. Further, under the FDA's current interpretation, it is possible that a biosimilar applicant could obtain approval for one or more of the indications approved for the innovator product by extrapolating clinical data from one indication to support approval for the other indications. We cannot predict to what extent the entry of biosimilars or other competing products will impact our business, financial condition, operating results and prospects.

Manufacturing and supply of the drug substance and other substances and materials used in product and product candidate is a complex and technically challenging undertaking, and there is potential for failure at many points in the manufacturing, testing, quality assurance and distribution supply chain, as well as the potential for latent defects after products have been manufactured and distributed.

Manufacturing and supply of drug substance, other substances and materials and finished drug products is technically challenging. Changes beyond our direct control can impact the quality, volume, price and successful delivery of our product and current or future product candidates and can impede, delay, limit or prevent the successful commercialization of QBREXZA and development of our current or future product candidates. Mistakes and mishandling are not uncommon and can affect successful production and supply. Some of these risks include:

- failure of our manufacturers to follow cGMP requirements or mishandling of product while in production or in preparation for transit;
- inability of our contract suppliers and manufacturers to efficiently and cost-effectively increase and maintain high yields and batch quality, consistency and stability;
- inability of our suppliers and manufacturers to meet our production demands due to issues related to their reliance on sole-source suppliers and manufacturers;
- difficulty in establishing optimal production, storage, packaging and shipment methods and processes;
- challenges in designing effective drug delivery devices and techniques;
- transportation and import/export risk, particularly given the global nature of our supply chain;
- delays in analytical results or failure of analytical techniques that we depend on for quality control and release of product;
- natural disasters, labor disputes, financial distress, lack of raw material supply, issues with facilities and equipment or other forms of disruption to the business operations of our contract manufacturers and suppliers; and
- latent defects that may become apparent after product has been released and which may result in recall and destruction of product.

Any of these factors could result in delays or higher costs in connection with our clinical trials, regulatory submissions, required approvals or commercialization of our product, which could harm our business, financial condition, operating results and prospects.

We may choose to discontinue the development of our current or any future product candidates or commercialization of any approved products, which would reduce or eliminate our potential return on investment for those product candidates or product.

At any time, we may decide to discontinue the development of our current or any future product candidates or commercialization of our approved products for a variety of reasons, such as the appearance of new technologies that make our product obsolete, competition from a competing product, changes in or failure to comply with applicable regulatory requirements, the discovery of unforeseen side effects after the approved product has been marketed or the occurrence of adverse events at a rate or severity level that is greater than experienced in our clinical trials. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to have allocated those resources to potentially more productive uses.

Our business involves the use of hazardous materials and we and our third-party suppliers and manufacturers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

The manufacturing activities of our third-party suppliers and manufacturers involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product, product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our suppliers' or manufacturers' facilities pending use and disposal. We and our suppliers and manufacturers cannot completely eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, injury to our service providers and others and environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party suppliers and manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources. We do not currently carry biological or hazardous waste insurance coverage.

Our employees, independent contractors, principal investigators, consultants, vendors, CROs, distributors, prescribers and any partners with which we may collaborate may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our business.

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, CROs, distributors, prescribers and any partners with which we may collaborate may engage in fraudulent or other illegal activity. Misconduct by these persons could include intentional, reckless or negligent conduct or unauthorized activity that violates: laws or regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or foreign regulatory authorities; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commissions, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations, and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our operating results.

We intend to in-license and acquire product candidates or engage in other strategic transactions, which could impact our liquidity, increase our expenses and present significant distractions to our management.

Our strategy is to in-license and acquire product candidates or engage in other strategic transactions. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such

transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions entail numerous potential operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- substantial acquisition and integration costs;
- write-downs of assets or impairment charges;
- increased amortization expenses;

- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers, partners or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain our key employees or those of any acquired businesses.

Accordingly, there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, and any transaction that we do complete could harm our business, financial condition, operating results and prospects. We have no current plan, commitment or obligation to enter into any transaction described above.

Our future operating results are difficult to predict and may fluctuate significantly. Our gross-to-net estimates related to revenue recognition from product sales are difficult to estimate and if our estimates differ significantly from actual product sales, we will be required to record an adjustment in a subsequent period. If our operating results fall below expectations, our stock price may be adversely impacted.

Our operations to date have been primarily limited to researching and developing our product candidates, undertaking preclinical studies and clinical trials of our product candidates and, more recently, preparing for the commercial launch of QBREXZA. QBREXZA, our only product approved for commercialization, became available in pharmacies nationwide on October 1, 2018. Our revenue and profitability will depend in large part on the successful commercialization of QBREXZA. Our future operating results are difficult to predict and may fluctuate significantly from period to period due to many factors, such as revenue from product sales, expenditures and payments relating to collaboration and license agreements and stock-based compensation expense.

Our gross-to-net estimates related to revenue recognition from product sales are difficult to estimate as they are based on multiple assumptions which may prove to be incorrect. For example, we contract with certain third-party payers for the payment of rebates with respect to the utilization of QBREXZA and rebates to these payers are based on contractual percentages applied to the amount of QBREXZA prescribed to patients who are covered by the plan or the organization with which the third-party payer contracts. We have also implemented a savings card program to provide assistance to eligible patients with out-of-pocket costs, such as deductibles, co-insurance and co-payments, for the patient's usage of QBREXZA. Reductions to product sales for the savings card program are estimated based on actual and expected program utilization. We recognize product sales at the transaction price, net of estimates of variable consideration, including commercial rebates, discounts related to a patient savings card program, distribution fees, trade discounts, government rebates and chargebacks and product returns. Our estimates of variable consideration are based on assumptions relating to, among other things, the mix of patients who purchase QBREXZA who are fully insured, underinsured and uninsured and the utilization of our savings card program, rebates, discounts and other pricing concessions and fees. If our gross-to-net estimates differ significantly from actual product sales, we will be required to record an adjustment in a subsequent period to reported product sales and earnings.

From time to time, we may enter into collaboration agreements and license agreements with other companies that include development funding and significant upfront and milestone expenditures and payments. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- delays in the commencement, patient enrollment and the timing of clinical testing for our current and any future product candidates;
- the timing and success or failure of clinical trials for our current and any future product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review and approval of current and any future product candidates in clinical development;

- the timing and cost of, and level of investment in, research and development activities relating to our current and any future product candidates, which may change from time to time;
- the cost of manufacturing our current and any future product candidates, which may vary depending on FDA guidelines and requirements, and the quantity of production;
- our ability to obtain additional funding to develop our current and any future product candidates;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the level of demand for our current and any future product candidates, should they receive approval, which may vary significantly;
- potential side effects of our current and any future product candidates that could delay or prevent commercialization or cause an approved drug to be taken off the market;
- the availability of formulary coverage and adequate reimbursement from private third-party payers for our current and any future product candidates that may be approved;
- gross-to-net deductions, including rebates, discount, other pricing concessions and fees that we may provide to integrated delivery networks, group purchasing organizations, other purchasers and pharmacy benefits managers and other third-party payers;
- the mix of fully insured, underinsured and uninsured patients who purchase QBREXZA and the utilization of our savings card program;
- our dependency on third-party manufacturers to supply or manufacture our current and any future product candidates;
- our ability to maintain an effective sales and our marketing and distribution infrastructure that supports our commercial growth;
- market acceptance of our current and any future products, if approved, and our ability to forecast demand for those products;
- our ability to receive regulatory approval and commercialize our current and any future product candidates;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability and third parties' abilities to protect intellectual property rights;
- costs related to and outcomes of potential litigation or other disputes;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively;
- potential liabilities associated with hazardous materials;
- our ability to maintain adequate insurance policies; and
- future accounting pronouncements or changes in our accounting policies.

Our operating results and liquidity needs could be negatively affected by market fluctuations and economic downturn.

Our operating results and liquidity could be negatively affected by economic conditions generally, both in the United States and elsewhere around the world. The market for discretionary medical products and procedures may be particularly vulnerable to unfavorable economic conditions. Some patients may consider QBREXZA as discretionary, and if full reimbursement for the product is not available, demand for the product may be tied to the discretionary spending levels of our targeted patient populations. Domestic and international equity and debt markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue or worsen and the markets continue to remain volatile, our operating results and liquidity could be adversely affected by those factors in many ways, including weakening demand for QBREXZA, making it more difficult for us to raise funds if necessary, and our stock price may decline.

Our ability to utilize our net operating loss ("NOL") carryforwards and research and development income tax credit carryforwards may be limited.

As of December 31, 2017, we had NOL carryforwards available to reduce future taxable income, if any, for federal, California and Canadian income tax purposes. If not utilized, the federal and California NOL carryforwards will begin expiring during the year ending December 31, 2030 and the Canadian NOL carryforwards will begin expiring during the year ending December 31, 2028. Under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We have experienced at least one ownership change since inception and our utilization of NOL carryforwards will therefore be subject to annual limitation. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

We may be adversely affected by natural disasters and other catastrophic events, and by man-made problems such as terrorism, that could disrupt our business operations and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters are located in Menlo Park, California, near major earthquake and fire zones. If a disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as enterprise financial systems, manufacturing resource planning or enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Our contract manufacturers' and suppliers' facilities are located in multiple locations, where other natural disasters or similar events, such as blizzards, tornadoes, fires, explosions or large-scale accidents or power outages, could severely disrupt our operations and have a material adverse effect on our business, financial condition, operating results and prospects. In addition, acts of terrorism and other geo-political unrest could cause disruptions in our business or the businesses of our partners, manufacturers or the economy as a whole. All of the aforementioned risks may be further increased if we do not implement a disaster recovery plan or our partners' or manufacturers' disaster recovery plans prove to be inadequate. To the extent that any of the above should result in delays in the regulatory approval, manufacture, distribution or commercialization of our product or product candidates, our business, financial condition, operating results and prospects would suffer.

Our business and operations would suffer in the event of failure, invasion, corruption, destruction or interruption of our or our partners' critical information technology systems or infrastructure.

Despite the implementation of security measures, our information technology systems and infrastructure, and those of our current and any future partners, contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our systems or in non-encrypted portable media or storage devices. We could also experience a business interruption, intentional theft of confidential information, or reputational damage from espionage attacks, malware or other cyber-attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our manufacturing activities, development programs and our business operations. For example, the loss of manufacturing records or clinical trial

data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our current and any future product candidates and commercialization of our product could be delayed.

Risks Related to Our Industry

Healthcare reform measures could hinder or prevent the commercial success of our product and product candidates.

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future revenue and profitability and the future revenue and profitability of any partner with which we may collaborate. Federal and state lawmakers regularly propose and, at times, enact legislation that results in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, in March 2010, former President Obama signed one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, "Affordable Care Act"). It contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which have impacted and are expected to continue to impact existing government healthcare programs and result in the development of new programs. The Affordable Care Act, among other things, (1) increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to certain individuals enrolled in Medicaid managed care organizations, (2) established annual fees on manufacturers of certain branded prescription drugs and (3) enacted a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

The current presidential administration and certain members of the majority of the U.S. Congress have sought to repeal all or part of the Affordable Care Act and implement a replacement program. For example, the so-called "individual mandate" was repealed as part of tax reform legislation adopted in December 2017, such that the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Code will be eliminated beginning in 2019. Additionally, in October 2018, the U.S. President has proposed to lower Medicare Part B drug prices, in addition to contemplating other measures to lower prescription drug prices. While this proposal has not yet been enacted, we expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our approved product or additional pricing pressures.

We may also be subject to healthcare laws, regulation and enforcement and our failure to comply with those laws could adversely affect our business, operations and financial condition.

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights, among other topics, are and will be applicable to our business. We are subject to regulation by both the federal government and the states in which we or our partners conduct our business. The healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual or in return for the purchase, lease, or order of any good, facility item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, including, for example, the federal civil False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e.g., public or private), knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which impose obligations on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal physician sunshine requirements under the Affordable Care Act, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members;
- federal and state laws requiring pricing transparency or limiting price increases, which are in existence today or are anticipated to be in existence in the near future, may limit the ability to raise prices, require disclosure of price increases or require disclosure of the wholesale acquisition cost of pharmaceutical products to governmental agencies and consumers; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payer, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be provided to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Achieving and sustaining compliance with these laws may prove costly. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental laws or regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment or the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

Risks Related to Our Intellectual Property

We may not be able to obtain or enforce patent rights or other intellectual property rights that cover our product, product candidates and technologies that are of sufficient breadth to prevent third parties from competing against us.

Our success will depend in part on our ability to obtain and maintain patent protection in both the United States and other countries, to preserve our trade secrets and to prevent third parties from infringing upon our proprietary rights. Our ability to protect against unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents.

Our patent portfolio includes patents and patent applications in the United States and foreign jurisdictions where we believe there is a market opportunity for our product and product candidates. The covered technology and the scope of coverage vary from country to country. For those countries where we do not have granted patents, we may not have any ability to prevent the unauthorized use of our technologies. Any patents that we may obtain may be narrow in scope and thus easily circumvented by competitors. Further, in countries where we do not have granted patents, third

parties may be able to make, use or sell products identical to or substantially similar to, our product or product candidates.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current licensors or licensees, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If our current licensors or licensees, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition and operating results.

Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering pharmaceutical inventions, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any existing patents or any patents we might obtain or license may not cover our product or product candidates, or may not provide us with sufficient protection for our product or product candidates to afford a commercial advantage against competitive products or processes, including those from branded and generic pharmaceutical companies. In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents have issued or will issue, we cannot guarantee that the claims of these patents are or will be held valid or enforceable if challenged in post-grant proceedings or by the courts or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us.

Competitors in the field of dermatologic therapeutics have created a substantial amount of prior art, including scientific publications, patents and patent applications. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Although we believe that our technology includes certain inventions that are unique and not duplicative of any prior art, we do not have outstanding issued patents covering all of the recent developments in our technology and we are unsure of the patent protection that we will be successful in obtaining, if any. Even if the patents do successfully issue, third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. In particular, due to the extensive prior art relating to anticholinergic agents to control hyperhidrosis and because glycopyrronium tosylate is a form of a generic anticholinergic agent, the patent protection available for glycopyrronium tosylate may not prevent competitors from developing and commercializing similar products. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our product or product candidates is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our product or product candidates.

The laws of some foreign jurisdictions do not provide intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property in foreign jurisdictions, our business prospects could be substantially harmed.

The degree of future protection of our proprietary rights is uncertain. Patent protection may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not have been the first to invent or the first to file the inventions covered by each of our pending patent applications and issued patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- the patents of others may have an adverse effect on our business;
- any patents we obtain or our licensors' issued patents may not encompass commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties;
- any patents we obtain or our in-licensed issued patents may not be valid or enforceable; and
- we may not develop additional proprietary technologies that are patentable or provide us with a competitive advantage.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our product and product candidates, we may be open to competition from generic versions of our product and product candidates. Further, the extensive period of time between patent filing and regulatory approval for a product or product candidate limits the time during which we can market a product under patent protection, which may particularly affect the profitability early-stage product candidates. The issued U.S. patents relating to glycopyrronium tosylate and lebrikizumab will expire between 2020 and 2037.

Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how by entering into confidentiality agreements with third parties, and intellectual property protection agreements with certain employees, consultants and advisors, third parties may still obtain this information or we may be unable to protect our rights. We also have limited control over the protection of trade secrets used by our suppliers, manufacturers and other third parties. There can be no assurance that binding agreements will not be breached, that we would have adequate remedies for any breach or that our trade secrets and unpatented know-how will not otherwise become known or be independently discovered by our competitors. If trade secrets are independently discovered, we would not be able to prevent their use. Enforcing a claim that a third party illegally obtained and is using our trade secrets or unpatented know-how is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secret information.

Changes in patent laws or the interpretations of patent laws could diminish the value of patents in general, thereby impairing our ability to protect our product and product candidates.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. The United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the scope and value of patents, once obtained.

For our U.S. patent applications containing a priority claim after March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, also known as the America Invents Act (“AIA”) was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the U.S. Patent and Trademark Office (“USPTO”) after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in

USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' ability to obtain new patents or to enforce existing patents we and our licensors or partners may obtain in the future.

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

Filing, prosecuting and defending patents on our product and product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement on infringing activities is inadequate. These products may compete with our product and product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and certain developing countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product and product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

If we fail to comply with our obligations under our intellectual property license agreements, we could lose license rights that are important to our business.

We are a party to certain license agreements that impose various diligence, milestone, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the respective licensors may have the right to terminate the license, in which event we may not be able to develop or market the affected product or product candidate. The loss of such rights could materially adversely affect our business, financial condition, operating results and prospects. For example, any dispute with Roche relating to compliance with the terms of the Roche Agreement could lead to delays in, or termination of, the development and commercialization of lebrikizumab for the treatment of atopic dermatitis and time consuming and expensive arbitration.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time-consuming, and an unfavorable outcome in that litigation could have a material adverse effect on our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our product and product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. We cannot provide assurances that marketing and selling such candidates and using such technologies will not infringe existing or future patents. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields relating to our product and product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that our product, product candidates, technologies or methods of delivery or use infringe their patent rights. Moreover, it is not always clear to industry participants, including us, which patents cover various drugs, biologics, drug delivery systems or their methods of use, and which of these patents may be valid and enforceable. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product, product candidates, technologies or methods.

In addition, there may be issued patents of third parties that are infringed or are alleged to be infringed by our product, product candidates or proprietary technologies. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our own and in-licensed issued patents or our pending applications. Our competitors may have filed, and may in the future file, patent applications covering our product, product candidates or technology similar to ours. Any such patent application may have priority over our own and in-licensed patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate, in the United States, in an interference proceeding to determine priority of invention.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product, product candidates or proprietary technologies infringe such third parties' intellectual property rights, including litigation resulting from filing under Paragraph IV of the Hatch-Waxman Act. These lawsuits could claim that there are existing patent rights for such drug and this type of litigation can be costly and could adversely affect our operating results and divert the attention of managerial and technical personnel, even if we do not infringe such patents or the patents asserted against us are ultimately established as invalid. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. To date, no litigation asserting infringement claims has ever been brought against us. If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product or technology at issue infringes or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
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- a court prohibiting us from selling or licensing the product or using the technology at issue unless the third party licenses its intellectual property rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties or upfront fees or grant cross-licenses to intellectual property rights for our product, product candidates or technologies; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could harm our ability to raise additional funds or otherwise adversely affect our business, financial condition, operating results and prospects.

Because we rely on certain third-party licensors, licensees and partners, and will continue to do so in the future, if one of our licensors, licensees or partners is sued for infringing a third party's intellectual property rights, our business, financial condition, operating results and prospects could suffer in the same manner as if we were sued directly. In addition to facing litigation risks, we have agreed to indemnify certain third-party licensors, licensees and partners against claims of infringement caused by our proprietary technologies, and we have entered or may enter into cost-sharing agreements with some our licensors, licensees and partners that could require us to pay some of the costs of patent litigation brought against those third parties whether or not the alleged infringement is caused by our proprietary technologies. In certain instances, these cost-sharing agreements could also require us to assume greater responsibility for infringement damages than would be assumed just on the basis of our technology.

The occurrence of any of the foregoing could adversely affect our business, financial condition, operating results and prospects.

We may become involved in lawsuits or other adverse proceedings to protect or enforce our patents or other intellectual property or the patents of our licensors, which could be expensive and time-consuming.

Competitors may infringe our intellectual property, including our patents or the patents of our licensors. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied. An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated, interpreted narrowly or amended such that they do not cover our product or product candidates. Moreover, such adverse determinations could put our patent applications at risk of not issuing, or issuing with limited and potentially inadequate scope to cover our product or product candidates or to prevent others from marketing similar products.

Interference, derivation or other proceedings such as inter partes review, post-grant review and reexamination brought at the USPTO may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or potential partners. Litigation or USPTO proceedings brought by us may fail or may be invoked against us by third parties. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or potential partners, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their former employers or their former or current customers.

As is common in the biotechnology and pharmaceutical industries, certain of our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants to assist us in the development of our product candidates, many of whom were previously employed at or may have previously been or are currently providing consulting services to, other

biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees and consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims. Even if we are successful in defending against any such claims, any such litigation could be protracted, expensive, a distraction to our management team, not viewed favorably by investors and other third parties and may potentially result in an unfavorable outcome.

Risks Related to the Securities Markets and Ownership of Our Common Stock

The stock price of our common stock has been, and is likely to continue to be, volatile and may decline and stockholders may not be able to resell their shares at or above the price at which they purchased the shares.

Prior to our initial public offering ("IPO") in October 2014, there had not been a public market for our common stock. The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- the level of, and fluctuations in, the commercial sales of QBREXZA;
- the development status of our product candidates, including whether any of our product candidates receive regulatory approval;
- regulatory or legal developments in the United States and foreign countries;
- the results of our clinical trials and preclinical studies;
- the clinical results of our competitors or potential competitors;
- safety or adverse events related to our product or product candidates;
- the success of, and fluctuations in, the commercial sales of additional products approved for commercialization, if any;
- the execution of our partnering and manufacturing arrangements;
- our execution of collaboration, co-promotion, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;
- variations in the level of expenses related to our preclinical and clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites;
- variations in the level of expenses related to our commercialization activities, if any product candidates are approved;
- the performance of third parties on whom we rely for clinical trials, manufacturing, marketing, sales and distribution, including their ability to comply with regulatory requirements;
- overall performance of the equity markets;
- changes in operating performance and stock market valuations of other pharmaceutical companies;
- market conditions or trends in our industry or the economy as a whole;
- the public's response to press releases or other public announcements by us or third parties, including our filings with the Securities and Exchange Commission ("SEC") and announcements relating to acquisitions, strategic transactions, licenses, joint ventures, capital commitments, intellectual property, litigation or other disputes impacting us or our business;
- developments with respect to intellectual property rights;
- litigation relating to our product or product candidates;
- our commencement of, or involvement in, litigation;
- FDA or foreign regulatory actions affecting us or our industry;
- changes in the structure of healthcare payment systems;
- changes to laws affecting our industry, including full or partial repeal of the Affordable Care Act;
- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- changes in financial estimates by any securities analysts who follow our common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our common stock;
- ratings downgrades by any securities analysts who follow our common stock;
- the development and sustainability of an active trading market for our common stock;
- the size of our market float;

- future sales of our common stock by our officers, directors and significant stockholders;
- future sales and purchases of any shares of our common stock issued upon conversion of the 3.00% Convertible Senior Notes due 2022 ("Notes");
- recruitment or departure of key personnel;
- changes in accounting principles;
- other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events; and
- any other factors discussed herein.

In addition, the stock markets, and in particular The Nasdaq Global Select Market, have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many pharmaceutical companies. Stock prices of many pharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies.

During the period between January 1, 2016 and October 31, 2018, the closing sale price of our common stock on The Nasdaq Global Select Market ranged from $7.12 to $38.03 per share. Because our stock price has been volatile, investing in our common stock is risky.

Significant past or future decreases in the stock price of our common stock could subject us to securities litigation, which is expensive and could divert management's attention, and could adversely impact our ability to raise additional capital to fund our operations.

The market price of our common stock has been volatile. For example, following our announcement that the investigational treatment olumacostat glasaretil (formerly DRM01) for moderate-to-severe acne vulgaris did not meet the co-primary endpoints in its two Phase 3 pivotal trials (CLAREOS-1 and CLAREOS-2) in patients ages nine years and older, the value of our common stock decreased significantly. Many companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could harm our business. Additionally, the volatility in the market price of our common stock could adversely impact our ability to raise additional capital to fund our operations and continue to support our planned research and development and commercialization activities. See also "—We have had significant and increasing operating expenses and we will require substantial additional financing to achieve our goals, which we may not be able to obtain when needed and on acceptable terms, or at all. We have a history of losses and may not be able to achieve or maintain profitability, which could cause our business and operating results to suffer."

If a large number of shares of our common stock are sold in the public market, the sales could reduce the trading price of our common stock, impede our ability to raise future capital and holders may have difficulty selling their shares based on current trading volumes of our stock.

Our stock is currently traded on The Nasdaq Global Select Market, but we can provide no assurance that we will be able to maintain an active trading market on The Nasdaq Global Select Market or any other exchange in the future. The trading volume of our stock tends to be low and we have several stockholders who hold a significant number of shares. If there is no active trading market or if the volume of trading is limited, holders of our common stock may have difficulty selling their shares.

As of September 30, 2018, we had 42,114,401 shares of common stock outstanding, and stockholders holding 5% or more of our stock, individually or with affiliated persons or entities, collectively beneficially owned or controlled approximately 42% of such shares. If stockholders holding a significant number of our shares sell, indicate an intention to sell, or if it is perceived that they will sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline and our ability to raise future capital may be adversely affected.

59

Furthermore, we completed a sale of $287.5 million aggregate principal amount of Notes in May 2017 in a private placement in reliance on Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), to qualified institutional buyers pursuant to Rule 144A promulgated under the Securities Act. The Notes mature on May 15, 2022, unless earlier converted or repurchased in accordance with their terms. Holders of the Notes may convert all or a portion of their Notes at their option at any time prior to the close of business on the business day immediately prior to May 15, 2022, in multiples of $1,000 principal amount. The Notes are convertible into shares of our common stock at an initial conversion rate of 28.2079 shares of common stock per $1,000 principal amount of the Notes, which is equivalent to an initial conversion price of approximately $35.45 per share of common stock. As of September 30, 2018, the Notes were convertible into 8,109,771 shares of our common stock. The conversion rate and the corresponding conversion price will be subject to adjustment upon the occurrence of certain events. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the Notes may encourage short selling by market participants because the conversion of the Notes could be used to satisfy short positions, or anticipated conversion of the Notes into shares of our common stock could depress our stock price.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

The Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley Act") requires us, among other things, to assess and report on the effectiveness of our internal control over financial reporting annually and disclosure controls and procedures quarterly. In addition, our independent registered public accounting firm is required to audit the effectiveness of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act annually.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. To maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, we have expended and will continue to expend significant resources, including accounting and professional services fees related costs and in providing diligent management oversight.

Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. Moreover, our independent registered public accounting firm could issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. Ineffective internal control could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. In addition, any future testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements, which could lead to financial statement restatements and require us to incur the expense of remediation.

Risks associated with use of our company-wide enterprise resource planning ("ERP") system may adversely affect our business and results of operations or the effectiveness of internal control over financial reporting.

We completed implementation of a company-wide ERP system in 2016 to handle the business and financial processes within our operations and corporate functions. To reap the benefits of our ERP system, we were required to change certain business and financial processes. Our business and results of operations may be adversely affected if we experience operating problems with the ERP system, or if the ERP system and the associated process changes do not give rise to the benefits that we expect. If the ERP system does not operate as intended, our business, results of

operations and internal controls over financial reporting may be adversely affected.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. Prior to our IPO in October 2014, there had not been a public market for our common stock and we did not have research coverage by securities and industry analysts. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

If we sell or issue additional shares of our common stock or securities convertible into our common stock in the future, the percentage ownership of our stockholders will be diluted.

On November 2, 2015, we filed a shelf registration statement on Form S-3 for the potential offering, issuance and sale by us of up to $300.0 million of our common stock, preferred stock, debt securities, warrants to purchase our common stock, preferred stock and debt securities, subscription rights to purchase our common stock, preferred stock and debt securities, and units consisting of all or some of these securities. Our shelf registration statement was declared effective by the SEC on November 24, 2015. In June 2016, we sold 5,175,000 shares of our common stock in an underwritten public offering pursuant to the shelf registration statement for aggregate gross proceeds of $144.9 million. The shelf registration statement will expire on November 24, 2018.

In addition, in February 2017, we filed an automatic shelf registration statement on Form S-3, which immediately became effective. In March 2017, we sold 5,750,000 shares of our common stock in an underwritten public offering pursuant to the automatic shelf registration statement for aggregate gross proceeds of $193.8 million. As long as we continue to satisfy the requirements to be deemed a “well-known seasoned issuer” under SEC rules, and subject to certain other requirements, we will be eligible to file automatic shelf registration statements that become immediately effective upon filing and allow us to issue registered shares of common stock and other securities in one or more offerings, in amounts, at prices and on the terms that we will determine at the time of the offering. If we sell additional common stock, preferred stock, convertible securities and other equity securities in future transactions pursuant to our shelf registration statements or otherwise, existing investors may be materially diluted by such subsequent sales and new investors could gain rights superior to our existing stockholders.

Furthermore, we completed a sale of the Notes in May 2017 in a private placement in reliance on Section 4(a)(2) of the Securities Act. The Notes mature on May 15, 2022, unless earlier converted or repurchased in accordance with their terms. Holders of the Notes may convert all or a portion of their Notes at their option at any time prior to the close of business on the business day immediately prior to May 15, 2022, in multiples of $1,000 principal amount. The Notes are convertible into shares of our common stock at an initial conversion rate of 28.2079 shares of common stock per $1,000 principal amount of the Notes, which is equivalent to an initial conversion price of approximately $35.45 per share of common stock. As of June 30, 2018, the Notes were convertible into 8,109,771 shares of our common stock. The conversion rate and the corresponding conversion price will be subject to adjustment upon the occurrence of certain events. The conversion of some or all of the Notes into shares of our common stock will dilute the ownership interests of existing stockholders.

We intend to file a new shelf registration statement on Form S-3 for the potential offering, issuance and sale by us of up to $300.0 million of our common stock, preferred stock, debt securities, warrants to purchase our common stock, preferred stock and debt securities, subscription rights to purchase our common stock, preferred stock and debt securities, and units consisting of all or some of these securities. Furthermore, pursuant to a sales agreement between us and Cowen and Company, LLC (“Cowen”), common stock with an aggregate offering price of up to $75.0 million may be issued and sold pursuant to an “at-the-market” offering for sales of our common stock. Subject to the declaration of effectiveness of the registration statement by the SEC, certain limitations in the sales agreement and compliance with applicable law, we have the discretion to deliver a sales notice to Cowen at any time throughout the term of the sales agreement, which has a term equal to the term of the registration statement on Form S-3 unless otherwise terminated earlier by us or Cowen pursuant to the terms of the sales agreement. The number of shares that are sold by Cowen after delivering a sales notice will fluctuate based on the market price of our common stock during the sales period and limits we set with Cowen. Because the price per share of each share sold will fluctuate based on the market price of our common stock during the sales period, it is not possible at this stage to predict the number of shares that will be ultimately issued. As of the date hereof, no shares of our common stock have been sold pursuant to the sales agreement.

Our directors and executive officers, together with their affiliates, will be able to exert significant influence over us and could impede a change of corporate control.

As of September 30, 2018, our directors and executive officers beneficially owned (determined in accordance with the rules of the SEC), in the aggregate, approximately 16% of our outstanding common stock. As a result, these stockholders, acting together, would have the ability to exert significant influence on matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, have the ability to significantly influence the management and affairs of our company. Accordingly, this concentration of ownership could harm the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of us.

Delaware law and provisions in our restated certificate of incorporation and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

The anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change of control by prohibiting us from engaging in a business combination with stockholders owning in excess of 15% of our outstanding voting stock for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our restated certificate of incorporation and restated bylaws contain provisions that may make the acquisition of our company more difficult, including the following:

- our board of directors is classified into three classes of directors with staggered three-year terms, with directors removable from office only for cause, so that not all members of our board of directors are elected at one time;
- only our board of directors has the right to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- only the chairman of our board of directors, our chief executive officer, our president or a majority of our board of directors are authorized to call a special meeting of stockholders;
- certain litigation against us can only be brought in Delaware;
- our restated certificate of incorporation authorizes the issuance of undesignated preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval, and which may include rights superior to the rights of the holders of common stock;
- all stockholder actions must be taken at meetings of our stockholders, and may not be taken by written consent;
- our board of directors is expressly authorized to make, alter or repeal our bylaws; and
- advance notice requirements apply for stockholders to nominate candidates for elections to our board of directors or to bring matters that can be acted upon by stockholders at stockholder meetings.

These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors of their choosing so as to cause us to take certain corporate actions they desire.

Because management has broad discretion as to the use of the net proceeds from our previous and future sales of securities, stockholders may not agree with how we use them, and such proceeds may not be applied successfully.

Our management will have considerable discretion over the use of proceeds from our previous and future sales of securities and could spend the proceeds in ways that do not necessarily improve our operating results or enhance the value of our common stock, or with which our stockholders otherwise disagree. The failure of our management to apply these funds effectively could, among other things, result in unfavorable returns and uncertainty about our prospects, each of which could cause the price of our common stock to decline. Pending their use, we may invest the net proceeds from our previous and future sales of securities in a manner that does not produce income or that loses value. These investments may not yield a favorable return to our investors.

We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have never declared nor paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment.

62

Risks Related to the Notes

We have indebtedness in the form of convertible senior notes, which could adversely affect our financial health and our ability to respond to changes in our business.

In May 2017, we completed an offering of the Notes in a private placement in reliance on Section 4(a)(2) of the Securities Act (the "Notes Offering"). The Notes mature on May 15, 2022, unless earlier converted or repurchased in accordance with their terms. Holders of the Notes may convert all or a portion of their Notes at their option at any time prior to the close of business on the business day immediately prior to May 15, 2022, in multiples of $1,000 principal amount. The Notes are convertible into shares of our common stock at an initial conversion rate of 28.2079 shares of common stock per $1,000 principal amount of the Notes, which is equivalent to an initial conversion price of approximately $35.45 per share of common stock. As of September 30, 2018, the Notes were convertible into 8,109,771 shares of our common stock. The conversion rate and the corresponding conversion price will be subject to adjustment upon the occurrence of certain events. The conversion of some or all of the Notes into shares of our common stock will dilute the ownership interests of existing stockholders. In addition, the indenture for the Notes provides that we are required to repay amounts due under the indenture in the event that there is an event of default for the Notes that results in the principal, premium, if any, and interest, if any, becoming due prior to the maturity date for the Notes. There can be no assurance that we will be able to repay this indebtedness when due, or that we will be able to refinance this indebtedness on acceptable terms or at all.

As a result of our level of increased debt after the completion of the Notes Offering:

- our vulnerability to adverse general economic conditions and competitive pressures is heightened;
- we are required to dedicate a larger portion of our cash flow from operations to interest payments, limiting the availability of cash for other purposes;
- our flexibility in planning for, or reacting to, changes in our business and industry may be more limited; and
- our ability to obtain additional financing in the future for working capital, capital expenditures, acquisitions, general corporate purposes or other purposes may be impaired.

We cannot be sure that our leverage resulting from the level of increased debt due to the Notes Offering will not materially and adversely affect our ability to finance our operations or capital needs or to engage in other business activities. In addition, we cannot be sure that additional financing will be available when required or, if available, will be on terms satisfactory to us. Further, even if we are able to obtain additional financing, we may be required to use such proceeds to repay a portion of our debt.

We may be unable to repurchase the Notes upon a fundamental change when required by the holders or repay prior to maturity any accelerated amounts due under the Notes upon an event of default, and our future debt agreements may contain limitations on our ability to pay cash upon conversion, repurchase or repayment of the Notes.

Holders of the Notes have the right to require us to repurchase their Notes upon the occurrence of a fundamental change at a fundamental change repurchase price equal to 100% of the principal amount of the Notes to be purchased, plus accrued and unpaid interest, if any, to, but not including, the fundamental change repurchase date. In addition, the indenture for the Notes provides that we are required to repay amounts due under the indenture in the event that there is an event of default for the Notes that results in the principal, premium, if any, and interest, if any, becoming due prior to the maturity date for the Notes. However, we may not have enough available cash or be able to obtain financing at the time we are required to repurchase Notes surrendered upon a fundamental change or repay prior to maturity any accelerated amounts.

In addition, our ability to purchase the Notes or repay prior to maturity any accelerated amounts under the Notes upon an event of default or redeem the Notes may be limited by law, by regulatory authority or by agreements governing

our future indebtedness. Our failure to repurchase Notes at a time when the repurchase is required by the indenture (whether upon a fundamental change or otherwise under the indenture) would constitute a default under the indenture. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing any of our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness or repurchase the Notes.

Servicing debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our debt.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the Notes, depends on our future financial condition and operating performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to satisfy our obligations under the Notes and any future indebtedness we may incur and to make necessary capital expenditures. We cannot assure you that we will have in the future a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our debt, including the Notes.

If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as reducing or delaying investments or capital expenditures, selling assets, refinancing or obtaining additional equity capital on terms that may be onerous or highly dilutive. These alternative measures may not be successful and may not permit us to meet our schedule debt servicing obligations. Further, we may need to refinance all or a portion of our debt on or before maturity, and our ability to refinance the Notes or future indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities on commercially reasonable terms or at all, which could result in a default on the Notes or future indebtedness.

We may still incur substantially more debt or take other actions which would intensify the risks discussed above.

We and our subsidiaries may incur substantial additional debt in the future, subject to the restrictions contained in our future debt instruments. We are not restricted under the terms of the indenture governing the Notes from incurring additional debt, securing existing or future debt, recapitalizing our debt, repurchasing our stock, pledging our assets, making investments, paying dividends, guaranteeing debt or taking a number of other actions that are not limited by the terms of the indenture governing the Notes that could have the effect of diminishing our ability to make payments on the Notes when due.

Conversion of the Notes will dilute the ownership interest of existing stockholders, including holders who had previously converted their Notes, or may otherwise depress our stock price.

The conversion of some or all of the Notes will dilute the ownership interests of existing stockholders. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the Notes may encourage short selling by market participants because the conversion of the Notes could be used to satisfy short positions, or anticipated conversion of the Notes into shares of our common stock could depress our stock price.

Our indebtedness could adversely affect our financial health and our ability to respond to changes in our business.

As a result of our level of debt following the completion of our sale of the Notes in May 2017:

- our vulnerability to adverse general economic conditions and competitive pressures is heightened;
- we are required to dedicate a larger portion of our capital resources to interest payments, limiting the availability of cash for other purposes;
- our flexibility in planning for, or reacting to, changes in our business and industry may be more limited; and
- our ability to obtain additional financing in the future for working capital, capital expenditures, acquisitions, general corporate purposes or other purposes may be impaired.

We cannot be sure that our leverage resulting from the level of debt after the completion of our sale of the Notes in May 2017 will not materially and adversely affect our ability to finance our operations or capital needs or to engage in

other business activities. In addition, we cannot be sure that additional financing will be available when required or, if available, will be on terms satisfactory to us. Further, even if we are able to obtain additional financing, we may be required to use such proceeds to repay a portion of our debt.

The Notes are effectively junior to any secured debt we may incur and structurally subordinated to any liabilities of our subsidiary.

The Notes are our unsecured obligations exclusively and are not guaranteed by our subsidiary. Our subsidiary is a separate and distinct legal entity and has no obligation, contingent or otherwise, to make payments on the Notes or to make any funds available for that purpose. In addition, the indenture for the Notes does not restrict us or our subsidiary from incurring additional debt or other liabilities. Accordingly, the Notes rank senior in right of payment to any of our indebtedness that is expressly subordinated in right of payment to the Notes; will rank equally in right of payment with any of our unsecured indebtedness that is not so subordinated; will be effectively junior in right of payment to any secured indebtedness we may incur to the extent of the value of the assets securing such indebtedness; and will be structurally junior to any indebtedness and other liabilities (including trade payables) of our subsidiaries. In the event of our bankruptcy, liquidation, reorganization or other winding up, our assets that secure any of our debt will be available to pay obligations on the Notes only after such secured debt we may incur has been repaid in full. There may not be sufficient assets remaining to pay amounts due on any or all of the Notes then outstanding.

Our right to receive assets from our subsidiary upon its liquidation or reorganization, and the right of holders of the Notes to participate in those assets, is structurally subordinated to claims of the subsidiary's creditors, including trade creditors. Even if we were a creditor of our subsidiary, our rights as a creditor would be subordinate to any security interest in the assets of the subsidiary and any indebtedness of the subsidiary senior to that held by us. Furthermore, our subsidiary is not under any obligation to make payments to us, and any payments to us would depend on the earnings or financial condition of our subsidiary and various business considerations. Statutory, contractual or other restrictions may also limit our subsidiary's ability to pay dividends or make distributions, loans or advances to us. For these reasons, we may not have access to any assets or cash flows of our subsidiary to make payments on the Notes.

The fundamental change repurchase feature of the Notes may delay or prevent an otherwise beneficial attempt to take over our company.

The terms of the Notes require us to repurchase the Notes in the event of a fundamental change. Under certain circumstances, a takeover of our company would trigger an option of the holders of the Notes to require us to repurchase the Notes. In addition, if a make-whole fundamental change occurs prior to the maturity date of the Notes, we will in some cases be required to increase the conversion rate for a holder that elects to convert its Notes in connection with such make-whole fundamental change. Furthermore, the indenture for the Notes prohibits us from engaging in certain mergers or acquisitions unless, among other things, the surviving entity assumes our obligations under the Notes. These and other provisions of the indenture may have the effect of delaying or preventing a takeover of our company that would otherwise be beneficial to investors in the Notes.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

Unregistered Sales of Equity Securities

None.

Issuer Purchases of Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.
None.

ITEM 4. MINE SAFETY DISCLOSURES.
Not applicable.

ITEM 5. OTHER INFORMATION.
None.

ITEM 6. EXHIBITS

		Incorporated by Reference			
Number	Exhibit Title	Form	File No.	Filing Date	Filed Herewith
31.1	Certification of Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*				X
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*				X
101.INS	XBRL Instance Document.				X
101.SCH	XBRL Taxonomy Extension Schema Document.				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				X

* As contemplated by SEC Release No. 33-8212, these exhibits are furnished with this Quarterly Report on Form 10-Q and are not deemed filed with the Securities and Exchange Commission and are not incorporated by reference in any filing of Dermira, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language contained in such filings.

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* As contemplated by SEC Release No. 33-8212, these exhibits are furnished with this Quarterly Report on Form 10-Q and are not deemed filed with the Securities and Exchange Commission and are not incorporated by reference in any filing of Dermira, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language contained in such filings.

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, in Menlo Park, California, on November 7, 2018.

DERMIRA, INC.

By: /s/ THOMAS G. WIGGANS
Thomas G. Wiggans
Chief Executive Officer and Chairman of the Board
(Principal Executive Officer)

By: /s/ ANDREW L. GUGGENHIME
Andrew L. Guggenhime
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)