REVLON INC /DE/
Form 10-Q
July 31, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2012

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: 1-11178

REVLON, INC.

(Exact name of registrant as specified in its charter)

Delaware	**13-3662955**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
237 Park Avenue, New York, New York	**10017**
(Address of principal executive offices)	(Zip Code)

212-527-4000

(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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or

for such shorter period that the registrant was required to submit and post such files).

Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer , accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨ Smaller reporting company ¨

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes ¨ No x

As of June 30, 2012, 49,224,583 shares of Class A Common Stock, 3,125,000 shares of Class B Common Stock and 9,336,905 shares of Series A Preferred Stock were outstanding. At such date, 37,544,640 shares of Class A Common Stock were beneficially owned by MacAndrews & Forbes Holdings Inc. and certain of its affiliates and all of the shares of Class B Common Stock were owned by REV Holdings LLC, a Delaware limited liability company and an indirectly wholly-owned subsidiary of MacAndrews & Forbes Holdings Inc.

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REVLON, INC. AND SUBSIDIARIES

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

REVLON, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(dollars in millions, except share and per share amounts)

	June 30, 2012 (Unaudited)	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 79.8	$ 101.7
Trade receivables, less allowance for doubtful accounts of $3.9 and $3.2 as of June 30, 2012 and December 31, 2011, respectively	204.5	212.0
Inventories	133.3	111.0
Deferred income taxes current	50.0	49.8
Prepaid expenses and other	66.5	44.2
Total current assets	534.1	518.7
Property, plant and equipment, net	98.5	98.9
Deferred income taxes noncurrent	219.2	232.1
Goodwill, net	194.6	194.7
Other assets	127.5	112.7
Total assets	$ 1,173.9	$ 1,157.1
LIABILITIES AND STOCKHOLDERS DEFICIENCY		
Current liabilities:		
Short-term borrowings	$ 8.5	$ 5.9
Current portion of long-term debt	11.4	8.0
Accounts payable	95.5	89.8
Accrued expenses and other	240.9	231.7
Total current liabilities	356.3	335.4
Long-term debt	1,158.9	1,107.0
Long-term debt affiliates	-	58.4
Redeemable preferred stock	48.5	48.4
Long-term pension and other post-retirement plan liabilities	224.6	245.5
Other long-term liabilities	51.2	55.3
Commitments and contingencies		
Stockholders deficiency:		
Class A Common Stock, par value $0.01 per share; 900,000,000 shares authorized; 49,986,651 shares issued as of June 30, 2012 and December 31, 2011	0.5	0.5
Class B Common Stock, par value $0.01 per share; 200,000,000 shares authorized; 3,125,000 shares issued and outstanding as of June 30, 2012 and December 31, 2011	-	-
Additional paid-in capital	1,015.0	1,014.1

Treasury stock, at cost: 750,900 and 671,271 shares of Class A Common Stock as of June 30, 2012 and December 31, 2011, respectively	(9.7)	(8.6)
Accumulated deficit	(1,478.4)	(1,498.0)
Accumulated other comprehensive loss	(193.0)	(200.9)
Total stockholders deficiency	(665.6)	(692.9)
Total liabilities and stockholders deficiency	$ 1,173.9	$ 1,157.1

See Accompanying Notes to Unaudited Consolidated Financial Statements

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REVLON, INC. AND SUBSIDIARIES

UNAUDITED CONSOLIDATED STATEMENTS OF INCOME AND COMPREHENSIVE INCOME

(dollars in millions, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Net sales	$ 357.1	$ 351.2	$ 687.8	$ 684.4
Cost of sales	124.4	121.9	240.1	235.2
Gross profit	232.7	229.3	447.7	449.2
Selling, general and administrative expenses	189.9	181.5	360.6	356.7
Operating income	42.8	47.8	87.1	92.5
Other expenses, net:				
Interest expense	19.6	21.7	39.6	44.3
Interest expense preferred stock dividends	1.6	1.6	3.2	3.2
Amortization of debt issuance costs	1.3	1.4	2.6	2.8
Loss on early extinguishment of debt, net	-	11.3	-	11.3
Foreign currency losses, net	0.4	3.0	2.1	3.3
Miscellaneous, net	0.1	0.3	0.3	1.0
Other expenses, net	23.0	39.3	47.8	65.9
Income from continuing operations before income taxes	19.8	8.5	39.3	26.6
Provision for income taxes	9.1	2.6	20.1	10.3
Income from continuing operations, net of taxes	10.7	5.9	19.2	16.3
Income from discontinued operations, net of taxes	0.4	0.6	0.4	0.6
Net income	$ 11.1	$ 6.5	$ 19.6	$ 16.9
Other comprehensive income:				
Currency translation adjustment, net of tax of $2.1 and nil for the three months ended June 30, 2012 and 2011, respectively, and $1.4 and nil for the six months ended June 30, 2012 and 2011, respectively	1.0	1.1	2.2	0.2
Amortization of pension related costs, net of tax benefit of $0.2 and $0.5 for the three months ended June 30, 2012 and 2011, respectively, and $0.5 and $1.0 for the six months ended June 30, 2012 and 2011, respectively	1.9	0.9	5.7	1.8
Other comprehensive income	2.9	2.0	7.9	2.0
Total comprehensive income	$ 14.0	$ 8.5	$ 27.5	$ 18.9

Basic income per common share:

Continuing operations	0.20	0.11	0.36	0.31
Discontinued operations	0.01	0.01	0.01	0.01
Net income	$ 0.21	$ 0.12	$ 0.37	$ 0.32
Diluted income per common share:				
Continuing operations	0.20	0.11	0.36	0.31
Discontinued operations	0.01	0.01	0.01	0.01
Net income	$ 0.21	$ 0.12	$ 0.37	$ 0.32
Weighted average number of common shares outstanding:				
Basic	52,349,583	52,175,628	52,340,463	52,164,735
Diluted	52,357,163	52,330,097	52,357,004	52,306,335

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—

Deferred tax liability

194

194

Accrued payment related to acquired in-process research and development, non-current

26,290

—

Other long-term liabilities

687

495

Total liabilities

475,722

65,231

Stockholders’ equity:

Preferred stock

—

—

Common stock

42

36

Additional paid-in capital

696,152

497,718

Accumulated other comprehensive loss

(86

)

(252

)

Accumulated deficit

(497,381

)

(250,132

)

Total stockholders’ equity

198,727

247,370

Total liabilities and stockholders’ equity

$

674,449

$

312,601

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

DERMIRA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue:				
Collaboration and license revenue	$1,066	$119	$3,198	$119
Operating expenses:				
Research and development	30,788	17,784	76,626	62,306
Acquired in-process research and development	128,555	—	128,555	—
General and administrative	19,754	8,276	44,667	20,550
Total operating expenses	179,097	26,060	249,848	82,856
Loss from operations	(178,031)	(25,941)	(246,650)	(82,737)
Interest and other income, net	1,721	431	3,585	1,036
Interest expense	(2,864)	—	(4,184)	—
Net loss	$(179,174)	$(25,510)	$(247,249)	$(81,701)
Net loss per share, basic and diluted	$(4.30)	$(0.72)	$(6.15)	$(2.54)
Weighted-average common shares used to compute net loss per share, basic and diluted	41,625,038	35,429,586	40,171,691	32,178,234

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,	
	2017	2016	2017	2016
Net loss	$(179,174)	$(25,510)	$(247,249)	$(81,701)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	125	(142)	166	(2)
Total comprehensive loss	$(179,049)	$(25,652)	$(247,083)	$(81,703)

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,	
	2017	2016
Cash flows from operating activities		
Net loss	$(247,249)	$(81,701)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	252	88
Stock-based compensation	15,220	7,920
Acquired in-process research and development	128,555	—
Amortization of discount for payments related to acquired in-process research and development	252	—
Net amortization of premiums on available-for-sale securities	1,939	1,267
Amortization of convertible note discount and issuance costs	686	—
Common stock issued in connection with license agreement	—	1,453
Changes in assets and liabilities:		
Collaboration receivables from a related party	21,400	(25,000)
Prepaid expenses and other current assets	3,818	(3,154)
Other assets	63	164
Accounts payable	(3,759)	(3,014)
Accrued liabilities	9,507	2,509
Other long-term liabilities	191	(211)
Deferred revenue	(3,198)	24,881
Net cash used in operating activities	(72,323)	(74,798)
Cash flows from investing activities		
Purchases of available-for-sale securities	(225,924)	(194,710)
Maturities of available-for-sale securities	188,662	80,031
Purchase of property and equipment	(49)	(105)
Net cash used in investing activities	(37,311)	(114,784)
Cash flows from financing activities		
Net proceeds from issuances of common stock	183,220	137,996
Net proceeds from issuance of convertible notes	278,252	—
Net cash provided by financing activities	461,472	137,996
Net increase (decrease) in cash and cash equivalents	351,838	(51,586)
Cash and cash equivalents at beginning of year	41,793	107,242
Cash and cash equivalents at end of period	$393,631	$55,656
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 and develop leading-edge medical dermatology clinical programs. Our pipeline includes three late-stage product candidates that could have a profound impact on the lives of patients: glycopyrronium tosylate (formerly DRM04), for which a New Drug Application is under review by the U.S. Food and Drug Administration (“FDA”) for the treatment of primary axillary hyperhidrosis (excessive underarm sweating beyond what is needed for normal body temperature regulation); olumacostat glasaretil (formerly DRM01), in Phase 3 development for the treatment of acne vulgaris; and lebrikizumab, for which we plan to initiate a Phase 2b dose-ranging study for the treatment of moderate-to-severe atopic dermatitis. We are headquartered in Menlo Park, California.

In March 2017, we sold 5,750,000 shares of our common stock (“2017 Public Offering”) pursuant to an automatic shelf registration statement on Form S-3 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 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.

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, 2017 are not necessarily indicative of the results to be expected for the full year ending December 31, 2017 or any other future period. The condensed consolidated balance sheet as of December 31, 2016 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.

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, 2016 included in our Annual Report on Form 10-K, filed with the SEC on February 28, 2017.

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, 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.

Revenue Recognition

We generate revenue from collaboration and license agreements related to the development and commercialization of our product candidates. We recognize revenue when persuasive evidence of an arrangement exists, services have been performed or products have been delivered, the fee is fixed and determinable and collection is reasonably assured. Collaboration and license agreements may include non-refundable upfront payments or reimbursement of research and development costs, contingent consideration payments based on achievement of defined milestones, and royalties on sales of commercialized products. Our responsibilities under collaboration and license agreements may include the transfer of intellectual property rights, such as licenses, obligations to provide research and development services, product supply and regulatory approval services, and participation on certain development and commercialization committees. For upfront payments that are recorded as deferred revenue and being recognized over the estimated period of performance, we regularly review the estimated periods of performance based on the progress made under each arrangement. The estimated performance period may change over the course of an arrangement's term. Such a change could have a material impact on the amount of revenue recorded in future periods.

Multiple Element Arrangements

To determine the appropriate revenue recognition for payments to us under our collaboration and license agreements with multiple element arrangements, we evaluate whether the non-contingent deliverables of an arrangement represent separate units of accounting or a single unit of accounting. For non-contingent deliverables of an arrangement to represent separate units of accounting, the delivered elements each must have standalone value to the customer. Factors to determine standalone value include whether the deliverable is proprietary to us, whether the customer can use the license or other deliverables for their intended purpose without the receipt of the remaining elements and whether there are other vendors that can provide the undelivered items. Deliverables that meet these criteria are considered separate units of accounting. Deliverables that do not meet these criteria are combined and accounted for as a single unit of accounting.

Milestones and Other Contingent Payments

We have adopted the milestone method as described in Accounting Standards Codification 605-28, Milestone Method of Revenue Recognition. Under the milestone method, contingent consideration received from the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is defined as an event having all of the following characteristics: (1) there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved; (2) the event can only be achieved based in whole or in part on either our performance or a specific outcome resulting from our performance; and (3) if achieved, the event would result in additional payments being due to us. Contingent payments that do not meet the definition of a milestone are recognized in the same manner as the consideration for the combined unit of accounting. If we have no remaining performance obligations under the combined unit of accounting, any contingent payments would be recognized as revenue upon the achievement of the triggering event.

We evaluate whether milestones meet all of the following conditions to be considered substantive: (1) the consideration is commensurate with either of (a) our performance to achieve the milestone or (b) the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from our performance to achieve the milestone; (2) the consideration relates solely to past performance; and (3) the consideration is reasonable relative to all the deliverables and payment terms within the arrangement. Substantive milestones are recognized as revenue upon achievement of the milestone and when collectability is reasonably assured.

Acquired In-Process Research and Development Expenses

We expense in-process research and development projects acquired as part of asset acquisitions that have no alternative future use. The fair value assigned to incomplete research projects that have not reached technological feasibility and are acquired in business combinations are capitalized and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the applicable project.

Accrued Research and Development Expenses

We record accruals for estimated costs of research, preclinical, non-clinical and clinical studies and manufacturing activities, which are a significant component of research and development expenses. A substantial portion of our ongoing research and development activities is conducted by third-party service providers, including contract research organizations (“CROs”). Our contracts with CROs generally include pass-through fees such as regulatory expenses, investigator fees, travel costs and other miscellaneous costs, including shipping and printing fees. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us. We accrue the costs incurred under agreements with these third parties based on our estimate of actual work completed in accordance with the respective agreements. In the event we make advance payments, the payments are recorded as a prepaid expense and recognized as the services are performed. We determine the estimated costs through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fees to be paid for such services. We accrue for costs associated with unused drug supplies that are both probable and estimable.

We make significant judgments and estimates in determining the accrual balance in each reporting period. As actual costs become known, we adjust our accruals. Although we do not expect our estimates to be materially different from amounts actually incurred, such estimates for the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any particular period. Our accrual is dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Variations in the assumptions used to estimate accruals including, but not limited to, the number of patients enrolled, the rate of patient enrollment and the actual services performed, may vary from our estimates, resulting in adjustments to clinical trial expenses in future periods. Changes in these estimates that result in material changes to our accruals could materially affect our condensed consolidated financial condition and results of operations.

Amortization of Debt Discount and Issuance Costs

Debt discount and issuance costs, consisting of legal and other fees directly related to the Notes, are offset against gross proceeds from the issuance of the Notes and are amortized to interest expense over the estimated life of the Notes based on the effective interest method.

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 computation of diluted net loss per share for the periods presented because their effect was antidilutive:

	Outstanding as of September 30,	
	2017	2016
Stock options to purchase common stock	5,823,687	4,460,024
Shares subject to outstanding restricted stock units	300,538	147,634

Estimated shares issuable under the employee stock purchase plan	140,283	82,972
Shares issuable upon conversion of Notes	8,109,771	—
	14,374,279	4,690,630

Recent Accounting Pronouncements

In January 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business ("ASU 2017-01"). ASU 2017-01 provides clarification on the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions of assets or business combinations. ASU 2017-01 is effective for fiscal years beginning after December 15, 2017 and interim periods within those years. Early adoption is permitted. We early adopted ASU 2017-01 in the third quarter of 2017. Pursuant to the guidance of ASU 2017-01, we concluded that our acquisition of intellectual property during the three months ended September 30, 2017 was an asset acquisition.

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. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early adoption is permitted. We are currently evaluating the impact that the adoption of ASU 2016-02 will have on our consolidated financial statements and related disclosures.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU 2014-09"), which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration including milestones, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures.

ASU 2014-09 outlines a five-step process for revenue recognition that focuses on transfer of control, as opposed to transfer of risk and rewards, and also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenues and cash flows from contracts with customers. Major provisions include determining which goods and services are distinct and require separate accounting (performance obligations), how variable consideration (which may include change orders and claims) is recognized, whether revenue should be recognized at a point in time or over time and ensuring the time value of money is considered in the transaction price.

The FASB issued supplemental adoption guidance and clarification to ASU 2014-09 in March 2016, April 2016 and May 2016 within ASU 2016-08, Revenue from Contracts with Customers: Principal vs. Agent Considerations, ASU 2016-10, Revenue from Contracts with Customers: Identifying Performance Obligations and Licensing, and ASU 2016-12, Revenue from Contracts with Customers: Narrow-Scope Improvements and Practical Expedients, respectively. ASU 2014-09 and the related supplemental ASUs are effective for us as of January 1, 2018. We currently anticipate adopting these ASUs using the modified retrospective method. We believe the key changes in the standard that could impact our revenue recognition relate to the determination of distinct performance obligations, material rights, constraints related to the estimation of variable consideration and accounting for licenses of intellectual property and the timing of when those revenues are recognized. We currently anticipate that we will record a cumulative adjustment to decrease accumulated deficit, as of January 1, 2018, to reflect the impact of the adoption of these ASUs. We are in the process of analyzing each of our collaboration agreements to determine the future impact that these ASUs will have on our consolidated financial statements.

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.

The following tables set forth the fair value of our financial instruments that were measured on a recurring basis (in thousands):

	As of September 30, 2017			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$199,193	$—	$ —	$199,193
U.S. Treasury securities	23,820	—	—	23,820
Corporate debt	—	201,535	—	201,535
Repurchase agreements	—	135,000	—	135,000
U.S. Government agency securities	—	19,157	—	19,157
Commercial paper	—	81,414	—	81,414
Certificates of deposit	—	900	—	900
Total financial assets	$223,013	$438,006	$ —	$661,019

	As of December 31, 2016			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$5,115	$—	$ —	$5,115
U.S. Treasury securities	6,112	—	—	6,112
Corporate debt	—	168,878	—	168,878
Repurchase agreements	—	22,550	—	22,550
U.S. Government agency securities	—	41,366	—	41,366
Commercial paper	—	30,836	—	30,836
Certificates of deposit	—	901	—	901
Total financial assets	$11,227	$264,531	$ —	$275,758

The estimated fair value of our Notes was $308.9 million as of September 30, 2017 and was based upon observable, Level 2 inputs, including pricing information from recent trades of the Notes as of September 30, 2017.

See Note 8 for information relating to payments which were measured using unobservable, Level 3 inputs, including a discount rate.

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.

4. Investments

Investments include available-for-sale securities and investment securities classified as cash equivalents. Investment securities consisted of the following (in thousands):

	As of September 30, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Financial assets:				
Money market funds	$199,193	$ —	$ —	$199,193
U.S. Treasury securities	23,823	1	(4)	23,820
Corporate debt	201,614	10	(89)	201,535
Repurchase agreements	135,000	—	—	135,000
U.S. Government agency securities	19,161	—	(4)	19,157
Commercial paper	81,414	—	—	81,414
Certificates of deposit	900	—	—	900
Total investments	$661,105	$ 11	$ (97)	$661,019

	As of December 31, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Financial assets:				
Money market funds	$5,115	$ —	$ —	$5,115
U.S. Treasury securities	6,112	1	(1)	6,112
Corporate debt	169,112	6	(240)	168,878
Repurchase agreements	22,550	—	—	22,550
U.S. Government agency securities	41,384	—	(18)	41,366
Commercial paper	30,836	—	—	30,836
Certificates of deposit	901	—	—	901
Total investments	$276,010	$ 7	$ (259)	$275,758

As of September 30, 2017, we did not hold any investments with a maturity exceeding one year. We do not intend to sell the securities that are in an unrealized loss position and 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, 2017 were temporary in nature.

5. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2017	December 31, 2016
Accrued outside research and development services	$ 11,874	$ 10,046
Accrued compensation	7,664	5,839
Accrued professional and consulting services	3,453	1,042
Accrued interest	3,246	—
Other	501	300
Total accrued liabilities	$ 26,738	$ 17,227

6. Convertible Notes

In May 2017, we sold $287.5 million aggregate principal amount of 3.00% Convertible Senior Notes due 2022 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, 2017, there were unamortized issuance costs and debt discounts of $8.6 million, which were recorded as a direct deduction from the Notes on the condensed consolidated balance sheets.

7. Commitments

Facility Lease

We lease our corporate headquarters in Menlo Park, California under a non-cancelable operating lease agreement initially entered into in July 2014 and amended in September 2014 ("Initial Lease"). Pursuant to the Initial Lease, we leased 18,651 square feet of space in a multi-suite building (the "Building"). Rent payments under the Initial Lease included base rent of $97,918 per month during the first year of the Initial Lease with an annual increase of three percent, and additional monthly fees to cover our share of certain facility expenses, including utilities, property taxes, insurance and maintenance.

The Initial Lease was amended in December 2015 to provide for our lease of an additional 26,541 square feet of space in the building, commencing December 2016 ("Amended Lease"). Rent payments for the additional space included base rent of $135,426 per month during the first year of the Amended Lease period with an annual increase of three percent, and additional monthly fees to cover our share of certain facility expenses, including utilities, property taxes, insurance and maintenance.

The Amended Lease was further amended in April 2016 to accelerate our lease commencement date for the additional space, subject to certain conditions, from December 2016 to (1) May 2016 with respect to 2,882 square feet of the additional space, and (2) October 2016 with respect to 23,659 square feet of the additional space (as further amended,

"Lease"). The Lease will expire on December 31, 2021, subject to our option to renew the Lease for an additional five-year term.

Pursuant to the terms of the Lease, we provided the lessor with a $500,000 letter of credit in August 2014, which is collateralized by a money market account. The letter of credit may be used by or drawn upon by the lessor in the event of our default of certain terms of the Lease. If no such event of default has occurred or then exists, the letter of credit may be reduced to $350,000 after June 1, 2019. The collateralized money market account is restricted cash and recorded in our condensed consolidated balance sheets in other assets.

In September 2017, to accommodate our expected growth, we entered into a sublease agreement ("Sublease") pursuant to which we will sublease an additional 23,798 square feet of space in the Building. Rent payments for the Sublease include base rent of $139,218 per month during the first year of the Sublease with an annual increase of three percent, and additional monthly fees to cover our share of certain facility expenses, including utilities, property taxes, insurance and maintenance. The Sublease term will commence on the earlier to occur of (1) January 1, 2018, and (2) the date on which we complete our tenant improvements to the Sublease premises, and end on April 30, 2024, unless terminated early pursuant to the terms of the Sublease. We expect to commence making rent payments in March 2018.

Pursuant to the terms of the Sublease, in October 2017, we provided the sublessor with a $300,000 irrevocable commercial letter of credit, which is collateralized by a money market account. The letter of credit may be used by or drawn upon by the sublessor in the event of our default of certain terms of the Sublease.

Rent expense was $1.0 million and $0.5 million for the three months ended September 30, 2017 and 2016, respectively, and $3.1 million and $1.3 million for the nine months ended September 30, 2017 and 2016, respectively. The terms of the Lease and the Sublease provide for rental payments on a monthly basis on a graduated scale. We recognize rent expense on a straight-line basis over the lease period and have accrued for rent expense incurred but not paid.

As of September 30, 2017, the aggregate total future minimum lease payments under the Lease and Sublease were as follows (in thousands):

Year Ending December 31,	
2017 (remainder)	$725
2018	4,428
2019	4,777
2020	4,918
2021	5,056
Thereafter	4,480
Total payments	$24,384

The table above excludes approximately $10.4 million of additional rent due over the period of the Lease and Sublease to cover our share of facility expenses, including utilities, property taxes, insurance and maintenance.

8. Technology and Financing 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 will be credited against certain payments payable by Maruho to us if we 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. As of September 30, 2017 and December 31, 2016, we recorded the $10.0 million payment related to the Maruho Right of First Negotiation Agreement as deferred revenue, non-current in our consolidated balance sheets. The revenue would be recognized in connection with and pursuant to a future license arrangement, if any, or at the time the parties decide not to enter into such a license, at which point the entire amount would be recognized as revenue.

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.

We identified the following non-contingent deliverables under the Maruho G.T. Agreement: (1) the transfer of intellectual property rights (the “license”) and (2) the supply of drug materials for clinical development purposes. We concluded that the license is not a separate unit of accounting because Maruho cannot obtain benefit from the use of the license rights for their intended purpose without the product supplied by us. Even if Maruho elects to establish its own supply of drug product, it must rely upon us to supply the drug substance necessary for Maruho’s development because Maruho does not have the right to manufacture the drug substance. We determined that neither of the deliverables has standalone value and, therefore, the deliverables are accounted for as one combined unit of accounting, with the upfront payment recognized as revenue on a straight-line basis over the estimated period of performance. We regularly evaluate the reasonableness of the estimated period of performance and revise the amortization of deferred revenue as deemed appropriate on a prospective basis.

Milestone payments under the Maruho G.T. Agreement could total up to $70.0 million. The achievement of any and all milestones is dependent solely upon the results of Maruho's activities and, therefore, the milestones are not deemed to be substantive. If regulatory approval for glycopyrronium tosylate is achieved and the product is commercialized in Japan, we would recognize any royalty revenue received from Maruho based on Maruho's net sales of the drug product in Japan.

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.

For the three months ended September 30, 2017 and 2016 and nine months ended September 30, 2017 and 2016, we recognized collaboration and license revenue related to the Maruho G.T. Agreement of $1.1 million, $0.1 million, $3.2 million and $0.1 million, respectively, in connection with the $25.0 million upfront payment. In addition, as of September 30, 2017, we have a deferred revenue balance related to the Maruho G.T. Agreement of $20.6 million, of which $4.3 million is recorded in deferred revenue, current on the condensed consolidated balance sheets.

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 retains certain rights, including exclusive rights to develop and promote lebrikizumab for interstitial lung diseases, such as idiopathic pulmonary fibrosis ("Retained Field") and certain 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. Unless earlier terminated, the Roche Agreement will remain in effect until no royalty or other payment obligations are or may become due.

Under the terms of the Roche Agreement, we made an initial payment of $80.0 million to Roche in October 2017 and will make additional payments to Roche in 2018 totaling $55.0 million. 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 indications other than interstitial lung disease. 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 a country (other than for the Retained Field) 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 (other than for the Retained Field) in such country, (b) the expiration of the last to expire valid claim of the applicable licensed compound patent rights, Dermira patent rights or joint patent rights in such country covering the use, manufacturing, import, offering for sale, or sale of lebrikizumab (other than for the Retained Field) 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 (other than for the Retained Field).

We determined that the acquired in-process research and development related to the Roche Agreement had no alternative future use and recorded an expense of $128.6 million during the three and nine months ended September 30, 2017 in the condensed 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, and the payments due in 2018 totaling $55.0 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, 2017, on the condensed consolidated balance sheets, we recorded $102.5 million to accrued payments related to acquired in-process research and development, current, for the $80.0 million initial payment and the $25.0 million payment due by September 2018, and $26.3 million to accrued payment related to acquired in-process research and development, non-current, for the $30.0 million payment due by December 2018. The remaining milestone payments will be recognized when the contingency related to the milestone is resolved and the consideration is paid or becomes payable.

9. Stock-Based Compensation

In 2010, we adopted the 2010 Equity Incentive Plan (the "2010 Plan"), which provided for the granting of stock options to our employees, directors and consultants. In September 2014, our board of directors approved the 2014 Equity Incentive Plan (the "2014 EIP"), which became effective on October 1, 2014. As of the effective date of the 2014 EIP, the 2010 Plan was terminated and no further stock awards will be granted pursuant to the 2010 Plan. Outstanding stock options granted under the 2010 Plan will continue to be governed by the provisions of the 2010 Plan until the earlier of the stock option's expiration or exercise. In September 2014, our board of directors approved the 2014 Employee Stock Purchase Plan (the "2014 ESPP"), which became effective on October 2, 2014.

The following table reflects a summary of stock option activity and related information for the period from December 31, 2016 through September 30, 2017:

	Shares Subject to Outstanding Stock Options	Weighted-Average Exercise Price Per Share
Stock options outstanding at December 31, 2016	4,526,079	$ 13.92
Stock options granted	1,543,270	$ 31.90
Stock options exercised	(171,171)	$ 7.45
Stock options forfeited	(74,491)	$ 31.99
Stock options outstanding at September 30, 2017	5,823,687	$ 18.64

The following table reflects a summary of restricted stock unit ("RSU") activity under our 2014 EIP and related information for the period from December 31, 2016 through September 30, 2017:

	Shares Subject to Outstanding RSUs	Weighted-Average Grant Date Fair Value Per Share
RSUs outstanding at December 31, 2016	147,634	$ 27.21
RSUs granted	221,765	$ 32.68
RSUs vested and settled	(64,270)	$ 28.88
RSUs forfeited	(4,591)	$ 32.38
RSUs outstanding at September 30, 2017	300,538	$ 30.81

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Research and development	$2,104	$1,020	$5,918	$2,964
General and administrative	3,397	1,845	9,302	4,956
Total stock-based compensation expense	$5,501	$2,865	$15,220	$7,920

10. Subsequent Events

In March 2014, we and UCB Pharma S.A., a limited liability corporation incorporated under the laws of Belgium ("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 FDA, 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 ("Transition Agreement"). The Transition Agreement, among other things, (a) provides that the UCB Agreement will terminate on February 15, 2018, (b) provides for the repurchase by UCB of all product rights, licenses and intellectual property relating to Cimzia, (c) specifies 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) terminates UCB's right to designate a director nominee to our Board of Directors and (e) provides for the resignation of UCB's designee from our Board of Directors.

Pursuant to the UCB Agreement, there are 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 will pay us $11.0 million by November 13, 2017 and, upon approval of Cimzia in psoriasis in the United States, an additional $39.0 million within 30 days of such approval. We are 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 are less than $10.0 million, we will pay to UCB the difference between such aggregate costs and $10.0 million. These terms replace 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.

We incurred expenses related to clinical materials supplied by UCB totaling $0.9 million and $0.7 million for the three months ended September 30, 2017 and 2016, respectively, and $2.9 million and $5.1 million for the nine months ended September 30, 2017 and 2016, respectively. As of September 30, 2017, we recorded $2.3 million in prepaid expense and other current assets, $0.6 million in accounts payable and $1.1 million in accrued liabilities related to the UCB Agreement. As of December 31, 2016, we recorded $2.8 million in prepaid expense and other current assets and $1.2 million in accounts payable related to UCB.

As of October 31, 2017, entities affiliated with UCB beneficially owned 1,841,234 shares of our outstanding common stock, representing approximately 4% of our outstanding common stock.

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, 2016, included as part of our Annual Report on Form 10-K for the year ended December 31, 2016, and our unaudited Condensed Consolidated Financial Statements for the three- and nine-month periods ended September 30, 2017 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 and develop 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 pipeline includes three late-stage product candidates that could have a profound impact on the lives of patients: glycopyrronium tosylate (formerly DRM04), for which a New Drug Application ("NDA") is under review by the U.S. Food and Drug Administration ("FDA") for the treatment of primary axillary hyperhidrosis, (excessive underarm sweating beyond what is needed for normal body temperature regulation); olumacostat glasaretil (formerly DRM01), in Phase 3 development for the treatment of acne vulgaris; and lebrikizumab, for which we plan to initiate a Phase 2b dose-ranging study for the treatment of moderate-to-severe atopic dermatitis.

Our three late-stage product candidates are:

- Glycopyrronium tosylate, a small-molecule anticholinergic product for topical application we are developing for the treatment of primary axillary hyperhidrosis (excessive underarm sweating), a medical condition that results in sweating beyond what is needed for normal body temperature regulation. In July 2015, we commenced a Phase 3 clinical program for glycopyrronium tosylate in patients with primary axillary hyperhidrosis that comprised three clinical trials – the ATMOS-1 and ATMOS-2 pivotal trials and the ARIDO open-label safety trial. In February 2016, we completed patient enrollment in ATMOS-1 and ATMOS-2 and in June 2016, we announced positive topline results from these trials. The ATMOS-1 and ATMOS-2 trials enrolled a total of 697 adult and adolescent (ages nine and older) patients with primary axillary hyperhidrosis. In the ATMOS-2 trial, glycopyrronium tosylate demonstrated statistically significant improvements for both co-primary endpoints and both secondary endpoints compared to vehicle. In the ATMOS-1 trial, glycopyrronium tosylate demonstrated statistically significant improvements for one of the co-primary endpoints and both secondary endpoints. Results from both Phase 3 trials were based on the overall dataset from the intent-to-treat population. For the second co-primary endpoint in the ATMOS-1 trial, when extreme outlier data from one analysis center were excluded in accordance with the pre-specified statistical analysis plan submitted to the FDA, glycopyrronium tosylate demonstrated statistically significant results compared to vehicle. Consistent with the results of an earlier Phase 2b trial, glycopyrronium tosylate was well-tolerated with side effects that were primarily mild to moderate in severity. In December 2016, the treatment period for ARIDO, the open-label Phase 3 trial assessing the long-term safety of glycopyrronium tosylate, was completed. The safety and tolerability profile for glycopyrronium tosylate in the ARIDO trial is consistent with what was observed in the ATMOS-1 and ATMOS-2 trials. Based on the results of the glycopyrronium tosylate Phase 3 program and a pre-NDA meeting with the FDA in February 2017, we submitted an NDA for glycopyrronium tosylate for the treatment of primary axillary hyperhidrosis to the FDA. In November 2017, we announced that the FDA had accepted our NDA, and that the formal notification indicated that the FDA had completed its filing review and the NDA was sufficiently complete to permit a substantive review. The Prescription Drug User Fee Act target date for the completion of the FDA's review of the NDA is June 30, 2018.
- Olumacostat glasaretil, a novel, small molecule designed to target sebum production following topical application that we are developing for the treatment of acne. Olumacostat glasaretil inhibits acetyl coenzyme-A carboxylase ("ACC"), the enzyme that plays an important role in the synthesis of up to 85 percent of the lipids that make up sebum. Sebum, an oily substance made up of lipids, is produced by glands in the skin called sebaceous glands. In April 2015, we commenced a Phase 2b dose-ranging clinical trial to evaluate the safety and efficacy of olumacostat glasaretil in adult patients with moderate-to-severe facial acne vulgaris. In January 2016, we completed patient enrollment in this study and in May 2016 we announced positive topline results. In the Phase 2b dose-ranging trial, which enrolled a total of 420 patients, olumacostat glasaretil demonstrated statistically significant improvements in all primary endpoints compared to vehicle at the highest dose and in most primary endpoints at the other doses. Olumacostat glasaretil was well-tolerated with adverse events primarily mild or moderate in severity. Based on these results, in December 2016, we initiated a Phase 3 program to evaluate the safety and efficacy of olumacostat glasaretil as a potential treatment for acne to support a potential NDA submission to the FDA. The Phase 3 program comprises three clinical trials – the CLAREOS-1 and CLAREOS-2 pivotal trials and the CLARITUDE open-label safety trial. In October 2017, we announced the completion of patient enrollment in CLAREOS-1 and CLAREOS-2 with a total of 1,503 adult and adolescent (ages nine and older) patients with moderate-to-severe acne. We expect to announce topline results from the CLAREOS-1 and CLAREOS-2 trials in the first quarter of 2018.
- Lebrikizumab, an injectable, humanized antibody targeting interleukin 13 that we are developing for the treatment of atopic dermatitis. In August 2017, we entered into a license 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 retains exclusive rights to develop and promote lebrikizumab for interstitial lung disease ("Retained Field") and certain rights to use lebrikizumab for internal research purposes and for in vitro diagnostic purposes ("Roche Agreement"). We plan to initiate a Phase 2b dose-ranging study assessing lebrikizumab in adult patients with moderate-to-severe atopic dermatitis in the first

quarter of 2018. The objective of the Phase 2b dose-ranging study will be to optimize the dose of lebrikizumab for the design of a Phase 3 program.

Key Developments

Below is a summary of selected key developments affecting our business that have occurred since December 31, 2016:

Glycopyrronium Tosylate

- Announced in November 2017 that the FDA had accepted our NDA for glycopyrronium tosylate, and that the formal notification indicated that the FDA had completed its filing review and the NDA was sufficiently complete to permit a substantive review.
- Completed a meeting with the FDA in February 2017 to discuss our planned submission of an NDA for glycopyrronium tosylate.

Olumacostat Glasaretil

- Announced in October 2017 the completion of patient enrollment in the CLAREOS-1 and CLAREOS-2 pivotal trials investigating the safety and efficacy of olumacostat glasaretil in patients with acne vulgaris. The two pivotal trials enrolled a total of 1,503 patients.
- Announced in January 2017 the initiation of a Phase 3 program to evaluate the safety and efficacy of olumacostat glasaretil as a potential treatment for acne to support a potential NDA submission to the FDA. The Phase 3 program comprises three clinical trials – the CLAREOS-1 and CLAREOS-2 pivotal trials and the CLARITUDE open-label safety trial.

Lebrikizumab

- Acquired exclusive, worldwide rights to develop and commercialize lebrikizumab for atopic dermatitis and all other indications except the Retained Field pursuant to the Roche Agreement, which became effective in September 2017.

Non-Program Developments

- Closed a private placement of 3.00% Convertible Senior Notes due 2022 (“Notes”) in May 2017, which generated net proceeds to us of $278.3 million.
- Closed an underwritten public offering in March 2017 (“2017 Public Offering”), which generated net proceeds to us of $181.5 million.

Other

- In November 2017, we announced that following our expressed intent to exercise our right to terminate 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, we and UCB entered into a transition agreement (“Transition Agreement”), which provides for an orderly transition of the development and commercialization activities under the UCB Agreement and termination of the collaboration on February 15, 2018.

Financial Overview

For the three months ended September 30, 2017, net loss increased 602% to $179.2 million from $25.5 million for the same period in 2016. The increase is primarily due to our recognition of acquired in-process research and development expenses of $128.6 million for the three months ended September 30, 2017 related to the costs to acquire exclusive worldwide rights to develop and commercialize lebrikizumab for atopic dermatitis and all other indications except the Retained Field. Research and development expenses increased 73% to $30.8 million for the three months ended September 30, 2017 compared to the same period in 2016, driven primarily by growth in clinical trial activities for our olumacostat glasaretil product candidate and by headcount growth and associated expenses. General and administrative expenses increased 139% to $19.8 million for the three months ended September 30, 2017 compared to

the same period in 2016, driven primarily by headcount growth and associated expenses, as well as expenses related to commercial readiness activities.

For the nine months ended September 30, 2017, net loss increased 203% to $247.2 million from $81.7 million for the same period in 2016. The increase is primarily due to our recognition of acquired in-process research and development expenses of $128.6 million for the nine months ended September 30, 2017 pursuant to the Roche Agreement. Research and development expenses increased 23% to $76.6 million for the nine months ended September 30, 2017 compared to the same period in 2016, driven primarily by growth in clinical trial activities for our olumacostat glasaretil product candidate and by headcount growth and associated expenses, partially offset by a reduction in clinical trial activities for Cimzia and our glycopyrronium tosylate product candidate. General and administrative expenses increased 117% to $44.7 million for the nine months ended September 30, 2017 compared to the same period in 2016, driven primarily by headcount growth and associated expenses, as well as expenses related to commercial readiness activities.

As of September 30, 2017, we had cash and cash equivalents and investments of $662.9 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, and 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 do not have any approved products and have never generated any revenue from product sales. Other than the revenue we may generate in connection with our agreements with UCB and Maruho, we do not expect to generate any revenue from any product candidates that we develop unless and until we obtain regulatory approval and commercialize our products or enter into other collaboration or license agreements with third parties for the development or license of those product candidates.

We have never been profitable and may never be profitable. As of September 30, 2017, we had an accumulated deficit of $497.4 million. We expect to continue to incur net losses for the foreseeable future as we advance our current and potential additional product candidates through clinical development, seek regulatory approval for them and prepare for and proceed to commercialization. We expect to incur significant commercialization costs in advance of any of our product candidates receiving regulatory approval. As a result, we will need substantial additional funding to support our operating activities. 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.

Acquired In-Process Research and Development Expenses

We expense in-process research and development projects acquired as part of asset acquisitions that have no alternative future use. The fair value assigned to incomplete research projects that have not reached technological feasibility and are acquired in business combinations are capitalized and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the applicable project. We determined that the acquired in-process research and development related to the Roche Agreement had no alternative future use and recorded an expense of $128.6 million during the three and nine months ended September 30, 2017 in the condensed 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, and the payments due in 2018 totaling $55.0 million that 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.

Amortization of Debt Discount and Issuance Costs

Debt discount and issuance costs, consisting of legal and other fees directly related to the 3.00% Convertible Senior Notes due 2022, are offset against gross proceeds from the issuance of the Notes and are amortized to interest expense over the estimated life of the Notes based on the effective interest method. As of September 30, 2017, there were unamortized issuance costs and debt discounts of $8.6 million, which were recorded as a direct deduction from the Notes on the condensed consolidated balance sheets.

Except for the policies described above, there were no other material changes in our critical accounting policies and significant estimates as disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” contained in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (“SEC”) on February 28, 2017.

Results of Operations

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2017	2016	$	%	2017	2016	$	%
	(in thousands, except percentages)							
Revenue:								
Collaboration and license revenue	$1,066	$119	$947	796%	$3,198	$119	$3,079	*
Operating expenses:								
Research and development	30,788	17,784	13,004	73	76,626	62,306	14,320	23 %
Acquired in-process research and development	128,555	—	128,555	*	128,555	—	128,555	*
General and administrative	19,754	8,276	11,478	139	44,667	20,550	24,117	117
Total operating expenses	179,097	26,060	153,037	587	249,848	82,856	166,992	202
Loss from operations	(178,031)	(25,941)	(152,090)	586	(246,650)	(82,737)	(163,913)	198
Interest and other income, net	1,721	431	1,290	299	3,585	1,036	2,549	246
Interest expense	(2,864)	—	(2,864)	*	(4,184)	—	(4,184)	*
Net loss	$(179,174)	$(25,510)	$(153,664)	602%	$(247,249)	$(81,701)	$(165,548)	203%

*Percentage not meaningful

Revenue. Our revenue has been comprised of upfront and milestone payments in connection with the UCB Agreement and our exclusive license agreement with Maruho Co., Ltd., 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 $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. We recognized $0.1 million in collaboration and license revenue for the three and nine months ended September 30, 2016 related to the ratable recognition of the $25.0 million upfront payment received pursuant to the Maruho G.T. Agreement.

Research and Development. Research and development expenses include external costs incurred for the development of our product candidates, including third-party expenses necessary for conducting clinical studies and developing and manufacturing clinical trial supplies, 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:

	Phase of Development as of	Three Months Ended

		Three Months Ended September 30,			Nine Months Ended September 30,		
	September 30, 2017 (in thousands)	2017	2016	$ Change	2017	2016	$ Change
External costs incurred by product candidate:							
Glycopyrronium tosylate[1]	Phase 3 Complete	$ 5,337	$ 3,526	$ 1,811	$ 11,211	$ 15,507	$ (4,296)
Olumacostat glasaretil[2]	Phase 3	10,189	1,066	9,123	25,836	5,563	20,273
Lebrikizumab[3]	Phase 2	89	—	89	89	—	89
Cimzia[4]	Phase 3	5,591	5,668	(77)	13,997	22,915	(8,918)
Other research and development expenses		689	1,464	(775)	1,341	1,548	(207)
Internal costs		8,893	6,060	2,833	24,152	16,773	7,379
Total research and development expenses		$ 30,788	$ 17,784	$ 13,004	$ 76,626	$ 62,306	$ 14,320

1. In June 2016, we announced topline results from the pivotal trials of the glycopyrronium tosylate Phase 3 program. In December 2016, the treatment period for ARIDO, an open-label Phase 3 trial assessing the long-term safety of glycopyrronium tosylate, was completed. We submitted an NDA to the FDA and, in November 2017, we announced that the FDA had accepted our NDA, and that the formal notification indicated that the FDA had completed its filing review and the NDA was sufficiently complete to permit a substantive review. The Prescription Drug User Fee Act target date for the completion of the FDA's review of the NDA is June 30, 2018.
2. In May 2016, we announced topline results from the olumacostat glasaretil Phase 2b study. Based on these results, we initiated a Phase 3 program in December 2016, announced completion of enrollment in the two pivotal clinical trials, CLAREOS-1 and CLAREOS-2, in October 2017 and expect to announce topline results from these trials in the first quarter of 2018.
3. In connection with the Roche Agreement, which became effective in September 2017, we acquired the exclusive, worldwide rights to develop and commercialize lebrikizumab for atopic dermatitis and all other indications except the Retained Field. We plan to initiate a Phase 2b dose-ranging study assessing lebrikizumab in adult patients with moderate-to-severe atopic dermatitis in the first quarter of 2018. The acquired in-process research and development expenses of $128.6 million related to the Roche Agreement are not included in this table.
4. In December 2014, we commenced a Phase 3 clinical program for Cimzia. We announced topline results for the three clinical trials in this Phase 3 program, CIMPASI-2, CIMPASI-1 and CIMPACT, in October 2016, December 2016 and January 2017, respectively. UCB submitted a supplemental Biologics License Application to the FDA and a Type II Variation to the European Medicines Agency in July 2017 to support potential approvals for Cimzia as a treatment option for patients with moderate-to-severe chronic plaque psoriasis. In November 2017, we entered into the Transition Agreement with UCB, which provides for an orderly transition of the development and commercialization activities under the UCB Agreement and termination of the collaboration on February 15, 2018.

Research and development expenses increased $13.0 million, or 73%, for the three months ended September 30, 2017 compared to the three months ended September 30, 2016. This increase was due to a $13.9 million increase driven primarily by growth in clinical trial activities for our olumacostat glasaretil product candidate related to our Phase 3 program, which commenced in December 2016 and for which we announced the completion of patient enrollment for the CLAREOS-1 and CLAREOS-2 pivotal trials in October 2017, an increase in internal costs related to headcount growth and associated expenses and growth in regulatory and manufacturing activities for our glycopyrronium tosylate product candidate, partially offset by a $0.8 million decrease in other research and development expenses.

Research and development expenses increased $14.3 million, or 23%, for the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016. This increase was due to a $27.7 million increase driven primarily by growth in clinical trial activities for our olumacostat glasaretil product candidate related to our Phase 3 program and an increase in internal costs related to headcount growth and associated expenses, partially offset by a $13.2 million decrease in external costs for Cimzia and our glycopyrronium tosylate product candidate.

We expect our research and development expenses to increase as we continue clinical trials, prepare for regulatory submissions, expand our manufacturing activities, develop new product candidates resulting from our early-stage research programs or business development activities and expand our development organization and capabilities. The timing and amount of expenses incurred will depend largely upon the outcomes of current or future clinical studies for our product candidates, related regulatory requirements and manufacturing costs and the timing and cost of potential additions to our portfolio of product candidates.

Acquired in-process research and development. Acquired in-process research and development expenses consist of in-process research and development projects acquired as part of asset acquisitions that have no future alternative use. Ongoing costs incurred for the development of our product candidates acquired in an asset acquisition are classified as research and development expenses.

Acquired in-process research and development expense was $128.6 million for the three and nine months ended September 30, 2017 and related to the initial $80.0 million payment made to Roche in October 2017 and the present value of the two additional payments totaling $55.0 million due to Roche in 2018 pursuant to the terms of the Roche Agreement.

General and Administrative. General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in our general and administrative functions, including our sales and marketing functions. Other general and administrative expenses include professional fees for audit, tax, legal, market research and commercial planning services.

General and administrative expenses increased $11.5 million, or 139%, for the three months ended September 30, 2017 compared to the three months ended September 30, 2016. This increase was due to headcount growth and associated expenses and higher expenses related to commercial readiness activities.

General and administrative expenses increased $24.1 million, or 117%, for the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016. This increase was due to headcount growth and associated expenses and higher expenses related to commercial readiness activities.

We expect our general and administrative expenses to increase substantially in the future as we expand our operating activities, prepare for the potential commercialization of our product candidates and increase our headcount.

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 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 also provides that we may issue and sell up to an aggregate offering of $75.0 million of our common stock through an at-the-market sales agreement with Cowen and Company, LLC. As of September 30, 2017, no sales had been made under this at-the-market sales agreement and $75.0 million of common stock remained available to be sold, subject to certain conditions as specified in the sales agreement.

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 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 May 2017, we sold $287.5 million aggregate principal amount of 3.00% Convertible Senior Notes due 2022 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, 2017, we had $662.9 million of cash and cash equivalents and investments. Our cash and cash equivalents 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, commercial paper and certificates of deposit. 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, 2017, we had an accumulated deficit of $497.4 million. We expect to incur additional losses and expend substantial cash resources for the foreseeable future for the clinical development and potential commercialization of our product candidates and development of any other indications and 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, 2017 and 2016:

	Nine Months Ended September 30,	
	2017	2016
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$(72,323)	$(74,798)
Investing activities	(37,311)	(114,784)
Financing activities	461,472	137,996
Net increase (decrease) in cash and cash equivalents	$351,838	$(51,586)

Operating Activities. 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 collaboration receivables from a related party 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. Net cash used in operating activities was $74.8 million for the nine months ended September 30, 2016 and consisted of a net loss of $81.7 million and a $3.8 million increase in net operating assets, partially offset by $10.7 million in non-cash charges. The increase in net operating assets consisted primarily of a $25.0 million increase in collaboration and license receivable pursuant to the Maruho G.T. Agreement, a $3.2 million increase in prepaid expenses and other current assets and a $3.0 million decrease in accounts payable, partially offset by a $24.9 million increase in deferred revenue and a $2.5 million increase in accrued liabilities. Non-cash charges included $7.9 million of stock-based compensation expense, $1.5 million of common stock issued in connection with an agreement with Takeda Pharmaceutical Company Limited (“Takeda”), pursuant to which we acquired the right to evaluate and conduct research on Takeda compounds directed to each of three biological targets and an option to license exclusive worldwide rights to selected compounds from each of these three programs, and $1.3 million of amortization of premiums on available-for-sale securities.

Investing Activities. 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. Net cash used in investing activities for the nine months ended September 30, 2016 was $114.8 million, which resulted primarily from purchases of investments of $194.7 million, partially offset by proceeds from maturities of investments of $80.0 million.

Financing Activities. 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. Net cash provided by financing activities for the nine months ended September 30, 2016 was $138.0 million, which resulted primarily from net proceeds from our underwritten public offering of $135.6 million in June 2016.

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 and commercialize any approved products. We believe that existing cash and cash equivalents and investments on hand as of September 30, 2017 are sufficient to meet our anticipated cash requirements into the first half of 2019 and to: complete and generate topline results from our ongoing Phase 3 pivotal clinical trials for olumacostat glasaretil; commercialize our glycopyrronium tosylate product candidate, assuming that we receive the necessary regulatory approvals; complete registration-enabling activities and submit an NDA to the FDA for potential approval related to olumacostat glasaretil assuming the data from our Phase 3 clinical trials are positive; 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 sell additional equity or convertible debt securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of convertible debt securities, these securities 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

The following table summarizes our contractual obligations as of September 30, 2017:

	Payment Due by Period				
	Total	Less than One Year	1 – 3 Years	3 – 5 Years	More than 5 Years
	(in thousands)				
Operating lease obligations	$24,384	$3,988	$9,625	$7,701	$3,070
Convertible notes	330,625	8,625	17,250	304,750	-
Roche license payments	135,000	105,000	30,000	-	-
Total contractual obligations	$490,009	$117,613	$56,875	$312,451	$3,070

Holders of the Notes have the right to require us to repurchase their Notes upon the occurrence of a fundamental change at a repurchase price equal to 100% of the principal amount of the repurchased Notes, plus any accrued and unpaid interest.

Pursuant to the Roche Agreement, we made an initial payment of $80.0 million in October 2017. Additionally, payments of $25.0 million and $30.0 million are due in September 2018 and December 2018, respectively, or upon the earlier achievement of certain development milestones.

Also related to the Roche Agreement, we will be obligated to make additional 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 indications other than interstitial lung disease. 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. These amounts are not included in the table above.

In September 2017, we entered into a sublease agreement (“Sublease”) pursuant to which we will sublease an additional 23,798 square feet of space. Rent payments for the Sublease include base rent of $139,218 per month during the first year of the Sublease with an annual increase of three percent, and additional monthly fees to cover our share of certain facility expenses, including utilities, property taxes, insurance and maintenance. The Sublease term will commence on the earlier to occur of (1) January 1, 2018, and (2) the date on which we complete our tenant improvements to the Sublease premises, and will end on April 30, 2024, unless terminated early pursuant to the terms of the Sublease. We expect to commence making rent payments in March 2018.

Other than the events described above, there have been 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, 2016, filed with the SEC on February 28, 2017.

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

We are subject to interest rate sensitivity on our outstanding 3.00% Convertible Senior Notes due 2011 ("Notes") that were sold in a private placement to qualified institutional buyers. Increases in interest rates would result in a decrease in the fair value of our outstanding debt and decreases in interest rates would result in an increase in the fair value of our outstanding debt. 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.

During the nine months ended September 30, 2017, there have been no other significant changes in market risks as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016.

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, or the 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, 2017, 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

There were no 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, 2017 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 Development, Regulatory Approval and Commercialization

Our business is dependent on the successful development, regulatory approval and commercialization of our product candidates.

Our pipeline includes three late-stage product candidates that could have a profound impact on the lives of patients: glycopyrronium tosylate (formerly DRM04), for which a New Drug Application ("NDA") is under review by the U.S. Food and Drug Administration ("FDA") for the treatment of primary axillary hyperhidrosis (excessive underarm sweating beyond what is needed for normal body temperature regulation); olumacostat glasaretil (formerly DRM01), in Phase 3 development for the treatment of acne vulgaris, or acne; and lebrikizumab, for which we plan to initiate a Phase 2b dose-ranging study for the treatment of moderate-to-severe atopic dermatitis. The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our late-stage product candidates. In the future, we may also become dependent on other product candidates that we may in-license, acquire or develop. The clinical and commercial success of our 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;
- 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 product candidates or any future product candidates;
- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our 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 product candidates or any future product candidates;
- the prevalence, duration and severity of potential side effects experienced with our product candidates or future product candidates or approved products, if any;
- 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 product candidates or any future product candidates or approved products, if any;
- the ability of third parties with whom we contract to manufacture clinical trial and commercial supplies of our product candidates 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 current good manufacturing practices ("cGMP");
- a continued acceptable safety profile during clinical development and following approval of our product candidates or any future product candidates;

- our ability to successfully commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;
- our and our partners' ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates;
- our and our partners' ability to avoid third-party patent interference or intellectual property infringement claims; and
- our ability to in-license or acquire additional product candidates that we believe can be successfully developed and commercialized.

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 obtain regulatory approvals or commercialize our product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any of our product candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our product candidates or any future product candidates to continue our business.

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.

We are a clinical-stage biopharmaceutical company with a limited operating history upon which investors can evaluate our business and prospects. We are not profitable and have incurred losses in each year since we commenced operations in August 2010. We have incurred net losses of $247.2 million and $81.7 million for the nine months ended September 30, 2017 and 2016, respectively, and of $89.1 million and $78.4 million for the fiscal years ended December 31, 2016 and 2015, respectively. As of September 30, 2017, we had an accumulated deficit of $497.4 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. The size of our future net losses will depend, in part, on our future expenses and our ability to generate revenue, if any. 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, 2017, we had capital resources consisting of cash and cash equivalents and investments of $662.9 million. We will continue to expend substantial cash resources for the foreseeable future for the clinical development and potential commercialization of our product candidates 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 cash equivalents and investments are sufficient to: complete and generate topline results from our ongoing Phase 3 pivotal clinical trials for olumacostat glasaretil; commercialize our glycopyrronium tosylate product candidate, assuming that we receive the necessary regulatory approvals; complete registration-enabling activities and submit an NDA to the FDA for potential approval related to olumacostat glasaretil

assuming the data from our Phase 3 clinical trials are positive; 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. Our currently anticipated expenditures for the development and potential commercialization of all of our current product candidates, glycopyrronium tosylate, olumacostat glasaretil and lebrikizumab, exceed our existing cash and cash equivalents and investments. 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:

- 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 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 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 relating to building our infrastructure to prepare for potential commercial launch of our products, which will be incurred even if our product candidates are not ultimately approved for sale;
- the cost of commercialization activities if our current or any future product candidates are approved for sale, including manufacturing, marketing, sales and distribution costs;
- the degree and rate of market acceptance of any approved products;
- costs under our third-party manufacturing and supply arrangements for our current and any future product candidates and any products we commercialize;
- costs and timing of completion of any additional outsourced commercial manufacturing or supply arrangements that we may establish;
- costs of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights associated with our 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 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 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.

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

Clinical drug development for our product candidates 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 our product candidates to meet specified endpoints;
- slower than expected rates of subject recruitment and enrollment rates 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 acne;
- difficulty in retaining subjects who have initiated 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 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.

In the case of our topical product candidates, we are seeking to deliver sufficient concentrations of the active pharmaceutical ingredient ("API") through the skin barrier to the targeted dermal tissue to achieve the intended therapeutic effect. As a result, safety and efficacy can be difficult to establish. The topical route of administration may involve new dosage forms, which can be difficult to develop and manufacture and may raise novel regulatory issues and result in development or review delays. For example, the dosage form for glycopyrronium tosylate is an API-saturated wipe, and we are not aware of previous FDA approvals of prescription drug wipes. In addition, it is possible that the FDA may require more exposure of individuals to glycopyrronium tosylate than we have collected in our safety database. If we are required to expose additional individuals to glycopyrronium tosylate in order to

establish a safety database sufficient for approval, approval of glycopyrronium tosylate, if at all, could be delayed and our costs could increase.

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 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, if additional clinical trials of glycopyrronium tosylate for the treatment of primary axillary hyperhidrosis are required, and we experience delays in the completion of, or if we terminate, the clinical trials, our business, financial condition, operating results and prospects would be adversely affected.

We may be unable to obtain regulatory approval for any of our 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 commercialization, our potential to generate revenue, our business and our operating results.

We currently have no products approved for sale, and we may never obtain regulatory approval to commercialize any of our current or 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 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 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 any of our current 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 such as glycopyrronium tosylate or olumacostat glasaretil or a biologic product such as lebrikizumab, 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. For example, in one of the two glycopyrronium tosylate Phase 3 trials, glycopyrronium tosylate demonstrated statistically significant results compared to vehicle for the objective measurement of sweat production only following exclusion of extreme outlier data from one analysis center in accordance with the pre-specified statistical analysis plan submitted to the FDA. The FDA may determine that we did not achieve statistically significant results for this objective measurement in this trial and may require us to conduct an additional Phase 3 study as a result of the extreme outlier data, and approval of glycopyrronium tosylate, if at all, could be delayed and our costs would increase. Further, as one of the primary assessments of efficacy in our glycopyrronium tosylate Phase 3 trials, we used a new patient-reported outcome assessment (“PRO”), the Axillary Sweating Daily Diary, the sweating severity item of which was validated in our Phase 2 clinical program to assess efficacy in a subjective manner. This PRO has not been previously used in an NDA filing to support potential approval of a product.

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 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 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 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;
- the FDA or the applicable foreign regulatory body may not approve or grant marketing clearance of a device intended to be used in combination with our product candidates, such as an auto-injector with Cimzia; 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, the FDA may not agree with our Phase 3 clinical trial protocols for our product candidates. In addition, our 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 product candidates and would harm our business, financial condition, operating results and prospects.

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

Preparing and obtaining approval of a BLA or NDA submission or equivalent foreign filing are complicated processes. Although our employees have prepared BLAs, and obtained approvals of BLAs, NDAs and equivalent foreign filings in the past while employed at other companies, we as a company have not done so. 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 and NDA submissions for glycopyrronium tosylate, olumacostat glasaretil or lebrikizumab, respectively, would prevent us from or delay us in commercializing our product candidates in the United States. The occurrence of any of the foregoing could have a material adverse impact on our business and financial performance.

Even if our current product candidates or any future product candidates obtain regulatory approval, they may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.

The commercial success of any of our current or future product candidates, if approved, will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications. Our product candidates may not be commercially successful. The degree and rate of physician and patient adoption of our current or future product candidates, if approved, will depend on a number of factors, including:

- the clinical indications for which the product is approved and patient demand for approved products that treat those indications;
- 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 our product provides an attractive alternative to the existing therapies;

- the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors for any of our product candidates that may be approved;
- the cost of treatment with our product candidates in relation to alternative treatments and willingness to pay for the product, if approved, on the part of patients;
- acceptance by physicians, major operators of clinics and patients of the product as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy over other available therapies to treat approved indications;
- in the case of hyperhidrosis, patients' perception of the condition as one 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 approved indications;
- proper training and administration of our product candidates by physicians and medical staff;
- patient satisfaction with the results and administration of our product candidates and overall treatment experience;
- the willingness of patients to pay for certain of our product candidates relative to other discretionary items, especially during economically challenging times;
- the revenue and profitability that our product candidate may offer a physician as compared to alternative therapies;
- the prevalence and severity of side effects;
- limitations or warnings contained in the FDA-approved labeling for our product candidates;
- any FDA requirement to undertake a risk evaluation and mitigation strategy ("REMS");
- the effectiveness of our sales, marketing and distribution efforts;
- adverse publicity about our product candidates or favorable publicity about competitive products; and
- potential product liability claims.

If any of our current or future product candidates are approved for use but fail to achieve the broad degree of physician, patient and payor 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.

Our product candidates, if approved, will 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. 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, certain of our 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 candidates, including: AbbVie Inc., Akaal Pharma Pty Ltd., Allergan plc, Almirall, S.A., Amgen Inc., AnaptysBio, Inc., Asana BioSciences, LLC, Astellas Pharma US, Inc., Bayer HealthCare AG (formerly Intendis, Inc.), BioPharmX Corporation, Inc., Boehringer Ingelheim, Brickell Biotech, Inc., Can-Fite BioPharma Ltd., Cassiopea S.p.A., Celgene International, Dermavant Sciences, Inc., DS Biopharma Limited, Eirion Therapeutics, Inc., Eli Lilly and Company, Foamix Pharmaceuticals Ltd., Galapagos NV, Galderma S.A., GlaxoSmithKline LLC, Glenmark Pharmaceuticals Limited, Janssen Biotech, 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), Miramar Labs, Inc., Momenta Pharmaceuticals Inc., MorphoSys AG, Mylan Inc., Novan, Inc., Novartis International AG, Pfizer Inc., Qurient Co., Ltd., Ralexar Therapeutics, Inc., Ranbaxy Pharmaceuticals Inc., Regeneron Pharmaceuticals, Inc., Sandoz International GmbH, Sanofi S.A., Shire plc, Teva Pharmaceutical Industries Ltd., TheraVida, Inc., Torii Pharmaceutical Co. Ltd., Ulthera, Inc. and Valeant Pharmaceuticals International.

The markets for dermatological therapies are competitive and are characterized by significant technological development and new product introduction. We anticipate that, if we obtain regulatory approval of our product candidates, we will face significant competition from other approved therapies. If approved, our product candidates may also compete with unregulated, unapproved and off-label treatments. Certain of our 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 products, if any, provide an attractive alternative to existing and other new therapies. The competition we face could lead to reduced market share for our product candidates and contribute to downward pressure on the pricing of our product candidates, 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 for our product candidates 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 any of our product candidates that are approved, or upon the "at-risk" launch, despite pending patent infringement litigation against the generic product, by a generic competitor of a generic version of any of our 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, our glycopyrronium tosylate product candidate 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.

Any product candidates that we commercialize, or that any partner with which we may collaborate commercializes, 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.

Even after we or our partners achieve U.S. regulatory approval for a product candidate, if any, we or our partners will be subject to continued regulatory review and compliance obligations. For example, with respect to our product candidates, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. A product candidate's approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials or other REMS, to monitor the safety and efficacy of the product. We will also be 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 our product candidates. 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") requirements and good laboratory practice ("GLP") requirements, which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical development, and for any clinical trials that we conduct post-approval. To the extent that a product candidate is approved for sale in other countries, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries.

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 candidates or the manufacturing facilities for our 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 have conducted, are conducting and may in the future conduct clinical trials for our 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, are conducting and may in the future choose to conduct, one or more of our clinical trials outside the United States, including in Australia, Canada and Europe. For example, our Phase 3 clinical program for olumacostat glasaretil is being 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 trials, which would be costly and time-consuming and delay aspects of our business plan.

Our product candidates may cause undesirable side effects or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in post-approval regulatory action, any of which may adversely impact our business, financial condition, operating results and prospects.

Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. Undesirable side effects caused by product candidates could cause us, any partners with which we may collaborate or regulatory authorities to interrupt, modify, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Results of clinical trials could reveal a high and unacceptable severity and prevalence of one or more of these side effects. In such an event, trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us, or our potential partners, to cease further development of or deny approval of product candidates for any or all targeted indications. Any drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in product liability claims. Any of these occurrences may harm our business, financial condition, operating results and prospects.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by our product candidates after obtaining U.S. or foreign regulatory approval 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 the product;
- regulatory authorities may require a recall of the product or we or our potential partners may voluntarily recall a product;
- regulatory authorities may require the addition of warnings or contraindications in the product labeling, narrowing of the indication in the product label or field alerts to physicians and pharmacies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or institute a REMS;
- we may have limitations on how we promote the product;

- we may be required to change the way the product 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 the product;
- sales of the product may decrease significantly;
- we could be sued and held liable for harm caused to patients; 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 the affected product candidate and could substantially increase the costs of commercializing our product candidates.

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 will face an even greater risk if we commercialize any products. 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. Our product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, failure to follow instructions, misuse or abuse associated with our 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 candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates, among others. 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:

- withdrawal of clinical trial participants;
- decreased enrollment rates of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- the inability to commercialize our product candidates;
- decreased demand for our product candidates;
- impairment of our business reputation;
- product recall or withdrawal from the market or labeling, marketing or promotional restrictions;
- 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 unanticipated side effects. Although we have obtained product liability insurance coverage for clinical trials, 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. We will need to increase our product liability coverage if any of our product candidates receive regulatory approval, which will be costly, and we may be unable to obtain this increased product liability insurance on commercially reasonable terms, or at all. 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 any of our product candidates are approved for marketing and we are found to have improperly promoted off-label uses, or if physicians misuse our products or use our products off-label, we may become subject to prohibitions on the sale or marketing of our products, 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 our glycopyrronium tosylate product candidate, if approved, may appeal to individuals who have not been diagnosed with hyperhidrosis, we will only be able to promote glycopyrronium tosylate for its approved indication. If we are found to have promoted off-label uses of any of our product candidates, we may receive warning or untitled letters and become subject to significant 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 products 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 using our product candidates outside of those indications for use when in the physician's independent professional medical judgment he or she deems appropriate. Physicians may also misuse our product candidates or use improper techniques, potentially leading to adverse results, side effects or injury, which may lead to product liability claims. If our product candidates are misused or used with improper technique, we may become subject to costly litigation by physicians or their patients. Furthermore, the use of our product candidates 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 may choose not to continue developing or commercializing any of our product candidates at any time during development or after approval, which would reduce or eliminate our potential return on investment for those product candidates.

At any time, we may decide to discontinue the development of any of our product candidates or not to continue commercializing one or more of our approved product candidates 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. See also "—Our product candidates may cause undesirable side effects or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in post-approval regulatory action, any of which may adversely impact our business, financial condition, operating results and prospects."

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 any of our product candidates, if approved for marketing, fail to meet specifications or are 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 approved products. In addition, a recall, withdrawal or seizure of any of our approved products would require significant management attention, would likely result in substantial and unexpected expenditures and would harm our business, financial condition and operating results.

If the FDA concludes that our glycopyrronium tosylate product candidate does not satisfy the requirements under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("Section 505(b)(2)" pathway), or if the requirements for our glycopyrronium tosylate product candidate under the Section 505(b)(2) pathway are not as we expect, the approval pathway for our glycopyrronium tosylate product candidate will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, any of which may adversely impact our business, financial condition, operating results and prospects.

We are currently developing our glycopyrronium tosylate product candidate and we currently intend to seek FDA approval through the Section 505(b)(2) pathway. Glycopyrronium tosylate is a novel form of an anticholinergic agent that has been approved for systemic administration in other indications. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, added Section 505(b)(2) to the Federal Food, Drug, and Cosmetic Act. The Section 505(b)(2) pathway permits the submission of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant, and for which the applicant either does not own or has not obtained a right of reference. Reliance on certain findings made by the FDA in approving the anticholinergic agent we intend to reference in our NDA could expedite the glycopyrronium tosylate development program by potentially decreasing the amount of non-clinical or clinical data that we would need to generate in order to obtain FDA approval.

Glycopyrronium tosylate differs from the approved product we intend to reference in chemical structure, route of administration, dosage form and indication, and if we are unable to demonstrate an acceptable clinical bridge through comparative pharmacokinetic data between glycopyrronium tosylate and the approved product, the FDA may not permit us to use the Section 505(b)(2) pathway for regulatory approval. If the FDA does not allow us to pursue the Section 505(b)(2) pathway as anticipated or determines that our clinical bridge is not adequate, or if the Section 505(b)(2) pathway fails to significantly decrease the amount of testing we must conduct, we may need to conduct additional non-clinical or clinical trials, provide additional data and information and meet additional standards for regulatory approval, which would substantially increase the time and financial resources required to obtain FDA approval for glycopyrronium tosylate and entail significantly greater complications and risks than anticipated. If this were to occur, our business, financial condition, operating results and prospects may be adversely impacted.

Moreover, inability to pursue the Section 505(b)(2) pathway could result in new competitive products reaching the market more quickly than our product candidate, which would likely harm our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) pathway, we cannot provide assurances that our product candidate will receive the requisite approvals for commercialization.

Notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain competitors and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its Section 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under the Section 505(b)(2) pathway. In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months depending on the outcome of any litigation. In addition, Section 505(b)(2) NDAs are subject to potential data or marketing exclusivity rights that reward certain research performed by the sponsors of previously approved drugs. The exercise of such exclusivity rights can delay FDA approval of a Section 505(b)(2) NDA, or certain proposed product uses, for a period ranging from three to seven years, depending on the type of exclusivity earned. It is not uncommon for a manufacturer of an approved referenced product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) pathway, there is no guarantee this would ultimately lead to faster product development or earlier approval.

If we or any partners with which we may collaborate are unable to achieve and maintain coverage and adequate levels of reimbursement for any of our product candidates for which we receive regulatory approval, or any future products we may seek to commercialize, their commercial success may be severely hindered.

For any of our product candidates that become available only by prescription, successful sales by us or by any partners with which we may collaborate depend on the availability of coverage and adequate reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. The availability of coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and private third-party payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If any of our product candidates do not demonstrate attractive efficacy profiles, they may not qualify for coverage and reimbursement. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high.

Patients may be unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for our product candidates will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors 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 alternative is available.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, although private third-party payors tend to follow Medicare, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. 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 candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for any of our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could harm our business, financial condition, operating results and prospects.

Healthcare reform measures could hinder or prevent the commercial success of our products 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. 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 products once approved 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 payor (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; 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 payor, 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 recently enacted 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.

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 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 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 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.

Risks Related to Our Dependence on Third Parties

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 commercialize, our

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 and the preparation for and submission of our filings with the FDA and comparable foreign regulatory authorities. See also "—We rely completely on third parties to supply, manufacture and distribute clinical drug supplies for our product candidates, including certain sole-source suppliers and manufacturers, we intend to rely on third parties for commercial supply, manufacturing and distribution if any of our product candidates receive regulatory approval and we expect to rely on third parties for supply, manufacturing and distribution of preclinical, clinical and commercial supplies of any future product candidates."

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 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 authority 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 or preclinical trials 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 one of 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 trials 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 or equity 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 our product candidates 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 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 rely completely on third parties to supply, manufacture and distribute clinical drug supplies for our product candidates, including certain sole-source suppliers and manufacturers, we intend to rely on third parties for commercial supply, manufacturing and distribution if any of our product candidates receive regulatory approval and we expect to rely on third parties for supply, manufacturing and distribution of preclinical, clinical and commercial supplies of any future product candidates.

We do not currently have, nor do we plan to acquire, the infrastructure or capability to supply, manufacture or distribute preclinical, clinical or commercial quantities of drug substances or products. Our ability to develop our product candidates depends and our ability to commercially supply our products will depend, in part, on our ability to successfully obtain the APIs and other substances and materials used in our 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 and commercialization. If we fail to develop and maintain supply relationships with these third parties, we may be unable to continue to develop or commercialize our product candidates.

We do not have direct control over the ability of our contract suppliers and manufacturers to maintain adequate capacity and capabilities to serve our needs, including quality control, quality assurance and qualified personnel. Although we are ultimately responsible for ensuring compliance with regulatory requirements such as cGMPs, we are dependent on our contract suppliers and manufacturers for day-to-day compliance with cGMPs for production of both

APIs and finished products. Facilities used by our contract suppliers and manufacturers to produce the APIs and other substances and materials or finished products for commercial sale must pass inspection and be approved by the FDA and other relevant regulatory authorities. 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 any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize or obtain regulatory approval for the affected product or product candidate, and we may be held liable for injuries sustained as a result. Any of these factors could cause a delay or termination of preclinical studies, clinical trials or regulatory submissions or approvals of our product candidates, and could entail higher costs or result in our being unable to effectively commercialize our approved products on a timely basis, or at all.

We also 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. The APIs, drug substances and other materials used in our product candidates are currently available only from one domestic or foreign supplier and foreign manufacturer and certain of our finished product candidates are manufactured by one or a limited number of contract manufacturers. In the event an existing supplier fails to supply product on a timely basis or in the requested amount, supplies product that fails to meet regulatory requirements, becomes unavailable through business interruption or financial insolvency or loses its regulatory status as an approved source or if we or our manufacturers are unable to renew current supply agreements when such agreements expire and we do not have a second supplier, we likely would incur added costs and delays in identifying or qualifying replacement manufacturers and materials and there can be no assurance that replacements would be available to us on a timely basis, on acceptable terms or at all. We may be required to obtain regulatory approval to use alternative suppliers, and this process of approval could delay production of our products or development of product candidates indefinitely. For example, we are dependent on our current suppliers of the nonwoven material and foil in our glycopyrronium tosylate finished product, and any need to find and qualify new suppliers for these materials would adversely affect our business. We and our manufacturers do not currently maintain inventory of these APIs, drug substances and other materials. Any interruption in the supply of an API, drug substance or other material or in the manufacture of a finished product could have a material adverse effect on our business, financial condition, operating results and prospects.

In addition, these contract manufacturers are engaged with other companies to supply and manufacture materials or products for such companies, which also exposes our suppliers and manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract supplier’s or manufacturer’s facility. If the FDA or a comparable foreign regulatory agency does not approve these facilities for the supply or manufacture of our product candidates, or if it withdraws its approval in the future, we may need to find alternative supply or manufacturing facilities, which would negatively impact our ability to develop, obtain regulatory approval of or market our product candidates, if approved.

To date, our drug substances and product candidates have been manufactured in relatively small quantities for clinical trials. As we prepare for potential commercialization, we have initiated the scale of production of some of our drug substances and product candidates, which may include transferring production to new third-party suppliers or manufacturers. If any of our product candidates is approved for sale, our contract manufacturers and suppliers will need to produce the resulting drug product and its components in larger quantities, more cost effectively and, in certain cases, at higher yields than they currently achieve. These third-party contractors may not be able to successfully increase the manufacturing capacity for any products in a timely or cost-effective manner or at all. Transferring technology to other sites and significant scale up of manufacturing may require additional processes, technologies and validation studies, which are costly, may not be successful and, in some cases, require review and approval by the FDA and foreign regulatory authorities. In addition, quality issues may arise during those scale-up activities because of the inherent properties of a product candidate itself or of a product candidate in combination with other components added during the manufacturing and packaging process, or during shipping and storage of the APIs or the finished product.

If our third-party contractors are unable to successfully scale up the manufacture of any of our product candidates in sufficient quality and quantity and at commercially reasonable prices, and we are unable to find one or more replacement suppliers or manufacturers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and we are unable to successfully transfer the processes on a timely basis, the commercial launch for any resulting products may be delayed, or there may be a shortage in supply, either of which could significantly harm our business, financial condition, operating results and prospects.

We expect to continue to depend on third-party contract suppliers and manufacturers for the foreseeable future. Our supply and manufacturing agreements, if any, do not guarantee that a contract supplier or manufacturer will provide services adequate for our needs. We and our contract suppliers and manufacturers continue to improve production processes, certain aspects of which are complex and unique, and we may encounter difficulties with new or existing processes. While we attempt to build in certain contractual obligations on such third-party suppliers and manufacturers, we may not be able to ensure that such third parties comply with these obligations. Depending on the extent of any difficulties encountered, we could experience an interruption in clinical or commercial supply, with the result that the development, regulatory approval or commercialization of our product candidates may be delayed or interrupted. In addition, third-party suppliers and manufacturers may have the ability to increase the price payable by us for the supply of the APIs and other substances and materials used in our product candidates, in some cases without our consent.

Additionally, any damage to or destruction of our third-party manufacturers' or suppliers' facilities or equipment may significantly impair our ability to have our product candidates manufactured on a timely basis. Furthermore, if a contract manufacturer or supplier becomes financially distressed or insolvent, or discontinues our relationship beyond the term of any existing agreement for any other reason, this could result in substantial management time and expense to identify, qualify and transfer processes to alternative manufacturers or suppliers, and could lead to an interruption in clinical or commercial supply.

Our reliance on contract manufacturers and suppliers further exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may misappropriate our trade secrets or other proprietary information.

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 products or product candidates or their components into the United States or other countries as a result of, among other things, regulatory agency approval requirements, local import requirements such as import duties or inspections, incomplete or inaccurate import documentation or defective packaging.

We are dependent on Roche for the manufacture and supply of lebrikizumab drug substance and product. 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 and product 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.

Pursuant to the terms of our license agreement with F. Hoffmann-La Roche Ltd and Genentech, Inc. (together, "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 product 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 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 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 preclinical, clinical or commercial quantities of lebrikizumab drug substances or products. 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 drug substance and product and 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.

If we experience any interruption in the supply of lebrikizumab drug substance and product, our ability to timely supply our clinical sites would be adversely impacted, causing potentially serious delays in the timing of our clinical studies and substantially increased costs if studies need to be adjusted or re-performed. See also "—We rely completely on third parties to supply, manufacture and distribute clinical drug supplies for our product candidates, including certain sole-source suppliers and manufacturers, we intend to rely on third parties for commercial supply, manufacturing and distribution if any of our product candidates receive regulatory approval and we expect to rely on third parties for supply, manufacturing and distribution of preclinical, clinical and commercial supplies of any future product candidates."

Manufacturing and supply of the APIs and other substances and materials used in our product candidates and finished drug products 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 APIs, 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 candidates and can impede, delay, limit or prevent the successful development and commercialization of our 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;
- difficulty in establishing optimal production, storage, packaging and shipment methods and processes;
- challenges in designing effective drug delivery substances 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 products, which could harm our business, financial condition, operating results and prospects.

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

The development and potential commercialization of our product candidates will require substantial additional cash to fund expenses. In order to fund further development of our 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 our partners' 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 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 revenue.

Our plans for the development and commercialization of lebrikizumab for the treatment of moderate-to-severe atopic dermatitis may be adversely impacted by Roche's decisions and actions regarding product development, regulatory strategy and commercialization of lebrikizumab for interstitial lung disease (the "Retained Field").

Pursuant to the terms of the Roche Agreement, we obtained the exclusive, worldwide rights to develop and commercialize lebrikizumab for atopic dermatitis and all other indications except Roche retained exclusive rights to develop and promote lebrikizumab in the Retained Field and certain rights to use lebrikizumab for internal research purposes and for in vitro diagnostic purposes. Roche's rights in the Retained Field will be relinquished to us (the "Roche Reversion"): (a) at Roche's election at any time following 30 days' prior written notice to us; or (b) automatically if at any time in a period of 18 consecutive months Roche is not conducting an active clinical study of lebrikizumab or recurring, bona fide activities aimed at receiving regulatory approval for the compound in the Retained Field, provided that such automatic reversion may not occur within three years of the effective date of the Roche Agreement or following regulatory approval for the compound in the Retained Field. Until the occurrence of the Roche Reversion, if at all, Roche has the sole right to develop lebrikizumab in the Retained Field and, if regulatory approval is obtained, will be responsible for promotion, market access, reimbursement, funding and listing activities relating to lebrikizumab in the Retained Field. In exercising its rights in the Retained Field, Roche may make decisions and take actions with respect to the development and promotion of lebrikizumab which may not align with and may adversely impact our efforts for the development and commercialization lebrikizumab for the treatment of moderate-to-severe atopic dermatitis. See also "—If any of our product candidates are approved for marketing and we are found to have improperly promoted off-label uses, or if physicians misuse our products or use our products off-label, we may become subject to prohibitions on the sale or marketing of our products, product liability claims and significant fines, penalties and sanctions, and our brand and reputation could be harmed."

Risks Related to Our Business and Financial Operations

We will need to further increase the size and complexity of our organization in the future, and we may experience difficulties in executing our growth strategy and managing any growth.

Our management, personnel, systems and facilities currently in place are not adequate to support our business plan and future growth. We will need to further expand our scientific, medical affairs, sales and marketing, managerial, operational, financial and other resources to support our planned research, development and commercialization activities.

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;
- attract and retain sufficient numbers of talented employees;
- develop a marketing, sales and distribution capability;
- manage our commercialization activities for our product candidates 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 our current product candidates 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. If we are not able to effectively manage our growth and expand our organization by hiring new employees and expanding our use of consultants, we might be unable to implement successfully the tasks necessary to execute effectively on our planned research, development and commercialization activities and, accordingly, might not achieve our research, development and commercialization goals.

If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates 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 the Board, Thomas G. Wiggans; our Chief Medical Officer and a member of our board of directors, Eugene A. Bauer, M.D.; our Chief Operating Officer and Chief Financial Officer, Andrew L. Guggenhime; our Chief Development Officer, Luis C. Peña; our Chief Commercial Officer, Lori Lyons-Williams; and our Senior Vice President, Corporate Development and Strategy, 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 product candidates 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.

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.

We currently have limited marketing capabilities and no sales organization. If we are unable to establish sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize our product candidates, if approved, or generate product revenue.

We currently have limited marketing capabilities and no sales organization. Although our employees have experience in the marketing, sale and distribution of pharmaceutical products from prior employment at other companies, we as a company have no prior experience in the marketing, sale and distribution of pharmaceutical products. To successfully commercialize our product candidates, if approved, in the United States, Canada, the European Union and other jurisdictions we seek to enter, we must effectively build our commercial infrastructure, including our marketing, sales, distribution, managerial and other non-technical capabilities, as well as substantially expand our organization cross-functionally to enable us to execute on our commercialization goals. There are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals,

generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. See also —"We will need to further increase the size and complexity of our organization in the future, and we may experience difficulties in executing our growth strategy and managing any growth." Any failure or delay in the development of our commercial infrastructure and sales, marketing and distribution capabilities would adversely impact the commercialization of our product candidates.

We may also choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of 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 our product candidates. The inability to successfully commercialize our product candidates, either on our own or through collaborations with one or more third parties, would harm our business, financial condition, operating results and prospects.

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. 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.

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 operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations, adversely impacting our stock price.

Our operations to date have been primarily limited to researching and developing our product candidates and undertaking preclinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market. 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, and we expect that amounts earned from or paid pursuant to these agreements will be a significant source of our capital expenditures and an important source of our revenue. Accordingly, our revenue and profitability will depend on the achievement of milestones under a license agreement with Maruho Co., Ltd. pursuant to which we granted Maruho an exclusive license to develop and commercialize glycopyrronium tosylate for the treatment of hyperhidrosis in Japan, as well as any potential future collaboration and license agreements and sales of our products, if approved. 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 product candidates;
- the timing and success or failure of clinical trials for our 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 product candidates in clinical development;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our 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 product candidates;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the level of demand for our product candidates, should they receive approval, which may vary significantly;
- potential side effects of our product candidates that could delay or prevent commercialization or cause an approved drug to be taken off the market;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our product candidates, if approved;
- our dependency on third-party manufacturers to supply or manufacture our product candidates;
- our ability to establish an effective sales, marketing and distribution infrastructure in a timely manner;
- market acceptance of our product candidates, if approved, and our ability to forecast demand for those product candidates;
- our ability to receive regulatory approval and commercialize our 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 certain of our product candidates to be discretionary, and if full reimbursement for such products is not available, demand for these products 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 certain of our approved products, if any, and making it more difficult for us to raise funds if necessary, and our stock price may decline. Additionally, although we plan to market our products primarily in the United States, our partners have extensive global operations, indirectly exposing us to additional risk.

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, 2016, 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, 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 candidates, our business, financial condition, operating results and prospects would suffer.

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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 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 commercialization and development of our product candidates could be delayed.

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 candidates and technologies that are of sufficient breadth to prevent third parties from competing against us.

Our success with respect to our product candidates and technologies 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 any of our product candidates from 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 products. 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 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 candidates, or may not provide us with sufficient protection for our 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 candidates is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our 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 candidates, we may be open to competition from generic versions of our product candidates. Further, the extensive period of time between patent filing and regulatory approval for a product candidate limits the time during which we can market a product candidate under patent protection, which may particularly affect the profitability of our early-stage product candidates. The issued U.S. patents relating to olumacostat glasaretil, glycopyrronium tosylate and lebrikizumab will expire between 2020 and 2034.

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 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 United States 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 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 products, 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 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 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 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 candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that our 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 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 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 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 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;
- 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 products 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 or operating results.

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 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 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 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;
- the success of, and fluctuations in, the commercial sales of 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;
- 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. In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were involved in securities litigation, we could incur substantial costs and our resources and the attention of management could be diverted from our business.

During the period between January 1, 2016 and November 3, 2017, the closing sale price of our common stock on The NASDAQ Global Select Market ranged from $18.67 to $38.03 per share. Because our stock price has been volatile, investing in our common stock is risky.

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, 2017, we had 41,668,638 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 44% 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. If a large number of shares of our common stock into our common stock are sold in the public market after they become eligible for sale, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

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, 2017, 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 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. 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 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.

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 September 30, 2017, 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.

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, 2017, our directors and executive officers beneficially owned (determined in accordance with the rules of the SEC), in the aggregate, approximately 13% 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 our 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.

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, 2017, 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 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 our 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:

- our vulnerability to adverse general economic conditions and competitive pressures will be heightened;
- we will be 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 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 will 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

Number	Exhibit Title	Incorporated by Reference			Filed Herewith
		Form	File No.	Filing Date	
10.1†	License Agreement dated as of August 8, 2017 between Dermira, Inc. and F. Hoffmann-La Roche Ltd and Genentech, Inc.				X
10.2	Sublease Agreement dated as of September 22, 2017 between Dermira, Inc. and McDermott Will & Emery LLP.				X
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

† Registrant is requesting confidential treatment with respect to portions of this exhibit.

* 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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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 6, 2017.

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 Operating Officer and Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)