Dermira, Inc.
Form 10-Q
November 10, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2015

or

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

For the transition period from to

Commission File Number 001-36668

DERMIRA, INC.

(Exact name of registrant as specified in its charter)

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

275 Middlefield Road, Suite 150

Menlo Park, CA 94025

(Address of principal executive offices) (Zip Code)

(650) 421-7200

(Registrant s telephone number, including area code)

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

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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

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

Large accelerated filer o	Accelerated filer o
Non-accelerated filer x (do not check if a smaller reporting company)	Smaller reporting company o

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

As of October 30, 2015, the registrant had 29,918,829 shares of common stock outstanding.

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PART I. FINANCIAL INFORMATION

ITEM 1. Financial Statements

DERMIRA, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	September 30, 2015 (unaudited)	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 120,276	$ 55,358
Short-term investments	94,740	41,793
Collaboration receivable from a related party	7,300	7,300
Prepaid expenses and other current assets	1,872	1,012
Total current assets	224,188	105,463
Property and equipment, net	284	192
Long-term investments	17,441	66,483
Intangible assets	3,520	3,520
Goodwill	771	771
Other assets	998	1,792
Total assets	$ 247,202	$ 178,221
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 6,769	$ 5,563
Accrued liabilities	12,338	6,327
Bank term loan, current	200	
Total current liabilities	19,307	11,890
Long-term liabilities:		
Deferred revenue	10,000	10,000
Bank term loan, non-current	1,748	1,936
Deferred tax liability	816	816
Other long-term liabilities	575	
Total liabilities	32,446	24,642
Commitments and contingencies (Note 7)		
Stockholders equity:		
Preferred stock		
Common stock	30	25
Additional paid-in capital	344,645	236,414
Accumulated other comprehensive loss	(22)	(211)
Accumulated deficit	(129,897)	(82,649)
Total stockholders equity	214,756	153,579
Total liabilities and stockholders equity	$ 247,202	$ 178,221

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

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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,	
	2015	2014	2015	2014
Collaboration revenue from a related party	$ 7,300	$	$ 7,300	$
Operating expenses:				
Research and development	18,890	6,028	42,473	19,676
General and administrative	4,684	1,688	12,678	5,240
Total operating expenses	23,574	7,716	55,151	24,916
Loss from operations	(16,274)	(7,716)	(47,851)	(24,916)
Interest and other income (expense), net	259	(84)	718	(118)
Interest expense	(39)	(47)	(115)	(114)
Net loss	$ (16,054)	$ (7,847)	$ (47,248)	$ (25,148)
Net loss per share, basic and diluted	$ (0.58)	$ (8.66)	$ (1.84)	$ (27.93)
Weighted-average common shares used to compute net loss per share, basic and diluted	27,553,952	906,239	25,645,246	900,350

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

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DERMIRA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net loss	$ (16,054)	$ (7,847)	$ (47,248)	$ (25,148)
Other comprehensive loss:				
Unrealized gain on available-for-sale securities, net of tax	77		189	
Total comprehensive loss	$ (15,977)	$ (7,847)	$ (47,059)	$ (25,148)

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

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DERMIRA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2015	**2014**
Cash flows from operating activities		
Net loss	$ (47,248)	$ (25,148)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	55	47
Stock-based compensation	3,668	634
Amortization of premiums on available-for-sale securities	1,515	
Revaluation of convertible preferred stock warrant liability		78
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(628)	(225)
Other assets	794	(2,209)
Accounts payable	1,164	(44)
Accrued liabilities	5,998	1,782
Other long-term liabilities	575	
Net cash used in operating activities	(34,107)	(25,085)
Cash flows from investing activities		
Purchases of available-for-sale securities	(41,618)	
Maturities of available-for-sale securities	36,155	
Purchase of property and equipment	(80)	(47)
Net cash used in investing activities	(5,543)	(47)
Cash flows from financing activities		
Net proceeds from issuances of convertible preferred stock		53,826
Net proceeds from issuances of common stock	104,568	7
Net cash provided by financing activities	104,568	53,833
Net increase in cash and cash equivalents	64,918	28,701
Cash and cash equivalents at beginning of period	55,358	22,144
Cash and cash equivalents at end of period	$ 120,276	$ 50,845

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

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DERMIRA, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

1. Organization

Dermira, Inc. (the Company) was incorporated in the State of Delaware in August 2010 under the name Skintelligence, Inc. The Company changed its name to Dermira, Inc. in September 2011. In August 2011, the Company acquired Valocor Therapeutics, Inc., which was subsequently renamed Dermira (Canada), Inc. (Dermira Canada) and is the Company s wholly owned subsidiary. The Company is a specialty biopharmaceutical company focused on bringing innovative and differentiated products to dermatologists and their patients. The Company s portfolio of five product candidates targets significant market opportunities and includes three late-stage product candidates: Cimzia (certolizumab pegol), in Phase 3 development in collaboration with UCB Pharma S.A., a related party (UCB), for the treatment of moderate-to-severe plaque psoriasis; DRM04, in Phase 3 development for the treatment of axillary hyperhidrosis; and DRM01, in Phase 2b development for the treatment of acne. The Company is headquartered in Menlo Park, California.

On August 11, 2015, the Company closed an underwritten follow-on public offering (Follow-on Offering) of 5,175,000 shares of its common stock sold by the Company, including 675,000 shares sold upon full exercise of the underwriters option to purchase additional shares of common stock, at a price to the public of $21.50 per share. The gross proceeds to the Company from the Follow-on Offering were $111.3 million, and the net proceeds to the Company, after deducting underwriting discounts and commissions of $6.7 million and offering expenses of approximately $0.5 million, were approximately $104.1 million.

2. Summary of Significant Accounting Policies

Significant accounting policies followed in the preparation of these condensed consolidated financial statements are as follows:

Basis of Presentation

The condensed consolidated financial statements of the Company 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 the Company s annual consolidated financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair presentation of the Company s financial information. The results of operations for the three- and nine-month periods ended September 30, 2015 are not necessarily indicative of the results to be expected for the full year ending December 31, 2015 or any other future period. The consolidated balance sheet as of December 31, 2014 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 the Company and its 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 the Company s audited consolidated financial statements and the related notes thereto for the year ended December 31, 2014 included in its Annual Report on Form 10-K, filed March 25, 2015 with the SEC.

Reverse Stock Split

The Company effected a 5.8-to-1 reverse stock split of each share of the Company s outstanding capital stock on September 18, 2014, the date that the Certificate of Amendment to the Restated Certificate of Incorporation was filed with the Delaware Secretary of State. The reverse stock split did not result in an adjustment to par value. All references to shares of common stock outstanding, average number of shares outstanding and per share amounts in these condensed consolidated financial statements and related notes thereto reflect the reverse stock split.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management 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, management evaluates its estimates, including those related to revenue recognition, investments, accrued research and development expenses, goodwill, intangible assets, other long-lived assets, stock-based compensation and the valuation of deferred tax assets. The Company bases its estimates on its historical experience and also on assumptions that it believes are reasonable; however, actual results could significantly differ from those estimates.

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Risks and Uncertainties

The product candidates developed by the Company require approvals from the U.S. Food and Drug Administration (FDA) and foreign regulatory agencies prior to commercial sales in the United States or foreign jurisdictions, respectively. There can be no assurance that the Company s current and future product candidates will receive the necessary approvals. If the Company is denied approval or approval is delayed, it may have a material adverse impact on the Company s business and its financial condition.

The Company is subject to risks common to early-stage companies in the pharmaceutical industry, including dependence on the clinical and commercial success of its product candidates, ability to obtain regulatory approval of its product candidates, compliance with regulatory requirements, the need for substantial additional financing to achieve its goals, uncertainty of broad adoption of its approved products, if any, by physicians and patients, significant competition and ability to manage third party manufacturers, suppliers and contract research organizations (CROs).

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash and cash equivalents, investments and collaboration receivable from a related party. The Company invests its excess cash primarily in money market funds, repurchase agreements and corporate debt. Bank deposits are primarily held by a single financial institution and these deposits may exceed insured limits. The Company is exposed to credit risk in the event of a default by the financial institution holding its cash and cash equivalents and issuers of investments to the extent recorded on the condensed consolidated balance sheets. The Company s investment policy limits investments to money market funds, certain types of debt securities issued by the U.S. government and its agencies, repurchase agreements, commercial paper, municipal bonds and corporate debt, and places restrictions on the credit ratings, maturities and concentration by type and issuer.

Collaboration receivables are typically unsecured. Accordingly, we may be exposed to credit risk generally associated with our collaboration agreement. To date, we have not experienced any losses related to these receivables.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company primarily applies the market approach for recurring fair value measurements.

The Company measures certain financial assets and liabilities at fair value based on 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. The carrying amount of the Company s cash and cash equivalents, collaboration receivable from a related party, prepaid expenses, other assets, accounts payable and accrued liabilities approximate fair value due to their short maturities. Based on borrowing rates currently available to the Company for bank term loans with similar terms, the carrying value of the Company s bank term loan approximates its

fair value.

Revenue Recognition

Collaboration and license agreements may include non-refundable upfront payments or partial reimbursement of research and development costs, contingent consideration payments based on achievement of defined milestones, and royalties on sales of commercialized products. Performance obligations under collaboration agreements may include the transfer of intellectual property rights (e.g., licenses), obligations to provide research and development services, obligations to provide regulatory approval services and obligations to participate on certain development and/or commercialization committees with the collaborators. Upfront payments are generally recorded as deferred revenue in the consolidated balance sheet and recognized as collaboration revenue over the estimated period of performance that is consistent with the terms of the research and development obligations contained in the collaboration agreement. The Company regularly reviews the estimated periods of performance related to its collaborations based on the progress made under each arrangement. The estimated performance period may change over the course of the collaboration term. Such a change could have a material impact on the amount of revenue recorded in future periods. The Company generates revenue from its activities under the collaboration agreement with UCB, a related party, for the development and commercialization of one of its product candidates. All revenue recognized to date under the agreement with UCB is non-refundable and has been classified as collaboration revenue from a related party.

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Multiple Element Arrangements

The Company evaluates revenue from its agreement with UCB to determine whether the components of the arrangement represent separate units of accounting. Management considers whether components of an arrangement represent separate units of accounting based upon whether certain criteria are met, including whether the delivered element has stand-alone value to the customer. Factors considered include whether the deliverable is proprietary to the Company, 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 a separate unit of accounting. Deliverables that do not meet these criteria are combined and accounted for as a single unit of accounting. To date, the Company s agreement with UCB has two deliverables which represent two units of accounting, which are (1) the delivery of services related to the development of Cimzia for the treatment of moderate-to-severe plaque psoriasis and (2) the marketing services needed to commercialize Cimzia in the United States and Canada. At the date of execution of this arrangement, potential future payments eligible to be received upon the achievement of development and regulatory milestones were all considered to be substantive. As such, payments will be recognized in their entirety in the period in which the milestone event is achieved and collectability is reasonably assured. Royalties and sales-based milestone payments will be recognized as revenue when earned and realizable. Non-refundable fees for which the Company has no continuing performance obligations are recognized as revenue when collection is reasonably assured and all other revenue recognition criteria have been met.

Milestones and Other Contingent Payments

The Company has adopted the milestone method as described in Accounting Standards Codification (ASC) 605-28, *Milestone Method of Revenue Recognition*. Under the milestone method, contingent consideration received from the achievement of a substantive milestone will be 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 the Company s performance or a specific outcome resulting from the Company s performance; and (3) if achieved, the event would result in additional payments being due to the Company. Contingent payments which do not meet the definition of a milestone are recognized in the same manner as the consideration for the combined unit of accounting. If the Company has 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.

The Company s agreement with UCB provides for payments to be paid to the Company upon the achievement of development, regulatory and sales milestones. Given the challenges inherent in developing biologic products, there was substantial uncertainty as to whether any such milestones would be achieved at the time the agreement was executed. The Company evaluates whether the development and regulatory milestones meet all of the conditions to be considered substantive. The conditions include: (1) the consideration is commensurate with either of (a) the vendor s 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 the vendor s 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.

Offering Costs

Offering costs, consisting of legal, accounting, filing and other fees directly related to the Initial Public Offering (IPO) and the Follow-on Offering, were offset against proceeds from each offering. Offering costs incurred prior to the completion of the IPO were initially recorded in other assets and subsequently reclassified as additional paid-in capital upon completion of the IPO in October 2014.

Research and Development Expenses

The Company expenses research and development expenses as they are incurred. The Company s research and development expenses consist primarily of costs incurred for the development of its product candidates and include: (1) expenses incurred under agreements with CROs, investigative sites and consultants to conduct clinical trials and preclinical and non-clinical studies; (2) costs to acquire, develop and manufacture supplies for clinical trials and other studies, including fees paid to contract manufacturing organizations (CMOs); (3) salaries and related costs, including stock-based compensation and travel expenses, for personnel in research and development functions; (4) costs related to compliance with drug development regulatory requirements; (5) depreciation and other allocated facility-related and overhead expenses; and (6) licensing fees and milestone payments incurred under product license agreements.

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Accrued Research and Development Expenses

The Company records accruals for estimated costs of research, preclinical, non-clinical and clinical studies and manufacturing development, which are a significant component of research and development expenses. A substantial portion of the Company s ongoing research and development activities is conducted by third-party service providers, including CROs. The Company s 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 negotiation, 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 the Company under such contracts. The Company accrues the costs incurred under agreements with these third parties based on actual work completed in accordance with the respective agreements. In the event the Company makes advance payments, the payments are recorded as a prepaid expense and recognized as the services are performed. The Company determines 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.

In addition, the Company s CRO for the Cimzia Phase 3 program (the Cimzia CRO) can earn bonuses or incur penalties based on the Cimzia CRO s achievement of certain milestones specified in the agreement. If, in any period, it becomes probable that the Cimzia CRO would earn a bonus and the amount is estimable, the Company would accrue the full amount of such bonus in the period in which the bonus is earned. If the Cimzia CRO incurs a penalty, it has the right to recoup such penalty if it achieves a subsequent milestone. In this case, the Company would continue to maintain the full amount owed to the Cimzia CRO until the right of recoupment has expired.

The Company makes significant judgments and estimates in determining the accrual balance in each reporting period. As actual costs become known, the Company adjusts its accruals. Although the Company does not expect its estimates to be materially different from amounts actually incurred, the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in the Company reporting amounts that are too high or too low in any particular period. The Company s accrual is dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. To date, there have been no material differences between the Company s accrued estimated expenses and the actual clinical trial expenses. However, 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 the Company s estimates, resulting in adjustments to clinical trial expense in future periods. Changes in these estimates that result in material changes to the Company s accruals could materially affect its condensed consolidated financial condition and results of operations.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares 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.

A reconciliation of the numerator and denominator used in the calculation of basic and diluted net loss per share is as follows (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net loss per share:				
Numerator:				
Net loss	$ (16,054)	$ (7,847)	$ (47,248)	$ (25,148)
Denominator:				
Weighted-average shares of common stock outstanding used in the calculation of basic and diluted net loss per share	27,553,952	907,514	25,645,246	905,074
Less: Weighted-average shares subject to repurchase		(1,275)		(4,724)
Denominator for basic and diluted net loss per share	27,553,952	906,239	25,645,246	900,350
Net loss per share, basic and diluted	$ (0.58)	$ (8.66)	$ (1.84)	$ (27.93)

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The following outstanding dilutive potential shares of common stock were excluded from the computations of diluted net loss per share for the periods presented as the effect of including such securities would be antidilutive:

	Outstanding as of September 30,	
	2015	2014
Convertible preferred stock, as converted to common stock		15,430,706
Warrant to purchase convertible preferred stock, as converted to a common stock warrant		11,276
Options to purchase common stock, and estimated shares issuable under the employee stock purchase plan	3,829,291	2,249,871
	3,829,291	17,691,853

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-15, *Presentation of Financial Statements Going Concern* (*Subtopic 205-40): Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern*, which requires management to evaluate, in connection with preparing financial statements for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about an entity s ability to continue as a going concern within one year after the date that the financial statements are issued and provide related disclosures. This ASU will be effective for the Company in fiscal year 2016. Early adoption is permitted. The Company is currently assessing the future impact of this ASU on its unaudited condensed consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers*, which converges the FASB and the International Accounting Standards Board standards on revenue recognition. Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. This guidance was initially effective for the fiscal years and interim reporting periods beginning after December 15, 2016, however, in July 2015, the FASB deferred the effective date for annual reporting periods beginning after December 15, 2017 (including interim periods within those periods). Early adoption is permitted to the original effective date of December 15, 2016 (including interim periods within those periods). This ASU s effective date for the Company will be the first quarter of fiscal year 2018, using one of two retrospective application methods. The Company has not selected a transition retrospective application method and is currently assessing the future impact of this ASU on its unaudited condensed 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 management s 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.

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

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The following tables set forth the fair value of the Company s financial instruments that were measured at fair value on a recurring basis as of September 30, 2015 and December 31, 2014 (in thousands):

	As of September 30, 2015			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 29	$	$	$ 29
Repurchase agreements		119,800		119,800
Corporate debt		111,636		111,636
Other short-term interest-bearing securities		545		545
Total financial assets	$ 29	$ 231,981	$	$ 232,010

	As of December 31, 2014			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 10,088	$	$	$ 10,088
Repurchase agreements		70,000		70,000
Corporate debt		83,276		83,276
Total financial assets	$ 10,088	$ 153,276	$	$ 163,364

Where quoted prices are available in an active market, securities are classified as Level 1. The Company classifies money market funds as Level 1. When quoted market prices are not available for the specific security, then the Company estimates 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. The Company classifies repurchase agreements, corporate debt and other short-term interest-bearing securities as Level 2. In certain cases where there is limited activity or less transparency around inputs to valuation, securities are classified as Level 3.

There were no transfers between Level 1 and Level 2 during the periods presented.

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, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Financial assets:				

Money market funds	$ 29	$	$	$ 29
Repurchase agreements	119,800			119,800
Corporate debt	111,658	22	(44)	111,636
Other short-term interest bearing securities	545			545
Total investments	$ 232,032	$ 22	$ (44)	$ 232,010

	As of December 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Financial assets:				
Money market funds	$ 10,088	$	$	$ 10,088
Repurchase agreements	70,000			70,000
Corporate debt	83,487	2	(213)	83,276
Total investments	$ 163,575	$ 2	$ (213)	$ 163,364

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As of September 30, 2015 and December 31, 2014, the Company held $17.4 million and $66.5 million, respectively, of available-for-sale investment securities with contractual maturity dates of more than one year and less than two years. The Company did not hold any investment securities exceeding a two-year maturity. As of September 30, 2015 and December 31, 2014, there were no investments with gross unrealized losses that had been in a continuous loss position for 12 months or more. The Company believes that it is more likely than not that the investments will be held until maturity or a forecasted recovery of fair value. There were no realized gains or losses on the available-for-sale securities during the three and nine months ended September 30, 2015 and 2014, respectively.

5. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2015	December 31, 2014
Accrued outside research and development services	$ 8,681	$ 3,670
Accrued compensation	2,985	2,463
Accrued professional and consulting services	412	108
Other	260	86
	$ 12,338	$ 6,327

6. Loan Agreement

The Company is party to a loan and security agreement (the Loan Agreement) with Square 1 Bank (the Bank) that provides for two term loans available to the Company: (1) $2.0 million under the first term loan (Term Loan A); and (2) $5.5 million under the second term loan (Term Loan B). Borrowings under the term loans bear interest at the greater of: (1) 5.10% above the treasury rate in effect on the date that a term loan is funded; or (2) 5.50%, which rate will be fixed on the date of funding of the term loan. The Company may prepay borrowings without paying a penalty or premium.

In December 2013, the Company borrowed $2.0 million under Term Loan A. The amount borrowed under Term Loan A matures December 19, 2018 and is secured by all assets of the Company other than the Company s intellectual property, subject to certain limited exceptions, and bears interest at a rate of 5.77% per annum. The amount borrowed under Term Loan A is to be repaid over a period of 60 months as follows: (1) commencing on January 11, 2014, 30 monthly payments of interest only; and (2) commencing on June 19, 2016, 30 equal monthly payments of $66,666.67, plus interest. Upon final repayment of Term Loan A, the Company is required to pay the Bank a fee of $120,000. The Company is accruing this fee monthly over the loan term on a straight-line basis and is recording it as interest expense in the condensed consolidated statements of operations. The Company incurred interest expense in connection with Term Loan A totaling $39,000 and $47,000 for the three months ended September 30, 2015 and 2014, respectively, and $115,000 and $114,000 for the nine months ended September 30, 2015 and 2014, respectively.

There were no amounts borrowed under Term Loan B and the Company s ability to borrow funds under Term Loan B expired on September 30, 2015.

The Loan Agreement is subject to certain representations and warranties, certain affirmative and negative covenants, certain conditions and events of default that are customarily required for similar financings. The affirmative covenants include, among other things, that the Company delivers timely consolidated financial statements and reports to the Bank, timely files taxes, maintains certain operating accounts subject to control agreements in favor of the Bank, maintains liability and other insurance, maintains at least two active and ongoing drug development programs and pledges security interests in any ownership interest of a future subsidiary. The negative covenants preclude, among other things, disposing of certain assets, engaging in certain mergers or acquisitions, incurring additional indebtedness, encumbering any collateral, paying dividends or making prohibited investments, in each case, without the prior consent of the Bank. As of September 30, 2015 and December 31, 2014, the Company was in compliance with all of the covenants under the Loan Agreement.

7. Commitments and Contingencies

Facility Lease

The Company leases its corporate headquarters facility in Menlo Park, California under a non-cancelable operating lease agreement. The leased space is a facility totaling 18,651 square feet. The base rent is $97,918 per month during the first year of the lease and increases by three percent annually. Rent expenses include the base rent plus additional fees to cover the Company s share of certain facility expenses, including utilities, property taxes, insurance and maintenance. The estimated amount of these additional fees is $22,381 per month during the first year of the lease. The term of the lease is five years, which commenced in December 2014 and will terminate in November 2019, with an option to renew for an additional three-year term.

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In addition, the Company is required to issue the lessor of the building either a security deposit or a letter of credit of $500,000 that may be used by or drawn upon by the lessor in the event of default of certain terms under the lease agreement. If there is no event of default under the agreement after the 30th month of the lease term, the letter of credit may be reduced to $250,000. The Company provided a letter of credit to the lessor in the amount of $500,000, which is collateralized by a money market account. The collateralized money market account is restricted cash and recorded in the Company s condensed consolidated balance sheet in other assets.

Prior to moving to its headquarters in Menlo Park, California in December 2014, the Company leased its corporate headquarters in Redwood City, California. All lease agreements associated with the Redwood City, California building expired in November 2014.

Rent expense for the three months ended September 30, 2015 and 2014 was $0.4 million and $0.2 million, respectively, and for the nine months ended September 30, 2015 and 2014 was $1.1 million and $0.4 million, respectively. The terms of the facility leases provide for rental payments on a monthly basis on a graduated scale. The Company recognizes rent expense on a straight-line basis over the lease period and has accrued for rent expense incurred but not paid.

CRO Agreement

Per the terms of the Company s agreement with its CRO for the Cimzia Phase 3 program, the Cimzia CRO can earn bonus payments or incur penalties (which are adjusted from the total amount payable pursuant to the agreement) based on the achievement of milestones specified in the agreement. The Cimzia CRO can earn a maximum aggregate bonus of $3.6 million and incur a maximum aggregate penalty of $3.2 million. If, in any period, it becomes probable that the Cimzia CRO would earn a bonus and the amount is estimable, the Company would recognize the full amount of such bonus in that same period as an expense, even if the bonus would not be earned by and paid to the Cimzia CRO until the milestone is achieved. If the Cimzia CRO incurs a penalty, it has the right to recoup the applicable amount if it achieves a subsequent milestone, and the Cimzia CRO would adjust subsequent billings as necessary to reflect such penalty and any recouped amount. If the Cimzia CRO incurs a penalty prior to the expiration of the right of recoupment, the Company would maintain the full amount owed to the Cimzia CRO in either accrued liabilities or other long-term liabilities, as appropriate, in its condensed consolidated balance sheet until (1) the right of recoupment has expired, at which time the Company would reflect the amount as a reduction in operating expenses and eliminate the liability, or (2) the Cimzia CRO has recouped the penalty, at which time the Company would increase the payment to the Cimzia CRO by the recouped amount and eliminate the liability. As of September 30, 2015, the Company has not recognized an increase in expense for a bonus earned, or a decrease in expense for a penalty incurred, under the agreement in its condensed consolidated statements of operations.

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company would accrue a liability for such matters when it is probable that future expenditures would be made and such expenditures could be reasonably estimated. The Company is not subject to any current pending legal matters or claims.

Indemnification

The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to these arrangements, the Company indemnifies, holds harmless and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual after the execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these agreements is not determinable because it involves claims that may be made against the Company in the future, but have not yet been made. The Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

The Company has entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct of the individual.

No amounts associated with such indemnifications have been recorded to date.

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8. Technology and Financing Agreements

Maruho Agreement

In March 2013, the Company entered into a Right of First Negotiation Agreement with Maruho Co., Ltd. Under the terms of the agreement, the Company provided Maruho with certain information and the right to negotiate an exclusive license to develop and commercialize certain of the Company s product candidates in specified territories. In connection with the entry into this agreement, Maruho paid the Company a non-refundable upfront payment of $10.0 million, which will be credited against certain payments payable by Maruho to the Company if the two parties enter into an exclusive license for any of the Company s products. If the parties do not enter into such an arrangement, the Company will be entitled to keep the funds without further obligation. As of September 30, 2015 and December 31, 2014, the Company recorded the $10.0 million as deferred revenue on its condensed consolidated balance sheets. The revenue will 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.

Rose U Agreement

In April 2013, the Company entered into an exclusive license agreement with Rose U, LLC to license certain patents, patent applications and know-how related to our DRM04 program. This agreement includes a sublicense and assignment of certain know-how licensed and assigned to Rose U by Stiefel Laboratories, Inc., a GSK Company, or Stiefel, the prior licensee of such patents. In connection with this agreement, the Company also entered into a letter agreement with Stiefel. As of September 30, 2015, the Company has paid license and other fees of $0.5 million to Rose U and is required to pay additional amounts totaling up to $4.4 million upon the achievement of specified development, commercialization and other milestones under these agreements to Rose U and Stiefel. In addition, the Company is also obligated to pay Rose U low-to-mid single-digit royalties on net product sales and low double-digit royalties on sublicense fees and certain milestone, royalty and other contingent payments received from sublicensees, to the extent such amounts are in excess of the milestone and royalty payments the Company is obligated to pay Rose U directly upon the events or sales triggering such payments.

UCB (a Related Party) Agreement

In March 2014, the Company entered into a development and commercialization agreement with UCB, a related party (the UCB agreement), which provides that the Company will develop Cimzia for the treatment of psoriasis in order for UCB to seek regulatory approval from the FDA, European Medicines Agency (EMA) and the Canadian federal department for health (Health Canada), and upon the grant of regulatory approval in the United States and Canada, for the Company to promote sales of Cimzia to dermatologists and conduct related medical affairs activities in the United States and Canada. Unless earlier terminated, the term of the UCB agreement is 12.5 years following the first commercial launch following regulatory approval of Cimzia for the treatment of psoriasis in the United States or Canada.

The Company has agreed with UCB on a development plan to obtain regulatory approval from the FDA, the EMA and Health Canada, which may be amended as necessary to meet the requirements of these regulatory authorities for approval. The Company is responsible for development costs under the development plan up to a specified cap greater than $75.0 million and less than $95.0 million, plus its internal development costs. Any development costs in excess of this cap or for any required clinical trials in pediatric patients will be shared equally.

Development costs for any EMA-specific post-approval studies will be borne solely by UCB. Development costs under the development plan include the costs of clinical trial materials, which are supplied by UCB and paid by the Company. The Company incurred expenses related to clinical materials supplied by UCB totaling $0.9 million and $0 for the three months ended September 30, 2015 and 2014, respectively, and $1.1 million and $0 for the nine months ended September 30, 2015 and 2014, respectively.

UCB is obligated to pay the Company up to an aggregate of $36.0 million if certain development milestones are met, and up to an additional aggregate of $13.5 million upon the grant of regulatory approval, including pricing and reimbursement approval, in certain European countries. In December 2014, the Company earned the first development milestone of $7.3 million for dosing of the first patient in the Phase 3 clinical program for Cimzia and recorded the amount as collaboration revenue from a related party in the consolidated statements of operations for the year ended December 31, 2014. In September 2015, the Company earned the second development milestone of $7.3 million for the completion of patient enrollment in a Phase 3 clinical trial for Cimzia and recorded the amount as collaboration revenue from a related party in the consolidated statements of operations for the three months ended September 30, 2015. As a result of achieving these milestones, there is $21.4 million in remaining development milestone payments that the Company is eligible to receive. No collaboration revenue was recognized for the three or nine months ended September 30, 2014.

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Under the terms of the UCB agreement, the Company will have the exclusive rights upon regulatory approval of the psoriasis indication to promote Cimzia to dermatologists in the United States and Canada. Following such regulatory approval, UCB will book sales and is obligated to pay the Company royalties representing a percentage of the annual gross profits (after subtracting the costs of certain commercialization support services to be provided by UCB) from Cimzia sales attributed to dermatologists in all indications in the United States and Canada. In each year, the royalties payable to the Company are tiered based upon increasing levels of annual net sales attributed to dermatologists in such year, with UCB retaining between 10% and, above $150.0 million of such annual net sales in such year, 50%, and the Company receiving the balance, of such annual gross profits. In addition, UCB is obligated to pay the Company up to an aggregate of $40.0 million upon the achievement of tiered milestones based on annual net sales of Cimzia attributed to dermatologists in the United States and Canada.

As of September 30, 2015, UCB beneficially owned 1,841,234 shares of the Company s outstanding common stock. One of the members of the Company s Board of Directors is an Executive Vice President and the Chief Operating Officer of UCB S.A.

9. Stock-Based Compensation

In 2010, the Company adopted the 2010 Equity Incentive Plan (the 2010 Plan), which provided for the granting of stock options to employees, directors and consultants of the Company. In September 2014, the Company s Board of Directors approved the 2014 Equity Incentive Plan (the 2014 EIP), which became effective on October 1, 2014, the day prior to the effective date of the Company s registration statement on Form S-1 (Form S-1). 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, the Company s Board of Directors approved the 2014 Employee Stock Purchase Plan (the 2014 ESPP), which became effective on October 2, 2014, the day of the effective date of the Form S-1.

The following table reflects a summary of stock option activity and related information for the period from December 31, 2014 through September 30, 2015:

	Shares Available for Grant	Shares Subject to Outstanding Options	Weighted-Average Exercise Price Per Share
Options outstanding at December 31, 2014	941,339	3,401,395	$ 6.88
Additional shares reserved under plan	738,860		
Options granted	(429,425)	429,425	20.34
Options exercised		(87,215)	1.62
Options forfeited	24,777	(24,777)	10.54
Options outstanding at September 30, 2015	1,275,551	3,718,828	8.53

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Total stock-based compensation expense related to the 2014 ESPP and options granted to employees and nonemployees was allocated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Research and development	$ 541	$ 210	$ 1,401	$ 436
General and administrative	920	114	2,267	198
Total stock-based compensation expense	$ 1,461	$ 324	$ 3,668	$ 634

There were no capitalized stock-based compensation costs or recognized stock-based compensation tax benefits during the three and nine months ended September 30, 2015 and 2014.

10. Subsequent Events

On November 2, 2015, the Company filed a shelf registration statement on Form S-3 for the potential offering, issuance and sale by the Company of up to $300 million of common stock, preferred stock, debt securities, warrants to purchase common stock, preferred stock and debt securities, subscription rights to purchase common stock, preferred stock and debt securities, and units consistenting of all or some of these securities. The shelf registration statement has not been declared effective by the SEC. Up to $75 million of the maximum aggregate offering price of $300 million under the registration statement, if declared effective by the SEC, may be issued and sold pursuant to an at-the-market offering for sales of the Company s common stock pursuant to a sales agreement between the Company and Cowen and Company, LLC.

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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, 2014, included as part of our Annual Report on Form 10-K for the year ended December 31, 2014, and our unaudited Condensed Consolidated Financial Statements for the three- and nine-month periods ended September 30, 2015 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, or the Exchange Act. These statements are often identified by the use of words such as may, will, expect, believe, anticipate, intend, could, should, potential, 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 report, 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. 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 specialty biopharmaceutical company focused on bringing innovative and differentiated products to dermatologists and their patients. Our management team has extensive experience in product development and commercialization, having served in leadership roles at several leading dermatology companies. Our strategy is to leverage this experience to in-license, acquire, develop and commercialize products that we believe can be successful in the dermatology marketplace.

Since our founding in 2010, we have executed three transactions resulting in a portfolio of five product candidates. In August 2011, we acquired Valocor Therapeutics, Inc., which gave us rights to a portfolio of intellectual property and product candidates to treat acne and inflammatory skin diseases. In April 2013, we entered into agreements with Rose U LLC and Stiefel Laboratories, Inc., a GSK Company, to obtain rights to intellectual property related to DRM04 for the treatment of hyperhidrosis. In March 2014, we entered into an agreement to collaborate with UCB Pharma S.A., a related party, or UCB, to develop and commercialize Cimzia (certolizumab pegol) in dermatology. Our portfolio of five product candidates targets significant market opportunities and includes three late-stage product candidates.

Our three late-stage product candidates are:

- Cimzia, an injectable biologic tumor necrosis factor-alpha inhibitor, or TNF inhibitor, that is currently approved and marketed by UCB for the treatment of numerous inflammatory diseases spanning multiple medical specialties in multiple countries, including the United States. In March 2014, we entered into a development and

commercialization agreement with UCB to develop Cimzia for the treatment of moderate-to-severe plaque psoriasis in the United States, Canada and the European Union and, upon regulatory approval, to market Cimzia to dermatologists in the United States and Canada. We commenced a Phase 3 clinical program for Cimzia in moderate-to-severe plaque psoriasis in December 2014. We expect topline results from the Phase 3 clinical program in 2017.

- DRM04, a topical, small-molecule anticholinergic product we are developing for the treatment of hyperhidrosis, or excessive sweating. Based on the results of a Phase 2 program comprising three randomized, double-blind, vehicle-controlled clinical trials in 341 patients and our end-of-Phase 2 meeting with the U.S. Food and Drug Administration, or FDA, in April 2015, we commenced a Phase 3 clinical program in patients with primary axillary, or underarm, hyperhidrosis in July 2015. We expect topline results from the Phase 3 clinical program in the second half of 2016.

- DRM01, a novel, topical, small-molecule sebum inhibitor we are developing for the treatment of acne. Based on the results of a 108-patient, randomized, multi-center, double-blind, vehicle-controlled Phase 2a clinical trial, we commenced a Phase 2b clinical study in April 2015. We expect topline results from the Phase 2b clinical program in the first half of 2016.

In addition, we have two early-stage product candidates in preclinical development:

- DRM02, a novel, topical, small-molecule inhibitor of phosphodiesterase 4, for the treatment of inflammatory skin diseases; and

- DRM05, a novel, topical photodynamic therapy, for the treatment of acne.

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Key Developments

Following is a summary of selected key developments affecting our business that have occurred since December 31, 2014.

- *Completed patient enrollment for first Cimzia Phase 3 clinical trial in psoriasis program.* In September 2015, we completed patient enrollment for the global CIMPASI-2 clinical trial of Cimzia, one of three Phase 3 clinical trials comprising the Cimzia Phase 3 program. Completion of patient enrollment for this Phase 3 study triggered a milestone payment of $7.3 million payable to us by UCB.

- *Presented Phase 2a clinical results for DRM01 in patients with acne*. In October 2015, June 2015 and March 2015, data were presented from our 108-patient, randomized, multi-center, double-blind, vehicle-controlled Phase 2a clinical trial, demonstrating statistical significance for DRM01 vs. vehicle in the study s primary efficacy endpoints.

- *Closed follow-on public offering of common stock.* In August 2015, we closed an underwritten follow-on public offering, or Follow-on Offering, of 5,175,000 shares of our common stock sold by us, including 675,000 shares sold upon full exercise of the underwriters option to purchase additional shares of common stock, at a price to the public of $21.50 per share. The gross proceeds to us from the Follow-on Offering were $111.3 million, and the net proceeds to us after deducting underwriting discounts and commissions of $6.7 million and offering expenses of approximately $0.5 million were approximately $104.1 million.

- *Initiated Phase 3 program for DRM04 in patients with axillary hyperhidrosis.* In July 2015, we dosed the first patients in a Phase 3 program for DRM04 in patients with axillary hyperhidrosis. The DRM04 Phase 3 program consists of two identical, randomized, double-blind, vehicle-controlled studies, ATMOS-1 and ATMOS-2, each enrolling approximately 330 patients. The program is designed to assess the safety and efficacy of DRM04 compared to vehicle to support a potential New Drug Application (NDA) submission to the FDA. The Phase 3 program also will include an open-label study, ARIDO, assessing the long-term safety of DRM04.

- *Initiated Phase 2b program for DRM01 in patients with acne*. In April 2015, we announced the dosing of the first patient in a Phase 2b dose-ranging trial, totaling 400 patients, for DRM01 in patients with facial acne vulgaris. The randomized, multi-center, double-blind, parallel-group, vehicle-controlled study is designed to assess the safety and efficacy of DRM01 compared to vehicle. The goal of the study is to establish the optimal dose for a potential Phase 3 program.

- *Achieved positive Phase 2b results for DRM04 in hyperhidrosis and completed end-of-Phase 2 meeting*. In February 2015, we announced positive Phase 2b study results for DRM04 in patients with axillary hyperhidrosis.

- *Initiated Phase 3 program for Cimzia, with UCB, in psoriasis*. In January 2015, we and UCB announced that the first patients had been dosed in the Phase 3 clinical program designed to evaluate the efficacy and safety of Cimzia in adult patients with moderate-to-severe chronic plaque psoriasis. The Cimzia Phase 3 clinical program consists of three studies that aim to enroll a total of approximately 1,000 patients. Two studies, CIMPASI-1 and CIMPASI-2, are expected to enroll approximately 225 patients each, and the third study, CIMPACT, is expected to enroll approximately 540 patients.

Financial Highlights

For the three months ended September 30, 2015, net loss increased to $16.1 million from $7.8 million for the three months ended September 30, 2014. We recognized collaboration revenue from UCB, a related party, of $7.3 million for the three months ended September 30, 2015 for the achievement of a substantive milestone pursuant to our agreement with UCB. No revenue was recognized for the three months ended September 30, 2014. Research and development expenses increased 213% to $18.9 million for the three months ended September 30, 2015 compared to the same period in 2014 due primarily to the advancement of our three-late stage product candidates. General and administrative expenses increased 177% to $4.7 million for the three months ended September 30, 2015 compared to the same period in 2014, driven by headcount growth and incentive compensation expenses, as well as costs associated with our public company status following our initial public offering, or IPO, in October 2014.

For the nine months ended September 30, 2015, net loss increased to $47.2 million from $25.1 million for the nine months ended September 30, 2014. We recognized collaboration revenue from UCB, a related party, of $7.3 million for the nine months ended September 30, 2015 for the achievement of a substantive milestone pursuant to our agreement with UCB. No revenue was recognized for the nine months ended September 30, 2014. Research and development expenses increased 116% to $42.5 million for the nine months ended September 30, 2015 compared to the same period in 2014 due primarily to the advancement of our product candidates. General and administrative expenses increased 142% to $12.7 million for the nine months ended September 30, 2015 compared to the same period in 2014, driven by headcount growth and incentive compensation expenses, as well as costs associated with our public company status following our IPO in October 2014.

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As of September 30, 2015, we had cash and cash equivalents and investments of $232.5 million and debt of $1.9 million.

Since our inception, we have devoted substantially all of our efforts to developing our product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. We have financed our operations primarily through the sale of equity securities and convertible debt securities, including the sale of common stock in our IPO and Follow-on Offering. 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 Co., Ltd., 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 collaborative agreements with third parties.

We have never been profitable and may never be profitable. As of September 30, 2015, we had an accumulated deficit of $129.9 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 licensing 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.

Results of Operations

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2015	2014	$	%	2015	2014	$	%
	(in thousands, except percentages)							
Collaboration revenue from a related party	$ 7,300	$	$ 7,300	*	$ 7,300	$	$ 7,300	*
Operating expenses:								
Research and development	18,890	6,028	12,862	213%	42,473	19,676	22,797	116%
General and administrative	4,684	1,688	2,996	177	12,678	5,240	7,438	142
Total operating expenses	23,574	7,716	15,858	206	55,151	24,916	30,235	121
Loss from operations	(16,274)	(7,716)	(8,558)	111	(47,851)	(24,916)	(22,935)	92
Interest and other income (expense), net	259	(84)	343	*	718	(118)	836	*
Interest expense	(39)	(47)	8	(17)	(115)	(114)	(1)	1
Net loss	$ (16,054)	$ (7,847)	$ (8,207)	105	$ (47,248)	$ (25,148)	$ (22,100)	88

* Percentage not meaningful

Revenue. Revenue consists of collaboration revenue for the achievement of development milestones pursuant to our development and commercialization agreement with UCB, a related party, or the UCB agreement. Under the UCB

agreement, we may generate revenue from development-, regulatory- and sales-based milestone payments and royalties. Under our Right of First Negotiation Agreement with Maruho Co., Ltd., or Maruho, if we enter into an exclusive license to develop and commercialize any of our product candidates with Maruho, we may generate license revenue. Other than the revenue we may generate in connection with these agreements, 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 collaborative agreements with third parties.

We recognized $7.3 million in collaboration revenue from a related party for the three and nine months ended September 30, 2015 for the achievement of a milestone, the completion of patient enrollment in the first Phase 3 clinical trial for Cimzia, pursuant to our agreement with UCB. We did not recognize any revenue for the three and nine months ended September 30, 2014.

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 costs to develop and manufacture clinical trial supplies, and internal expenses consisting primarily of employee compensation costs. We track external research and

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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 expenses to operations as they are incurred.

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

	Phase of Development as of September 30, 2015	Three Months Ended September 30, 2015	2014	$ Change	Nine Months Ended September 30, 2015	2014	$ Change
				(in thousands)			
External costs incurred by product candidate:							
Cimzia (1)	Phase 3	$ 7,775	$ 697	$ 7,078	$ 16,845	$ 782	$ 16,063
DRM04 (2)	Phase 3	4,672	2,226	2,446	9,093	8,042	1,051
DRM01 (3)	Phase 2b	2,492	733	1,759	6,149	2,499	3,650
Other research and development expenses (4)		19	352	(333)	78	2,956	(2,878)
Internal costs		3,932	2,020	1,912	10,308	5,397	4,911
Total research and development expenses		$ 18,890	$ 6,028	$ 12,862	$ 42,473	$ 19,676	$ 22,797

(1) We acquired the rights to develop Cimzia for the treatment of moderate-to-severe psoriasis under our collaboration with UCB in March 2014.

(2) In July 2015, we commenced a Phase 3 clinical program for DRM04.

(3) In April 2015, we commenced a Phase 2b clinical program for DRM01.

(4) Amount consists of costs for early-stage product candidates, specifically DRM02 and DRM05.

Research and development expenses increased $12.9 million, or 213%, for the three months ended September 30, 2015 compared to the three months ended September 30, 2014. This increase was primarily due to a $11.3 million increase in external costs to advance our Cimzia, DRM04, and DRM01 product candidates and a $1.9 million increase in internal costs related primarily to headcount growth and incentive compensation expenses. These increases in research and development expenses were partially offset by a $0.3 million decrease in external costs associated with our early-stage product candidates.

Research and development expenses increased $22.8 million, or 116%, for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014. This increase was primarily due to a $20.8 million increase in external costs to advance our Cimzia, DRM04, and DRM01 product candidates and a $4.9 million increase in internal costs related primarily to headcount growth and incentive compensation expenses. These increases in research and development expenses were partially offset by a $2.9 million decrease in external costs associated with our early-stage product candidates.

We expect our future research and development efforts will be focused on our late-stage clinical programs, Cimzia, DRM04 and DRM01. For Cimzia, we and UCB commenced our Phase 3 clinical program in December 2014 and we expect to continue to enroll patients in this program throughout 2015. With respect to DRM01, we commenced a Phase 2b dose-ranging trial in April 2015 and expect this trial to continue to enroll patients throughout 2015. For DRM04, we commenced a Phase 3 clinical program in July 2015 and we expect to enroll patients in this program throughout 2015. In addition, we expect to continue to evaluate our early-stage product candidates, DRM02 and DRM05, to determine which, if any, we would advance into later stages of development.

As a result, we expect our research and development expenses to increase substantially in the future as we continue development of our product candidates. The timing and amount of expenses incurred will depend largely upon the outcomes of current or future clinical studies for our product candidates as well as the related regulatory requirements, manufacturing costs and any costs associated with the advancement of our early-stage product candidates.

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

General and administrative expenses increased $3.0 million, or 177%, for the three months ended September 30, 2015 compared to the three months ended September 30, 2014. This increase was primarily due to a $1.5 million increase in personnel-related expenses related primarily to headcount growth and incentive compensation expenses, a $0.7 million increase in market research and planning expenses and a $0.5 million increase in costs associated with our public company status following our IPO in October 2014.

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General and administrative expenses increased $7.4 million, or 142%, for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014. This increase was primarily due to a $4.2 million increase in personnel-related expenses related primarily to headcount growth and incentive compensation expenses, a $1.9 million increase in costs associated with our public company status following our IPO in October 2014 and a $1.4 million increase in market research and planning expenses. These increases in general and administrative expenses were partially offset by $0.8 million of legal and consulting services incurred in the first nine months of 2014, but not in 2015, for the evaluation, due diligence and negotiations associated with the UCB collaboration transaction.

We expect our general and administrative expenses to increase substantially in the future as we expand our operating activities and prepare for potential commercialization of our product candidates, increase our headcount, and support our operations as a public company, including increased expenses related to legal, accounting, regulatory and tax-related services associated with maintaining compliance with exchange listing and U.S. Securities and Exchange Commission, or SEC, requirements, directors and officers liability insurance premiums and investor relations activities.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through the issuance and sale of equity securities and convertible debt securities. As of September 30, 2015, we had $232.5 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, repurchase agreements and corporate debt. 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, which consist principally of research and development expenditures. As of September 30, 2015, we had an accumulated deficit of $129.9 million. We expect to incur additional losses in the future as we conduct research and development and pre-commercialization activities, and potential commercialization and marketing activities, and to support the administrative and reporting requirements of a public company. Therefore, we will need to raise additional capital to fund 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. We also may be required to 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.

As of September 30, 2015, we believe that existing cash and cash equivalents and investments are sufficient to meet our anticipated cash requirements for at least the next 12 months.

Cash Flows

The following table shows a summary of our cash flows for the nine months ended September 30, 2015 and 2014 (in thousands):

	Nine Months Ended September 30,	
	2015	2014
Net cash (used in) provided by:		
Operating activities	$ (34,107)	$ (25,085)
Investing activities	(5,543)	(47)
Financing activities	104,568	53,833
Net increase in cash and cash equivalents	$ 64,918	$ 28,701

Operating Activities. Net cash used in operating activities was $34.1 million for the nine months ended September 30, 2015 and consisted primarily of our net loss of $47.2 million, partially offset by $5.2 million in non-cash charges and an $7.9 million decrease in net operating assets. Non-cash charges included $3.7 million of stock-based compensation expense and $1.5 million of amortization of premiums on available-for-sale securities. The decrease in net operating assets was driven primarily by a $6.0 million increase in accrued liabilities and a $1.2 million increase in accounts payable related primarily to higher clinical trial accruals. Net cash used in operating activities was $25.1 million for the nine months ended September 30, 2014 and consisted primarily of our net loss of $25.1 million and a $2.2 million increase in other assets as a result of IPO costs paid and restricted cash associated with our lease agreement entered into in July 2014, partially offset by a $1.8 million increase in accrued liabilities primarily due to higher research and development accruals and IPO costs.

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Investing Activities. Net cash used in investing activities for the nine months ended September 30, 2015 was $5.5 million which resulted primarily from purchases of investments of $41.6 million, partially offset by proceeds from maturities of investments of $36.2 million. Net cash used in investing activities for the nine months ended September 30, 2014 was $47,000 related to the purchase of property and equipment.

Financing Activities. Net cash provided by financing activities was $104.6 million for the nine months ended September 30, 2015 and consisted primarily of $104.1 million of net proceeds from the sale of our common stock by us in our Follow-on Offering in August 2015. Net cash provided by financing activities was $53.8 million for the nine months ended September 30, 2014 and consisted of $48.8 million of net proceeds from the sale of our Series C convertible preferred stock in August 2014 and net proceeds of $5.0 million from the sale of our Series B convertible preferred stock in April 2014.

Operating and Capital Expenditure Requirements

We have incurred losses since our 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 begin to commercialize any approved products. Additionally, as a public company, we will incur significant audit, legal and other expenses that we did not incur as a private company. We believe that existing cash and cash equivalents and investments on hand as of September 30, 2015 are sufficient to meet our anticipated cash requirements through 2017. However, 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 may not be able to obtain additional equity or debt financing on terms acceptable to us, if at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations, and financial condition.

Please see Risk Factors for additional risks associated with our substantial capital requirements.

Contractual Obligations and Other Commitments

There were no material changes in our commitments under contractual obligations, as disclosed in Management s Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2014, filed with the SEC on March 25, 2015.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate and foreign exchange sensitivities as follows:

Interest Rate Risk

As of September 30, 2015, we had cash and cash equivalents and investments of $232.5 million, which consisted primarily of money market funds, repurchase agreements and corporate debt. These interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant. Our outstanding debt obligation carries a fixed interest rate.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. We have not been exposed nor do we anticipate being exposed to material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our condensed consolidated financial statements.

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Foreign Exchange Risk

Our operations are primarily conducted in the United States using the U.S. dollar. However, we conduct operations in Canada, primarily to fund Dermira (Canada), Inc., our wholly owned subsidiary, and engage in contracts with third-party clinical and regulatory suppliers that are denominated in currencies other than U.S. dollars, whereby settlement of our obligations for these activities are denominated in the local currency. Transactions denominated in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction with the resulting assets and liabilities being translated into the U.S. dollar at exchange rates prevailing at the balance sheet date. The resulting foreign exchange impact, a $2,000 loss and a $15,000 loss for the three months ended September 30, 2015 and 2014, respectively, and a $5,000 loss and a $55,000 loss for the nine months ended September 30, 2015 and 2014, respectively, is included in interest and other income (expense), net in our condensed consolidated statements of operations. We do not use currency forward exchange contracts to offset the related effect on the underlying transactions denominated in a foreign currency.

A hypothetical 10% change in foreign exchange rates during any of the preceding periods presented would not have had a material impact on our condensed consolidated financial statements.

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. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. 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 in 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. Our significant accounting policies are more fully described in Note 2 of the accompanying unaudited condensed consolidated financial statements and in Note 2 to our audited consolidated financial statements contained in the Annual Report on Form 10-K filed with the SEC on March 25, 2015. During the nine months ended September 30, 2015, there were no material changes to our critical accounting policies.

ITEM 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2015. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls

and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its 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, 2015, 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 control over financial reporting during the quarter ended September 30, 2015 identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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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 various risks and uncertainties, including those described below, which could adversely affect 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.

Risks Related to Development, Regulatory Approval and Commercialization

Our business is dependent on the successful development, regulatory approval and commercialization of our product candidates, primarily Cimzia, which we are developing in collaboration with UCB Pharma S.A., DRM04 and DRM01.

Our portfolio of five product candidates includes three late-stage product candidates: Cimzia (certolizumab pegol), an injectable biologic tumor necrosis factor-alpha inhibitor, or TNF inhibitor, for the treatment of moderate-to-severe plaque psoriasis; DRM04, a topical treatment for hyperhidrosis, or excessive sweating; and DRM01, a topical sebum inhibitor for the treatment of acne. We are also developing DRM02, a topical treatment targeting phosphodiesterase-4 for inflammatory skin diseases, and DRM05, a topical photodynamic therapy for acne. 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. The successful development and commercialization of Cimzia is subject to a number of risks under our development and commercialization agreement with UCB, or the UCB agreement. For more information about these risks, see Risks Related to Our Collaboration with UCB. In the future, we may also become dependent on one or more of our early-stage product candidates or any future 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 U.S. Food and Drug Administration, or the FDA, or similar foreign regulatory agencies to conduct additional clinical trials 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 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, or cGMP;

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- 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, sale and distribution in such countries and territories, whether alone or in collaboration with others;

- acceptance by physicians 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 or commercial-stage products 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 assure you 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 specialty biopharmaceutical company with a limited operating history upon which you 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 $16.1 million and $7.8 million for the three months ended September 30, 2015 and 2014, respectively, and $47.2 million and $25.1 million for the nine months ended September 30, 2015 and 2014, respectively. As of September 30, 2015, we had an accumulated deficit of $129.9 million.

We have financed our operations primarily through the sale of equity securities and convertible debt securities, including shares of common stock sold in our initial public offering, or IPO, and underwritten follow-on public offering, or Follow-on Offering. Since our inception, most of our resources have been dedicated to the preclinical and clinical 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, 2015, we had capital resources consisting of cash and cash equivalents and investments of $232.5 million. We will continue to expend substantial cash resources for the foreseeable future for the clinical development 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 research and development, conducting preclinical studies and clinical trials, manufacturing and supply, as well as marketing and selling any products approved for sale. In particular, our Phase 3 clinical programs for our product candidates will require substantial funds to complete. We plan to finance the development and commercialization of Cimzia in part through milestone payments made by UCB under the UCB agreement. 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.

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As of September 30, 2015, we believe that existing cash and cash equivalents and investments are sufficient to meet our anticipated cash requirements for at least the next 12 months. 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 our lead product candidates, Cimzia, DRM04 and DRM01, 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. We have substantial contractual obligations to UCB. In the event we are unable to raise sufficient capital to fund our development and commercialization obligations to UCB, we will face significant contractual liability.

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;

- 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. Our current loan and security agreement contains negative covenants that restrict our ability to obtain additional debt financing. 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.

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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 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.

The UCB agreement requires us to pay substantial development costs in order for UCB to seek approval of Cimzia for the treatment of moderate-to-severe plaque psoriasis from the FDA, the European Medicines Agency and the Canadian federal department for health. Our inability to fund our obligations under the UCB agreement would harm our business and operating results.

The UCB agreement requires us to pay all development costs in order for UCB to seek approval of Cimzia for the treatment of moderate-to-severe plaque psoriasis from the FDA, the European Medicines Agency, or the EMA, as established by Regulation (EC) 2309/93 and Regulation (EC) 726/2004, and the Canadian federal department for health, or Health Canada, up to a specified amount greater than $75.0 million and less than $95.0 million, with any development costs in excess of this amount to be shared equally by us and UCB. Delays in the commencement, enrollment and completion of clinical trials, including as a result of regulatory requirements, could substantially increase our product development costs. We do not know whether our planned clinical trials will begin on time or will be completed on budget or on schedule, or at all. While UCB is obligated to pay us if certain development and regulatory approval milestones are met, these milestone payments will not increase even if our development costs increase, so we would be required to bear a greater portion of any increased costs, which would adversely impact our financial position. The costs associated with product development can increase for a variety of reasons, including:

- the terms of agreements with prospective contract research organizations, or CROs, and trial sites, which can be subject to extensive negotiation and may vary significantly among different CROs, trial sites and other third-party contractors;

- identification and maintenance of a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs;

- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;

- inability to obtain institutional review board, or IRB, approval to conduct a clinical trial at prospective sites;

- increase in the time and expense required to conduct clinical trials due to difficulties in recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the treatment of psoriasis; and

- inability to retain patients in clinical trials due to the treatment protocol, length of treatment period, personal issues, side effects from the therapy or lack of efficacy, particularly for those patients receiving placebo.

In addition, a clinical trial may be suspended or terminated by us, UCB, the FDA, the EMA, Health Canada or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

- failed inspection of the clinical trial operations or trial sites by the FDA, the EMA, Health Canada or other regulatory authorities;

- unforeseen safety issues or any determination that a clinical trial presents unacceptable health risks;

- inability to fully enroll clinical trials; and

- lack of adequate funding to continue the clinical trial due to unforeseen costs resulting from enrollment delays, requirements to conduct additional trials and studies, increased expenses associated with the services of our CROs and other third parties or other reasons.

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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. Our product candidates are in various stages of development. We expect that clinical trials for these product candidates will continue for several years, but 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 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 psoriasis, or clinical trials for indications for which patients do not as commonly seek treatment, such as hyperhidrosis;

- 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.

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In the case of our topical product candidates, we are seeking to deliver sufficient concentrations of the active pharmaceutical ingredient, or 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 DRM04 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 short-term exposure of individuals to DRM04 than we currently anticipate collecting in our safety database. If we are required to expose additional individuals to DRM04 in order to establish a safety database sufficient for approval, approval of DRM04, 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. In particular, for Cimzia, if we experience delays in the completion of, or if we terminate, clinical trials, our ability to receive development-, regulatory- or sales-based milestone payments and royalties under the UCB agreement will be reduced, delayed or prevented.

We may be unable to obtain regulatory approval for Cimzia, DRM04, DRM01 or our early-stage 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 drug products 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 a new drug application, or NDA, or biologics license application, or 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 biologic product such as Cimzia or a new drug such as DRM04 or DRM01, 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 biologic and new drug products involves a long, expensive and uncertain process, and delay or failure can occur at any stage. 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 the Phase 2 clinical trial for Cimzia in moderate-to-severe plaque psoriasis, a six-point physical global assessment, or PGA, scale was used, and in our Phase 3 clinical trials, we are using a five-point PGA scale similar to the scale that was used to support the approval of Cosentyx. As a result, data from our Phase 2 clinical trial may not accurately predict Phase 3 results. For DRM04, the results of our Phase 2 clinical trials may not accurately predict results in our Phase 3 clinical trials, which will have larger numbers of patients and will use a different tool to measure our patient-reported outcomes than that used as the primary endpoint in our Phase 2 trials. In addition, for DRM04, the FDA commented that it believes that we may not have identified the optimal dose and concentration for use in our Phase 3 trials. If the FDA determines that we have not provided sufficient dose response information to select the dose to study in our Phase 3 trials, then approval of DRM04, if at all, could be delayed and our costs could increase. Even for a drug such as Cimzia that has been approved for multiple

indications, regulatory review processes are lengthy and uncertain.

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 or implementation 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;

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- 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 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 also 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 light source with DRM05; 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 Cimzia. 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. In our collaboration with UCB, we are required to pursue development in support of UCB seeking approval from each of the FDA, the EMA and Health Canada, although we have the right to abandon pursuit of regulatory approval in Canada. If UCB is unable to obtain and retain regulatory approval for the marketing of Cimzia for psoriasis, we could lose our ability to receive royalties and regulatory- and sales-based milestone payments, which would adversely affect our financial position and business.

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.

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UCB substantially controls the governance of our collaboration, and may make decisions regarding product development, regulatory strategy and commercialization that may not be in our best interests.

To oversee the parties activities in the collaboration, the UCB agreement provides for the establishment of a joint steering committee, joint development team, joint development committee, joint commercialization team and joint commercialization committee on which we each have representation, and while the parties have agreed to make committee decisions by consensus, UCB has final decision-making authority for the overall regulatory, development and commercialization strategy for Cimzia, market access activities, pricing and reimbursement activities, promotion, distribution, packaging, sales and safety and pharmacovigilance.

In exercising its final decision-making authority, UCB may make decisions regarding product development or regulatory strategy based on its determination of how to best preserve and extend regulatory approvals for Cimzia in indications other than psoriasis, which may delay or prevent achieving regulatory approval for Cimzia for the treatment of psoriasis.

If Cimzia does receive regulatory approval for the treatment of psoriasis in the United States or Canada, UCB could use its final decision-making authority to direct our market access, promotional or medical affairs activities to dermatologists in ways that would adversely impact sales attributable to dermatologists, including due to a concern that such activities could adversely impact sales of Cimzia attributable to physicians other than dermatologists, for which UCB is not required to pay us royalties or milestone payments. If such limitations resulted in reduced sales of Cimzia to dermatologists, the royalties and sales-based milestone payments we could receive under the UCB agreement would be adversely affected, negatively impacting our financial performance.

We have never completed a Phase 3 clinical trial, and may be unable to successfully do so for any of our product candidates.

The conduct of a Phase 3 clinical trial is a complicated process. Although our employees have conducted Phase 3 clinical trials in the past while employed at other companies, we as a company have not completed a Phase 3 clinical trial, and as a result may require more time and incur greater costs than we anticipate. For example, we commenced the Phase 3 clinical program for Cimzia in December 2014 and commenced the Phase 3 clinical program for DRM04 in July 2015. Failure to commence or complete, or delays in, our planned Phase 3 clinical trials would prevent us from or delay us in obtaining regulatory approval of and commercializing our product candidates and could prevent us from or delay us in receiving development- or regulatory-based milestone payments and commercializing Cimzia for the treatment of psoriasis and DRM04 for hyperhidrosis, which would adversely impact our 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;

- the effectiveness of our product as compared to other available 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;

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- 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, or 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 and patient 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.

According to Decision Resources, Enbrel, Humira and Stelara, injectable biologics for the treatment of moderate-to-severe plaque psoriasis, achieved aggregate worldwide sales of $5.1 billion in 2013 and we are uncertain whether this market, including off-label use of other injectable biologics for the treatment of psoriasis, has peaked or may still grow and whether we could displace any existing market share if Cimzia is approved for the treatment of moderate-to-severe plaque psoriasis. In particular, Cimzia s administration schedule may not be perceived as advantageous and its theoretical advantages may not lead to a perception of Cimzia being safer or comparably effective to Humira or Enbrel. Even if approved for moderate-to-severe plaque psoriasis, we may not be able to utilize directly comparative head-to-head data on the clinical performance of Cimzia relative to other TNF inhibitors or biologics in our marketing materials and may not be able to promote any theoretical advantages that are not in our approved product labeling.

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 health care 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 treatments, for a share of some patients discretionary budgets and for physicians attention within their clinical practices.

Many pharmaceutical companies currently offer products, and continue to develop additional alternative product candidates and technologies, for indications similar to those targeted by our product candidates, including AbbVie Inc., Allergan plc, Amgen Inc., Anacor Pharmaceuticals, Inc., Anterios, Inc., Astellas Pharma US, Inc., Bayer HealthCare AG (formerly Intendis, Inc.), Brickell Biotech, Inc., Celgene International, Eisai Co., Ltd., Galderma S.A., GlaxoSmithKline LLC, or GSK, Janssen Biotech, Inc., Johnson & Johnson, LEO Pharma A/S, Eli Lilly and Company, Maruho Co., Ltd., Merck & Co., Inc., Miramar Labs, Inc., Mitsubishi Tanabe Pharma Corporation, Mylan Inc., Novartis International AG, Pfizer Inc., Regeneron Pharmaceuticals, Inc., Revance Therapeutics, Inc., Takeda Pharmaceutical Company Limited, Teva Pharmaceutical Industries Ltd. 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, will present novel therapeutic approaches for the approved indications and will 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. Such competition 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.

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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 them. As a result, we expect to face more competition in these markets than in the United States.

Cimzia faces intense competition and most of our competitors have significantly greater resources than we do.

If approved for the treatment of psoriasis, Cimzia will face direct competition from numerous other injectable products such as Cosentyx, Enbrel, Humira, Remicade and Stelara, and the existence of these products may limit the market size for Cimzia. In addition, Cimzia will compete against oral systemic treatments for psoriasis, which include acitretin, apremilast, methotrexate and cyclosporine, and against a number of approved topical treatments for psoriasis, including branded drugs and generic versions where available. There are a number of other treatments used for psoriasis, including light-based treatments, topical corticosteroids and non-prescription topical treatments. Certain alternative treatments offered by competitors may be available at lower prices and may offer greater efficacy or better safety profiles.

Additional products and treatments, including numerous injectable biological products currently in clinical trials, may also receive regulatory approval in one or more territories in which we compete, and these existing and new products may be more effective, more widely used and less costly than ours, which may reduce the sales on which we receive royalties and sales-based milestone payments under the UCB agreement. Even if a generic product or an over-the-counter product is less effective than our product candidates, a less effective generic or over-the-counter product may be more quickly adopted by health insurers, physicians and patients than our competing product candidates based upon cost or convenience.

Cimzia may face competition from biosimilars, which may have an adverse impact on future sales.

Even if Cimzia for the treatment of psoriasis achieves regulatory approval, we may face competition from biosimilars. In the United States, the Biologics Price Competition and Innovation Act of 2009, or 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 new pathway could allow 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. In his proposed budget for fiscal year 2014, President Obama proposed to reduce this 12-year period of exclusivity to seven years and proposed to prohibit additional periods of exclusivity due to minor changes in product formulations, a practice often referred to as evergreening. It is possible that Congress may take these or other measures to reduce or eliminate periods of exclusivity. The BPCIA is complex and only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could have an adverse effect on the future commercial prospects for Cimzia. If competitors are able to obtain marketing approval for biosimilars referencing Cimzia or other branded biologic products against which Cimzia competes, Cimzia may become subject to competition from such biosimilars. Such competition could lead to off-label use of the biosimilar for psoriasis or reduced market share and contribute to downward pressure on pricing and reduced profit margins.

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We expect to face generic competition for our product candidates, 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 DRM04 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.

Use of subjective assessments of efficacy by patients, including patient-reported outcome assessments, or PROs, in our DRM04 clinical trials may delay the development of DRM04 or increase our development costs.

Due to the difficulty of objectively measuring the symptoms of hyperhidrosis, subjective assessments of efficacy by patients are expected to have an important role in the development and regulatory approval of our DRM04 product candidate. Subjective assessments, such as PROs, involve patients subjective assessments of efficacy, and this subjectivity increases the uncertainty of determining clinical endpoints. Such assessments can be influenced by factors outside of our control, and can vary widely from day to day for a particular patient, from patient to patient and from site to site within a clinical trial. Furthermore, in our Phase 2 clinical program, we have used an existing tool, the Hyperhidrosis Disease Severity Scale, or HDSS, which the FDA has determined is not a validated PRO, and a new PRO, the Axillary Sweating Daily Diary, or ASDD, which was validated in our Phase 2 clinical program to assess efficacy in a subjective manner. We are using the new ASDD PRO, along with an objective measure, sweat production, for the primary assessment of efficacy in our planned Phase 3 clinical program for DRM04. The FDA may not agree with our endpoints or that we have demonstrated that our objective endpoint of sweat production is a clinically meaningful endpoint, potentially making additional clinical trials necessary which would delay the development of DRM04 and increase our costs.

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.

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, registration, as well as continued compliance with cGMP requirements and with the FDA s good clinical practice, or GCP, requirements and good laboratory practice, or GLP, requirements, which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical and preclinical 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;

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- 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 regulation 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.

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 Canada and Europe. For example, in December 2014, we commenced our Phase 3 clinical program for Cimzia 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.

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 authorities. For example, if we obtain regulatory approval for Cimzia for the treatment of moderate-to-severe plaque psoriasis, we expect that regulatory authorities will require us to include the same box warning regarding increased risk of serious infections that may lead to hospitalization or death and a potential association with increased cancer risk in TNF inhibitors, of which Cimzia is one, that is currently included in labeling for Cimzia for the treatment of other indications. 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. In addition, the FDA recently created a Tracked Safety Issue, or TSI, for all TNF inhibitors, including Cimzia, based on a potential signal of psychiatric and nervous system disorders including: anxiety, hallucination, paranoia, psychotic disorder, cognitive impairment, depression, and suicide/suicidal ideation. This TSI may have in impact on our development program or the labeling for Cimzia. 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.

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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 products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, 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 assure you 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, health care 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;

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- 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.

We have obtained product liability insurance coverage for clinical trials. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects. 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, if Cimzia is approved for use in the United States for the treatment of moderate-to-severe plaque psoriasis, due to the design of our Phase 3 clinical trial comparing Cimzia to Enbrel, the prescribing information may not include data comparing the clinical performance of Cimzia and Enbrel and we may not be able to utilize directly comparative head-to-head data on the clinical performance of Cimzia to Enbrel in our marketing materials. Similarly, although our DRM04 product candidate, if approved, may appeal to individuals who have not been diagnosed with hyperhidrosis, we will only be able to promote DRM04 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 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 use, 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 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.

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We may choose not to continue developing or commercializing any of our product candidates other than Cimzia 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 other than Cimzia or not to continue commercializing one or more of our approved product candidates other than Cimzia for a variety of reasons, including the appearance of new technologies that make our product obsolete, competition from a competing product or changes in or failure to comply with applicable regulatory requirements. 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. We are, however, required to develop and commercialize Cimzia in accordance with our obligations to UCB regardless of our potential return on our investment with respect to Cimzia.

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 the manufacture, labeling, promotion, sale or distribution. Any recall, withdrawal or seizure in the future could materially and adversely affect consumer confidence in our brands 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 does not conclude that certain of our product candidates satisfy the requirements under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or Section 505(b)(2), or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We are currently developing one product candidate, DRM04, for which we intend to seek FDA approval through the Section 505(b)(2) regulatory pathway. DRM04 is a topical formulation of 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. Section 505(b)(2) 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 has not received a right of reference. Reliance on safety findings made by the FDA in approving the anticholinergic agent we intend to reference in our NDA could expedite the development program for our product candidates by potentially decreasing the amount of preclinical or clinical data that we would need to generate in order to obtain FDA approval. DRM04 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 DRM04 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) regulatory pathway as anticipated, or if the Section 505(b)(2) regulatory pathway fails to significantly decrease the amount of testing we must conduct, we may need to conduct additional preclinical or clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for DRM04, or any other product candidate for which we seek approval pursuant to the Section 505(b)(2) regulatory pathway in the future, and complications and risks associated with these product candidates, would likely substantially increase. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than our product candidates, which would likely harm our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will

receive the requisite approvals for commercialization.

In addition, 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 Section 505(b)(2). 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. 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) regulatory pathway, there is no guarantee this would ultimately lead to faster product development or earlier approval.

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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. In addition, certain currently approved therapies for the treatment of hyperhidrosis have received limited or no reimbursement coverage by insurers and, accordingly, coverage for DRM04, if approved, may not be available. 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, 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, or collectively, the 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 are expected 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.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals and imaging centers.

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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 ab