

Dermira, Inc.
Form 10-Q
November 12, 2014
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2014

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
(State or other jurisdiction of
incorporation or organization)

27-3267680
(I.R.S. Employer
Identification Number)

2055 Woodside Road

Redwood City, CA 94061

(Address of principal executive offices) (Zip Code)

(650) 421-7200

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically 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 No

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 <input type="radio"/>	Accelerated filer <input type="radio"/>
Non-accelerated filer <input checked="" type="checkbox"/> (do not check if a smaller reporting company)	Smaller reporting company <input type="radio"/>

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

As of November 1, 2014, the registrant had 24.6 million shares of common stock outstanding.

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Quarterly Report on Form 10-Q

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Table of Contents**PART I. FINANCIAL INFORMATION****ITEM 1. Financial Statements****DERMIRA, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS****(in thousands, except share and per share amounts)**

	September 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	\$ 50,845	\$ 22,144
Prepaid expenses and other current assets	569	344
Total current assets	51,414	22,488
Property and equipment, net	79	61
Intangible assets	3,520	3,520
Goodwill	771	771
Restricted cash	500	
Other assets	3,332	31
Total assets	\$ 59,616	\$ 26,871
Liabilities, convertible preferred stock and stockholders deficit		
Current liabilities:		
Accounts payable	\$ 3,165	\$ 2,322
Accrued liabilities	4,486	1,999
Convertible preferred stock warrant liability	139	61
Bank term loan, current portion		133
Total current liabilities	7,790	4,515
Long-term liabilities:		
Deferred revenue	10,000	10,000
Bank term loan, net of current portion	1,937	1,786
Deferred tax liability	785	785
Total liabilities	20,512	17,086
Commitments and contingencies		
Convertible preferred stock, \$0.001 par value per share; 40,874,365 shares authorized as of September 30, 2014; 15,430,706 shares issued and outstanding as of September 30, 2014; 10,107,111 shares authorized as of December 31, 2013; 9,540,158 shares issued and outstanding as of December 31, 2013	113,414	59,588
Stockholders deficit:		
Common stock: \$0.001 par value per share; 126,000,000 shares authorized as of September 30, 2014; 907,514 shares issued and outstanding as of September 30, 2014; 23,275,862 shares authorized as of December 31, 2013; 901,308 shares issued and outstanding as of December 31, 2013	1	1
Additional paid-in capital	1,611	970
Accumulated deficit	(75,922)	(50,774)
Total stockholders deficit	(74,310)	(49,803)

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Total liabilities, convertible preferred stock and stockholders' deficit	\$	59,616	\$	26,871
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The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents**DERMIRA, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS****(in thousands, except share and per share amounts)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Operating expenses:				
Research and development	\$ 6,028	\$ 3,619	\$ 19,676	\$ 12,397
General and administrative	1,688	1,009	5,240	3,214
Total operating expenses	7,716	4,628	24,916	15,611
Loss from operations	(7,716)	(4,628)	(24,916)	(15,611)
Interest and other income (expense), net	(84)	(37)	(118)	(25)
Interest expense	(47)		(114)	
Net loss and comprehensive loss	\$ (7,847)	\$ (4,665)	\$ (25,148)	\$ (15,636)
Net loss per share, basic and diluted	\$ (8.66)	\$ (5.57)	\$ (27.93)	\$ (19.40)
Weighted-average common shares used to compute net loss per share, basic and diluted	906,239	836,876	900,350	806,137

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

Table of Contents**DERMIRA, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(in thousands)

	Nine Months Ended September 30,	
	2014	2013
Cash flows from operating activities Net loss	\$ (25,148)	\$ (15,636)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	29	16
Stock-based compensation	634	205
Loss on disposal of property and equipment		1
Amortization of bank term loan issuance costs	18	
Revaluation of convertible preferred stock warrant liability	78	
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(225)	(317)
Other assets	(1,709)	124
Restricted cash	(500)	
Accounts payable	(44)	(460)
Accrued liabilities	1,782	(671)
Deferred revenue		10,000
Net cash used in operating activities	(25,085)	(6,738)
Cash flows from investing activities		
Purchase of property and equipment	(47)	(30)
Net cash used in investing activities	(47)	(30)
Cash flows from financing activities		
Net proceeds from issuance of convertible preferred stock	53,826	24,499
Proceeds from common stock option exercises	7	
Net cash provided by financing activities	53,833	24,499
Net increase in cash and cash equivalents	28,701	17,731
Cash and cash equivalents at beginning of period	22,144	7,872
Cash and cash equivalents at end of period	\$ 50,845	\$ 25,603

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

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 2010, 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 biopharmaceutical company focused on bringing medical dermatology products to dermatologists and their patients. The Company's portfolio of five product candidates includes three late-stage product candidates, Cimzia (certolizumab pegol), which the Company is developing in collaboration with UCB Pharma S.A. for the treatment of moderate-to-severe plaque psoriasis, DRM04, which the Company is developing for the treatment of hyperhidrosis, or excessive sweating, and DRM01, which the Company is developing for the treatment of acne. The Company also has two early-stage programs in preclinical development for the treatment of inflammatory skin diseases and acne. The Company's corporate headquarters are located in Redwood City, California, where it occupies facilities totaling approximately 14,700 square feet.

2. Summary of Significant Accounting Policies

Basis of Presentation

The condensed consolidated financial statements include the accounts of the Company and Dermira Canada and have been prepared in conformity with U.S. generally accepted accounting principles (U.S. GAAP) and applicable rules and regulations of the 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 nine-month period ended September 30, 2014 are not necessarily indicative of the results to be expected for the full year ending December 31, 2014 or any other future period. The balance sheet as of December 31, 2013 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. All significant intercompany transactions and balances have been eliminated during consolidation.

The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2013 included in the Company's Prospectus dated October 2, 2014 filed pursuant to Rule 424(b)(4) with the SEC on October 3, 2014 in connection with the Registration Statement on Form S-1 (No. 333-1984410).

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 notes to the condensed consolidated financial statements reflect the reverse stock split.

Use of Estimates

The preparation of 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 consolidated financial statements and reported amounts of expenses during the reporting periods. On an ongoing basis, management evaluates its estimates, including those related to accrued research and development expenses, goodwill, intangible assets, other long-lived assets, fair value of common stock, convertible preferred stock and related warrants, 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).

Cash and Cash Equivalents

The Company considers all highly liquid investment securities with remaining maturities at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include deposits, money market accounts, repurchase agreements and obligations of U.S. government agencies.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash and cash equivalents. The Company invests its excess cash in money market funds, repurchase agreements and obligations of U.S. government agencies. Bank deposits are held by a single financial institution with a strong credit rating and these deposits may at times be in excess of 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 balance sheets. The Company's investment policy limits investments to certain types of debt securities issued by the U.S. government and its agencies and places restrictions on maturities and concentration by type and issuer.

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.

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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, prepaid expenses, accounts payable and accrued liabilities approximate fair value due to their short maturities.

Impairment of Long-Lived Assets

The Company assesses changes in the performance of its product candidates in relation to its expectations, and industry, economic and regulatory conditions and makes assumptions regarding estimated future cash flows in evaluating the value of its property and equipment, goodwill and in-process research and development (IPR&D).

The Company periodically evaluates whether current facts or circumstances indicate that the carrying values of its long-lived assets to be held and used may not be recoverable. If such circumstances are determined to exist, an estimate of the undiscounted future cash flows of these assets is compared to the carrying value to determine whether impairment exists. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows approach.

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Goodwill represents the excess of the consideration transferred over the fair value of the net assets acquired in connection with the acquisition of Valocor. The Company tests goodwill for impairment on at least an annual basis, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the goodwill is less than its carrying amount. Some of the factors considered by the Company in its assessment include general macro-economic conditions, conditions specific to the industry and market, and the successful development of its product candidates. If the Company concludes it is more likely than not that the fair value of the goodwill is less than its carrying amount, a quantitative fair value test is performed.

IPR&D represents the fair value assigned to incomplete research projects that the Company acquired through the acquisition of Valocor which, at the time of acquisition, had not reached technological feasibility. The amount was capitalized and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the project. The Company tests IPR&D for impairment at least annually, or more frequently, if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the IPR&D intangible asset is less than its carrying amount. If the Company concludes it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value of the IPR&D intangible asset with its carrying value is performed.

Deferred Offering Costs

Deferred offering costs, consisting of legal, accounting, filing and other fees related to the Company's initial public offering (the IPO), are capitalized. The deferred offering costs will be offset against proceeds from the IPO for periods subsequent to the IPO. As of September 30, 2014, \$3.3 million of deferred offering costs were capitalized, which are included in other assets in the condensed consolidated balance sheet. No amounts were deferred as of December 31, 2013.

Research and Development Expenses

The Company expenses both internal and external research and development expenses to operations 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.

Accrued Research and Development Expenses

The Company records accruals for estimated costs of research, preclinical 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 negotiations, which vary from contract to contract and may result in payment flows that do not match the

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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 asset 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.

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 Company understands 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 from the Company's accrued estimated expenses to 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 financial condition and results of operations.

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Income Taxes

The Company uses the liability method to account for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial statement carrying amounts of existing assets and liabilities and their tax bases. Deferred tax assets and liabilities are measured using enacted tax rates applied to taxable income in the years in which those temporary differences are expected to be recovered or settled. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized. Financial statement effects of uncertain tax positions are recognized when it is more-likely-than-not, based on the technical merits of the position, that it will be sustained upon examination. Interest and penalties related to unrecognized tax benefits are included within the provision for income tax. The Company has not been subject to any interest and penalties through December 31, 2013.

Stock-Based Compensation

The Company maintains an equity incentive plan under which incentive stock options may be granted to employees and nonqualified stock options, restricted stock awards, restricted stock units and stock appreciation rights may be granted to employees, officers, directors, consultants and advisors.

For stock options granted to employees and directors, the Company recognizes compensation expense for all stock-based awards based on the grant-date estimated fair values, net of an estimated forfeiture rate. The value of the portion of the award that is ultimately expected to vest is recognized as expense ratably over the requisite service period. The fair value of stock options is determined using the Black-Scholes option-pricing model. The Company estimates its forfeiture rate based on an analysis of its actual forfeitures and the experience of other companies in the same industry, and will continue to evaluate the adequacy of the forfeiture rate assumption based on actual forfeitures, analysis of employee turnover, and other related factors.

Stock-based compensation expense related to stock options granted to nonemployees is recognized based on the fair value of the stock options, determined using the Black-Scholes option-pricing model, as they are earned. The awards vest over the time period during which the nonemployee provides services to the Company.

Convertible Preferred Stock Warrant Liability

The freestanding warrant for shares that are puttable is classified as a liability on the balance sheet and is carried at estimated fair value. At the end of each reporting period, changes in the estimated fair value during the period are recorded in interest and other income (expense), net, in the condensed consolidated statement of operations. The Company will continue to adjust the carrying value of the warrant until the earlier of the exercise of the warrant or the completion of a liquidation event, including the completion of an IPO, at which time the liability will be reclassified to additional paid-in capital in the condensed consolidated statement of stockholders' (deficit) equity.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. For the three and nine months ended September 30, 2014 and 2013, comprehensive loss was equal to net loss.

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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net loss per share:				
Numerator:				
Net loss	\$ (7,847)	\$ (4,665)	\$ (25,148)	\$ (15,636)
Denominator:				
Weighted-average shares of common stock outstanding used in the calculation of basic and diluted net loss per share	907,514	901,308	905,074	901,308
Less: Weighted-average shares subject to repurchase	(1,275)	(64,432)	(4,724)	(95,171)
Denominator for basic and diluted net loss per share	906,239	836,876	900,350	806,137
Net loss per share, basic and diluted	\$ (8.66)	\$ (5.57)	\$ (27.93)	\$ (19.40)

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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:

	As of September 30,	
	2014	2013
Convertible preferred stock, as converted to common stock	15,430,706	9,540,158
Warrant to purchase convertible preferred stock, as converted to a common stock warrant	11,276	
Options to purchase common stock	2,249,871	1,714,106
Common stock subject to repurchase		24,064
	17,691,853	11,278,328

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* (ASU 2014-15), which is an amendment to the accounting guidance related to the evaluation of an entity's ability to continue as a going concern. ASU 2014-15 establishes management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern in connection with preparing financial statements for each annual and interim reporting period. The update also gives guidance to determine whether to disclose information about relevant conditions and events when there is substantial doubt about an entity's ability to continue as a going concern. This guidance is effective for annual and interim reporting periods ending after December 15, 2016, with early adoption permitted. The Company will evaluate the guidance under ASU No. 2014-15 and present the required disclosures in its consolidated financial statements at the time of adoption.

In June 2014, the FASB issued Accounting Standards Update 2014-10, *Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation* (ASU 2014-10), which eliminates the definition of a development stage entity, eliminates the development stage presentation and disclosure requirements under Accounting Standards Codification (ASC) 915, *Development Stage Entities* (ASC 915), and amends provisions of existing variable interest entity guidance under ASC 810, *Consolidation*. As a result of the changes, entities which meet the former definition of a development stage entity will no longer be required to: (1) present inception-to-date information in the statements of income, cash flows, and shareholder equity; (2) label the financial statements as those of a development stage entity; (3) disclose a description of the development stage activities in which the entity is engaged; and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. Furthermore, ASU 2014-10 clarifies disclosures about risks and uncertainties under ASC Topic 275, *Risks and Uncertainties*, that apply to companies that have not commenced planned principal operations. Finally, variable interest entity rules no longer contain an exception for development stage entities and, as a result, development stage entities will have to be evaluated for consolidation in the same manner as non-development stage entities.

Under ASU 2014-10, entities are no longer required to apply the presentation and disclosure provisions of ASC 915 during annual periods beginning after December 15, 2014. In addition, the revisions to the consolidation standards are effective for annual periods beginning after December 15, 2015 for public entities and are effective for annual periods beginning after December 15, 2016 for nonpublic entities. Early adoption is permitted for any annual reporting period or interim period for which the entity's financial statements have not yet been issued (public business entities) or made available for issuance (other entities).

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The Company has adopted ASU 2014-10 effective as of its issuance date. Adoption of this standard had no impact on the Company's financial position, results of operations, or cash flows; however, the presentation of the consolidated financial statements has been changed to eliminate the disclosures that are no longer required.

In May 2014, the FASB issued Accounting Standards Update 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), 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 is effective for the fiscal years and interim reporting periods beginning after December 15, 2016. The Company is currently evaluating the impact that the adoption of ASU 2014-09 will have on its consolidated financial statements and related disclosures.

The Company has reviewed other recent accounting pronouncements and concluded they are either not applicable to the business or no material effect is expected on the consolidated financial statements as a result of future adoption.

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.

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

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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, 2014 and December 31, 2013 (in thousands):

	As of September 30, 2014			Total
	Level 1	Level 2	Level 3	
Financial assets:				
Repurchase agreements	\$ 46,000	\$	\$	\$ 46,000
U.S. government agencies		4,430		4,430
Total financial assets	\$ 46,000	\$ 4,430	\$	\$ 50,430
Financial liabilities:				
Preferred stock warrant liability	\$	\$	\$ 139	\$ 139

	As of December 31, 2013			Total
	Level 1	Level 2	Level 3	
Financial assets:				
Money market funds	\$ 19,441	\$	\$	\$ 19,441
Financial liabilities:				
Preferred stock warrant liability	\$	\$	\$ 61	\$ 61

Level 3 liabilities are entirely comprised of the convertible preferred stock warrant liability (see Note 10). The following table sets forth a summary of the changes in the estimated fair value of the Company's convertible preferred stock warrant, which were measured at fair value on a recurring basis (in thousands):

Balance as of December 31, 2013	\$ 61
Increase in fair value included in other income (expense), net	78
Balance as of September 30, 2014	\$ 139

Where quoted prices are available in an active market, securities are classified as Level 1. The Company classifies money market funds and repurchase agreements 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, broker/dealer quotes. The Company classifies obligations of U.S. government agencies as Level 2. In certain cases where there is limited activity or less transparency around inputs to valuation, securities are classified as Level 3. Level 3 liabilities that are measured at fair value on a recurring basis consist of convertible preferred stock warrant liability.

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

Table of Contents**4. Property and Equipment**

The following table is a summary of property and equipment (in thousands):

	September 30, 2014	December 31, 2013
Computer equipment	\$ 94	\$ 55
Office furniture	49	41
Total property and equipment	143	96
Less accumulated depreciation and amortization	(64)	(35)
Property and equipment, net	\$ 79	\$ 61

Property and equipment depreciation and amortization expense for the three months ended September 30, 2014 and 2013 was \$11,000 and \$6,000, respectively, and for the nine months ended September 30, 2014 and 2013 was \$29,000 and \$16,000, respectively.

5. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2014	December 31, 2013
Accrued compensation	\$ 1,668	\$ 949
Accrued outside research and development services	1,880	596
Accrued professional and consulting services	849	400
Other	89	54
	\$ 4,486	\$ 1,999

6. Intangible Assets***In-Process Research and Development***

In connection with the acquisition of Valocor in 2011, the Company acquired intangible assets that were associated with IPR&D projects relating to preclinical product candidates. The acquisition-date fair value of these intangible assets was \$3.5 million. As of all periods presented, these assets are considered to be indefinite-lived and will not be amortized, but will be tested for impairment on an annual basis, as well as between annual tests if changes in circumstances indicate a reduction in the fair value of the IPR&D projects below their respective carrying

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amounts. If and when development is complete, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives.

Goodwill

The Company recorded the goodwill resulting from the Valocor acquisition separately on its consolidated balance sheet as of the acquisition date. Goodwill is tested for impairment on an annual basis, as well as between annual tests if there are changes in circumstances that would indicate a reduction in the fair value of the goodwill below its carrying amount.

The net book value of intangible assets and goodwill as of September 30, 2014 and December 31, 2013 was as follows (in thousands):

	Net Book Value
Intangible assets IPR&D	\$ 3,520
Goodwill	771
Total intangible assets with indefinite lives	\$ 4,291

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7. Loan Agreement

In December 2013, the Company entered into a loan and security agreement (the "Loan Agreement") with Square 1 Bank (the "Bank") that provides for two term loans available to the Company of \$2.0 million and \$5.5 million, respectively. In September 2014, the Company entered into an amendment to the Loan Agreement to (1) extend the interest only end date and maturity date for the Company's outstanding term loan and potential borrowings under the second term loan, (2) extend the date through which the second term loan is available to the Company and (3) increase the fee the Company will pay the Bank upon the final repayment of the amounts borrowed under one of the term loans. 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.

On the closing date of the Loan Agreement, the Company borrowed \$2.0 million under the first term loan ("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 statement of operations.

The second term loan ("Term Loan B") of \$5.5 million is available to the Company any time between the date the Company achieves certain positive top-line Phase 2 clinical trial results and September 30, 2015. In August 2014, the Company's Board of Directors determined the Company achieved positive top-line Phase 2 clinical trial results from two of its Phase 2 programs, which satisfied the condition to the Company's ability to borrow funds under Term Loan B. As a result, the Company is now entitled to borrow funds under Term Loan B. Borrowings, if any, under Term Loan B would be repaid over a period of months as follows: (1) commencing on the 11th day following the date of Term Loan B, monthly payments of interest only to the earlier of (a) June 19, 2016 or (b) six months following the date of Term Loan B; and (2) commencing on the last day of the month immediately following the interest only end date, equal monthly payments of principal, plus interest, to the maturity date of December 19, 2018. Upon final repayment of Term Loan B, the Company would be required to pay the Bank a fee equal to 2.75% of the original principal amount borrowed under Term Loan B.

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 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, 2014 and December 31, 2013, the Company was in compliance with all of the covenants.

In connection with the Loan Agreement, the Company agreed to issue the Bank a warrant to purchase up to 17,805 shares of the Company's Series B convertible preferred stock, with an exercise price of \$8.4245 per share. The number of shares issuable pursuant to the warrant at any date is 8,902 shares plus 1% of the amount of borrowings under the Loan Agreement as of such date divided by 8.4245. Following the entry into the Loan Agreement and the concurrent funding of Term Loan A, and as of September 30, 2014 and December 31, 2013, the warrant was exercisable for 11,276 shares of Series B convertible preferred stock, consisting of the 8,902 initial shares related to the Loan Agreement and an additional 2,374 shares related to Term Loan A. The fair value of the warrant of approximately \$61,000 was recorded as a debt discount and amortized to interest expense using the straight-line method over the loan term. The Company recognized interest expense of \$5,000 and

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\$14,000 from the amortization of the warrant-related debt discount for the three and nine months ended September 30, 2014, respectively. The unamortized debt discount balance was \$47,000 and \$61,000 as of September 30, 2014 and December 31, 2013, respectively.

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As of September 30, 2014, future principal and interest payments under Term Loan A are as follows (in thousands):

<i>Year Ending December 31,</i>	
2014	\$ 29
2015	117
2016	519
2017	872
2018	945
Total payments	2,482
Less:	
Cash interest payments and balloon payment accretion	(482)
Unamortized bank fees and warrant value issued	(63)
Total representing principal payments	1,937
Less: current portion	
Long-term portion of bank term loan	\$ 1,937

The Company incurred interest expense in connection with Term Loan A totaling \$47,000 and \$114,000 during the three and nine months ended September 30, 2014, respectively. No interest expense was incurred for the same periods during 2013.

8. Commitments and Contingencies

Facility Lease

The Company leases its corporate headquarters facility in Redwood City, California under a noncancelable operating lease agreement. The lease agreement was entered into in September 2011, and amended in November 2011 for additional space in the same facility. The lease terminates in November 2014. In March 2014 and May 2014, the Company entered into sublease agreements for additional office space in the same facility. The subleases commenced in May 2014 and terminate in November 2014. As of September 30, 2014, the future minimum lease payments for all space in this facility totaled approximately \$100,000.

In July 2014, the Company entered into a lease agreement and an amendment on September 2014 for a separate facility totaling approximately 18,651 square feet in Menlo Park, California and intends to relocate its corporate headquarters to this facility in the fourth quarter of 2014. The term of the lease is five years, commencing in December 2014 and terminating in November 2019, with an option to renew for an additional three-year term. The base rent is approximately \$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 approximately \$22,381 per month during the first year of the lease.

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. In August 2014, the Company provided a letter of credit to the lessor in the amount of \$500,000, which is collateralized by a certificate of deposit. The collateralized certificate of deposit is

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restricted cash and recorded in the Company's condensed consolidated balance sheet as a non-current asset.

Rent expense for the three months ended September 30, 2014 and 2013 was \$168,000 and \$72,000, respectively, and for the nine months ended September 30, 2014 and 2013 was \$393,000 and \$184,000, 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.

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As of September 30, 2014, the aggregate total future minimum lease payments under the Menlo Park non-cancelable operating lease were as follows (in thousands):

<i>Year Ending December 31,</i>		
2014	\$	98
2015		1,178
2016		1,213
2017		1,250
2018 and thereafter		2,499
Total payments	\$	6,238

The table above excludes approximately \$1.4 million of additional rent due over the period of the operating lease to cover the Company's share of facility expenses, including utilities, property taxes, insurance and maintenance.

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can 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.

9. Technology 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 nonrefundable 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, 2014 and December 31, 2013, the Company recorded the \$10.0 million as deferred revenue on its consolidated balance sheet. 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.

In connection with the execution of the Right of First Negotiation Agreement, Maruho purchased 1,187,014 shares of the Company's Series B convertible preferred stock for an aggregate purchase price of \$10.0 million.

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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. This agreement includes a sublicense and assignment of certain know-how licensed and assigned to Rose U by Stiefel Laboratories, Inc., a GSK Company, the prior licensee of such patents. In connection with this agreement, the Company also entered into a letter agreement with Stiefel. The Company paid fees of \$0.3 million to Rose U in connection with execution of these agreements and is required to pay additional amounts totaling up to \$4.6 million upon the achievement of specified development, commercialization and other milestones under these agreements. 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. The initial fee of \$0.2 million was recorded to research and development expense in the statement of operations for the year ended December 31, 2013.

UCB Agreement

In March 2014, the Company entered into a development and commercialization agreement with UCB (the "UCB agreement"), for the Company to develop Cimzia in order for UCB to seek regulatory approval from the FDA, European Medicines Agency ("EMA") and the Canadian federal department for health ("Health Canada") for the treatment of psoriasis, 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. 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.

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.

In connection with the UCB agreement, UCB purchased \$5.0 million of the Company's Series B preferred stock at \$8.4245 per share in April 2014. Concurrently with the IPO, entities affiliated with UCB agreed to purchase from the Company in a private placement shares of the Company's common stock with an aggregate purchase price of \$7.5 million, at a price per share equal to the initial public offering price. The sale

of these shares to entities affiliated with UCB will not be registered in the IPO.

10. Series B Convertible Preferred Stock Warrant

On December 11, 2013, in connection with the Square 1 Bank Term Loan A (see Note 7), the Company issued the Bank a warrant to purchase up to 17,805 shares of the Company's Series B convertible preferred stock with an exercise price of \$8.4245 per share and a contractual term of seven years from issuance. The number of shares issuable pursuant to the warrant at any date is 8,902 shares plus 1% of the amount drawn through that date under the Loan Agreement divided by 8.4245. Following the entry into the Loan Agreement and the concurrent funding of Term Loan A, the warrant was exercisable for 11,276 shares of Series B convertible preferred stock. The fair value of the warrant of approximately \$61,000 was recorded as debt discount and warrant liability upon issuance. The fair value of the warrant on the date of issue was determined using the Black-Scholes option-pricing model with the following weighted-average assumptions: (1) seven-year contractual term; (2) 66.0% expected volatility; (3) 1.6% risk-free interest rate; and (4) no expected dividend.

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The fair value of the outstanding convertible preferred stock warrant was remeasured as of September 30, 2014 and December 31, 2013 using a Black-Scholes option-pricing model with the following assumptions:

	September 30, 2014	December 31, 2013
Expected term (in years)	6.2	7.0
Expected volatility	75.7%	66.0%
Risk-free interest rate	2.0%	1.6%
Expected dividend rate	0.0%	0.0%

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The fair value of the warrant as of September 30, 2014 and December 31, 2013 was \$139,000 and \$61,000, respectively. The change in fair value for the nine months ended September 30, 2014 was an increase of \$78,000, which was reflected in interest and other income (expense), net.

11. Common Stock

As of September 30, 2014, the Company was authorized to issue up to 126,000,000 shares of common stock, par value \$0.001 per share.

The Company had reserved shares of common stock, on an as converted basis, for issuance as follows:

	As of September 30, 2014	As of December 31, 2013
Share-based payments outstanding under stock incentive plans	2,249,871	1,743,590
Conversion of convertible preferred stock	15,430,706	9,540,158
Issuances upon exercise of convertible preferred stock warrant	11,276	11,276
Shares available for future stock option grants	200,712	142,506
	17,892,565	11,437,530

From August 2010 to October 2010, the Company issued 400,857 shares of restricted common stock at \$0.001 per share to service providers of the Company under common stock purchase agreements. The shares purchased under the stock purchase agreements vest over time. The unvested shares of common stock are subject to a right of repurchase by the Company in the event of cessation of services. Included in common stock outstanding as of December 31, 2013 were 9,788 shares, which were subject to the Company's right to repurchase relating to these common stock purchase agreements. There were no shares of common stock subject to the Company's right of repurchase as of September 30, 2014.

12. Convertible Preferred Stock

As of September 30, 2014 and December 31, 2013, the Company was authorized to issue up to 40,874,365 shares and 10,107,111 shares, respectively, of preferred stock, par value \$0.001 per share. In August 2014, the Company issued 5,297,041 shares of Series C convertible preferred stock at a purchase price of \$9.628 per share for net proceeds of \$48.8 million.

As of September 30, 2014, outstanding convertible preferred stock was comprised of the following (in thousands, except share and per share amounts):

Shares Authorized	Shares Issued and Outstanding	Carrying Value	Liquidation Value per Share	Liquidation Value
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Series A	6,572,629	6,572,625	\$	35,089	\$	5.3650	\$	35,262
Series B	3,578,847	3,561,040		29,499		8.4245		30,000
Series C	30,722,889	5,297,041		48,826		9.6280		51,000
	40,874,365	15,430,706	\$	113,414			\$	116,262

As of December 31, 2013, outstanding convertible preferred stock was comprised of the following (in thousands, except share and per share amounts):

	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Liquidation Value per Share	Liquidation Value
Series A	6,572,629	6,572,625	\$ 35,089	\$ 5.3650	\$ 35,262
Series B	3,534,482	2,967,533	24,499	8.4245	25,000
	10,107,111	9,540,158	\$ 59,588		\$ 60,262

The Company recorded the convertible preferred stock at fair value, net of issuance costs, on the dates of issuance. The Company classifies the convertible preferred stock outside of stockholders' deficit because the shares contain liquidation features that are not solely within the Company's control. For the nine months ended September 30, 2014, the Company did not adjust the carrying values of the convertible preferred stock to the deemed redemption values of such shares since a liquidation event was not probable. Subsequent adjustments to the carrying values to the ultimate redemption values will be made only if and when it becomes probable that such a liquidation event will occur.

The rights, preferences and privileges of the convertible preferred stock are as follows:

Conversion

Each share of Series A, Series B and Series C convertible preferred stock is convertible into shares of common stock at an initial conversion price of \$5.365 per share, \$8.4245 per share and \$9.628, respectively. Each share of convertible preferred stock is convertible, at the option of the holder, at any time into fully paid and nonassessable shares of common stock. Conversion of all shares of convertible preferred stock is automatic upon: (1) affirmative election of the holders of a majority of the shares of convertible preferred stock outstanding; or (2) the closing of a firm commitment underwritten public offering of common stock with a price per share of not less than the conversion price of the Series C convertible preferred stock then in effect and gross cash proceeds to the Company of at least \$50.0 million (before deduction of underwriters commissions and expenses).

The number of shares of common stock to which a convertible preferred stockholder is entitled upon conversion of such stockholder's convertible preferred stock is the product obtained by multiplying the convertible preferred stock conversion rate by the number of shares of convertible preferred stock being converted, subject to adjustments as provided in the Company's Restated Certificate of Incorporation. As of December 31, 2013 and September 30, 2014, all shares of Series A, Series B and Series C convertible preferred stock were convertible into common stock on a one-for-one basis.

The Series A, Series B and Series C convertible preferred stock conversion prices are subject to adjustment upon any future stock splits or stock combinations, reclassifications or exchanges of similar shares, or upon a reorganization, merger or consolidation of the Company. In addition, the conversion prices are subject to adjustment upon any issuance of stock below the stated conversion prices for each series of convertible preferred stock, subject to certain exceptions.

Special Mandatory Conversion

At any time prior to the automatic conversion of the convertible preferred stock or conversion of the convertible preferred stock pursuant to a liquidation, dissolution or winding up of the Company or a deemed liquidation event, if certain investors do not participate in a qualified financing by purchasing their pro rata amount (based upon designated commitment percentages) up to a threshold amount, on the terms generally applicable to other investors in the qualified financing, then each share of convertible preferred stock held by those investors will be automatically converted into the number of shares of common stock equal to 50% of the shares of common stock that such investors would be entitled to receive upon an optional conversion at the applicable conversion price for the series of preferred stock in question that is in effect immediately prior to the consummation of such qualified financing. Once each such investor has purchased preferred stock in an amount equal to the threshold amount, such automatic special mandatory conversion provision is no longer applicable as to such investor.

Voting

Stockholders of the Series A, Series B and Series C convertible preferred stock are entitled to the number of votes equal to the number of shares of common stock into which such shares of convertible preferred stock are convertible on the record date for the determination of stockholders entitled to vote on such matters or, if no such record date is established, the date such vote is taken or written consent is solicited. Holders of convertible preferred stock vote together as one class with the common stock, and have voting rights and powers that differ from the common stock as specified in the Company's Amended and Restated Certificate of Incorporation. For so long as at least 25% of the shares of convertible preferred stock remain outstanding, the approval of convertible preferred stockholders is required for a number of significant changes to the Company, including the creation of a new class or series of shares of capital stock and amendments to the Company's Amended and Restated Certificate of Incorporation and Bylaws.

So long as at least 25% of the shares of Series A convertible preferred stock remain outstanding, the holders of Series A convertible preferred stock, voting as a separate series, will be allowed to elect three directors of the Company, the holders of the common stock, voting as a separate class, are allowed to elect two directors of the Company.

Liquidation

In the event of a liquidation, dissolution, or winding up of the Company, whether voluntarily or involuntarily, and upon certain other defined events, the holders of the Series A, Series B and Series C convertible preferred stock are also entitled to receive liquidation preferences in amounts per share equal to the original issue price of \$5.3650, \$8.4245 and \$9.628, respectively, plus the amount of any declared and unpaid dividends on such shares of convertible preferred stock. Liquidation payments are made in preference to any payments to the holders of common stock. If the funds or assets from the liquidation event are insufficient to permit the payment of Series A, Series B and Series C convertible preferred stock holders their full liquidation preferences, then all the funds or assets will be distributed among the holders Series A, Series B and Series C convertible preferred stock pro rata, on a pari passu basis, according to their respective liquidation preferences. If there are any funds remaining after the payment of the liquidation preference of \$5.3650 per share, \$8.4245 per share and \$9.628 per share to the holders of the Series A, Series B and Series C convertible preferred stock, respectively, then all remaining funds shall be distributed among the holders of the shares of Series A, Series B and Series C convertible preferred stock and common stock, pro rata based on the number of shares held by each such holder (on an as-converted to common stock basis), provided, however, that if the aggregate amount the holders of Series A and Series B preferred stock are entitled to receive exceeds \$16.0950 per share, \$25.2735 per share and \$28.884, respectively, then each holder of Series A, Series B and Series C convertible preferred stock shall only be entitled to receive the greater of (1) \$16.0950 per share, \$25.2735 per share and \$28.884, respectively, or (2) the amount such holder would have received if all shares of Series A, Series B and Series C convertible preferred stock had been converted into common stock immediately prior to a liquidation, dissolution or winding up of the Company.

Dividends

Holders of Series A, Series B and Series C convertible preferred stock are entitled to receive dividends out of any assets legally available only when, as, and if declared by the Board of Directors, prior to and in preference to any declaration or payment of any dividend on the common stock. Such dividends shall be noncumulative. The dividend rate for the Series A, Series B and Series C convertible preferred stock per share per annum is \$0.4292, \$0.67396 and \$0.754, respectively. To date, the Board of Directors has not declared any dividends.

Redemption

The convertible preferred stock is not redeemable as it does not have a set redemption date or a date after which the shares may be redeemed by the holders.

13. Equity Incentive Plans

As of September 30, 2014 and December 31, 2013, the Company had reserved 2,456,785 and 1,886,095 shares of common stock for issuance under the 2010 Equity Incentive Plan, respectively.

The following summary of stock option activity for the periods presented is as follows (in thousands, except share and per share amounts):

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	Shares Available for Grant	Shares Subject to Outstanding Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2013	142,506	1,743,590	\$ 1.18		
Additional shares reserved under plan	570,693				
Options granted	(533,955)	533,955	5.28		
Options exercised		(6,206)	1.10		
Options forfeited	21,468	(21,468)	1.37		
Options outstanding at September 30, 2014	200,712	2,249,871	\$ 2.15	7.5	\$ 31,153
Vested and expected to vest as of September 30, 2014		2,079,367	\$ 2.11	8.2	\$ 28,879
Exercisable as of September 30, 2014		990,193	1.11	7.5	14,748

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The following table summarizes information with respect to stock options outstanding and currently exercisable as of September 30, 2014:

Exercise Price		Number of Options	Options Outstanding Weighted- Average Remaining Contractual Life (in years)	Options Exercisable
\$	0.0058	25,169	6.1	24,644
\$	0.986	879,375	7.1	652,006
\$	1.218	508,060	8.3	211,686
\$	1.74	332,621	8.9	97,404
\$	5.51	504,646	9.7	4,453
		2,249,871		990,193

Stock Options Granted to Employees

During the nine months ended September 30, 2014, the Company granted stock options to employees and nonemployee directors to purchase shares of common stock with a weighted-average grant date fair value of \$3.58 per share and a weighted-average exercise price of \$5.34 per share, respectively. As of September 30, 2014, there was total unrecognized compensation expense of \$2.0 million to be recognized over a period of approximately 2.2 years.

Stock Options Granted to Nonemployees

Stock-based compensation expense related to stock options granted to nonemployees is recognized as the stock options are earned. During the three and nine months ended September 30, 2014 and 2013, the Company did not grant any options to purchase shares of common stock to nonemployees.

Compensation expense related to these options during the three months ended September 30, 2014 and 2013 was approximately \$108,000 and \$12,000, respectively, and during the nine months ended September 30, 2014 and 2013 was approximately \$215,000 and \$25,000, respectively.

Total Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development:	\$ 210	\$ 59	\$ 436	\$ 138

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Sales, general and administrative:	114	26	198	67
Total stock-based compensation expense	\$ 324	\$ 85	\$ 634	\$ 205

There were no capitalized stock-based compensation costs or recognized stock-based compensation tax benefits during the three and nine months ended September 30, 2014 and 2013, respectively.

14. Subsequent Events**Initial Public Offering and Concurrent Private Placement**

On October 8, 2014, the Company closed its IPO of 7,812,500 shares of its common stock, all of which were sold by the Company. The public offering price of the shares sold in the IPO was \$16.00 per share. The net proceeds from the IPO to the Company were approximately \$112.8 million, after deducting the underwriting discounts and commissions of \$8.75 million and the payment of offering expenses of approximately \$3.45 million. As of September 30, 2014, approximately \$1.6 million of IPO costs remained unpaid, which costs are expected to be paid in the Company's fourth fiscal quarter.

Concurrently with the IPO, the Company issued and sold in a private placement 468,750 shares of common stock at the public offering price of \$16.00 per share, which resulted in net proceeds of \$7.5 million, pursuant to a Common Stock Purchase Agreement by and between the Company and UCB, S.A., the parent company of UCB Pharma S.A., dated September 19, 2014.

The table below shows, on a pro forma basis, the impact of the IPO and the concurrent private placement on certain condensed balance sheet items. The as adjusted condensed balance sheet data below gives effect to the sale of 8,281,250 shares of common stock from the IPO and the concurrent private placement, at the initial public offering price of \$16.00 per share, after deducting the underwriting discounts and commissions and estimated offering related transaction expenses.

	September 30, 2014	
	Actual	Pro Forma As Adjusted
	(in thousands)	
Condensed Consolidated Balance Sheet Data:		
Cash and cash equivalents	\$ 50,845	\$ 171,145
Working capital	43,624	164,063
Total assets	59,616	179,916
Convertible preferred stock warrant liability	139	
Bank term loan, current and non-current	1,937	1,937
Convertible preferred stock	113,414	
Additional paid-in capital	1,611	235,439
Accumulated deficit	(75,922)	(75,922)
Total stockholders' (deficit) equity	(74,310)	159,543

Approval of Restated Certificate of Incorporation

On September 9, 2014, the Company's Board of Directors approved a Restated Certificate of Incorporation that became effective upon its filing with the Secretary of State of the State of Delaware on October 8, 2014, immediately prior to the closing of the IPO. The Restated Certificate of Incorporation increased the authorized share capital to 500,000,000 shares of common stock, \$0.001 par value per share, and reduced the authorized share capital to 10,000,000 shares of undesignated preferred stock, \$0.001 par value per share.

Option Grants

On September 9, 2014, the Company's Board of Directors approved the grant of options to purchase 244,835 shares of the Company's common stock at an exercise price per share equal to the initial public offering price, all of which were granted on October 2, 2014, the day that the Company's Registration Statement on Form S-1 (the "S-1") was declared effective.

2014 Equity Incentive Plan

On September 9, 2014, the Company's Board of Directors adopted and approved the 2014 Equity Incentive Plan (the "2014 EIP"), which became effective on October 1, 2014, the day prior to the day that the S-1 was declared effective. The 2014 EIP authorizes the reservation of 1,896,551 shares of the Company's common stock, plus any shares reserved or remaining for issuance, or that become available upon forfeiture or repurchase by the Company, under the 2010 Plan. On January 1 of each of the first ten years commencing after the effective date of the IPO, the number of shares of the Company's common stock reserved for issuance under the 2014 EIP will increase automatically by an amount equal to 4% of the number of shares of the Company's common stock outstanding on the preceding December 31, unless the Company's Board of Directors elects to authorize a lesser number of shares.

2014 Employee Stock Purchase Plan

On September 9, 2014, the Company's Board of Directors adopted and approved the 2014 Employee Stock Purchase Plan (the "2014 ESPP"), which became effective on October 2, 2014, the day of that the S-1 was declared effective. The 2014 ESPP authorizes the reservation of 301,724 shares of the Company's common stock. On January 1 of each of the first ten years commencing after the effective date of the IPO, the number of shares of the Company's common stock reserved for issuance under the 2014 ESPP will increase automatically by an amount equal to 1% of the number of shares of the Company's common stock outstanding on the preceding December 31, unless the Company's Board of Directors elects to authorize a lesser number of shares.

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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 financial statements and notes thereto for the year ended December 31, 2013, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, contained in the Prospectus filed with the SEC pursuant to Rule 424(b)(4) on October 3, 2014. 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 medical dermatology 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. Our portfolio of five product candidates targets significant market opportunities and includes three late-stage product candidates, Cimzia (certolizumab pegol), which we are developing in collaboration with UCB Pharma S.A., for the treatment of moderate-to-severe plaque psoriasis, DRM04, which we are developing for the treatment of hyperhidrosis, or excessive sweating, and DRM01, which we are developing for the treatment of acne.

Since our founding in 2010, we have executed three significant 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 GlaxoSmithKline LLC Company, or Stiefel, 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 to develop and commercialize Cimzia in dermatology.

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, including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and Crohn's disease, in multiple countries including the United States. Biologic TNF inhibitors are a class of pharmaceutical products that are manufactured by biological processes and designed to exert their effect by inhibiting TNF, a naturally occurring molecule that plays an important role in promoting inflammation within the body, including in patients with psoriasis. We have entered into an agreement to collaborate 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. UCB has conducted two Phase 2 clinical trials, including a 176-patient, randomized, multi-center, double-blind, placebo-controlled trial, that demonstrated significant reductions in the signs and symptoms of moderate-to-severe plaque psoriasis. We and UCB conducted an end-of-Phase 2 meeting

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with the U.S. Food and Drug Administration, or the FDA, in June 2014, filed an investigational new drug application, or IND, for the treatment of moderate-to-severe plaque psoriasis with the FDA in September 2014 and intend to commence Phase 3 clinical trials in the first half of 2015.

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- DRM04, a topical, small-molecule anticholinergic product we are developing for the treatment of hyperhidrosis. Anticholinergics are a class of pharmaceutical products that exert their effect by blocking the action of acetylcholine, a molecule that transmits signals within the nervous system that are responsible for a range of bodily functions, including the activation of sweat glands. DRM04 is a topical formulation of a novel form of an anticholinergic agent that has been approved for systemic administration in other indications, and it is designed to inhibit sweat production by blocking the activation of sweat glands following topical administration. Two randomized, double-blind, vehicle-controlled Phase 2 clinical trials, including a 198-patient, multi-center Phase 2b clinical trial and a 38-patient Phase 2a clinical trial, have demonstrated significant reductions in the signs and symptoms of primary axillary, or underarm, hyperhidrosis in patients treated with a topical formulation of the anticholinergic agent that has been approved for systemic administration in other indications, which we call the topical formulation of the reference agent. In addition, we are currently conducting a Phase 2b clinical trial in patients with primary axillary hyperhidrosis in which we are comparing DRM04 to the topical formulation of the reference agent. We expect data from this trial in the first half of 2015. If successful, we intend to commence a Phase 3 clinical program, which would include one or more Phase 3 clinical trials, in the second half of 2015.
- DRM01, a novel, topical, small-molecule sebum inhibitor we are developing for the treatment of acne. Sebum is an oily substance made up of lipids produced by glands in the skin called sebaceous glands, and excessive sebum production is an important aspect of acne that is not addressed by available topical therapies. DRM01 is a prodrug designed to inhibit the production of sebum by delivering a widely-studied lipid synthesis inhibitor to the skin following topical administration. We have completed a 108-patient, randomized, multi-center, double-blind, vehicle-controlled Phase 2a clinical trial that demonstrated significant reductions in the signs and symptoms of acne. Based on the results of this Phase 2a clinical trial, we intend to file an IND with the FDA and commence a Phase 2b clinical program, which would include one or more clinical trials, in the first half of 2015.

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

- DRM02, a novel, topical, small-molecule inhibitor of phosphodiesterase-4, or PDE4, for the treatment of inflammatory skin diseases; and
- DRM05, a novel, topical photodynamic therapy, or PDT, for the treatment of acne.

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 do not have any approved products and have never generated any revenue from product sales or otherwise. We have financed our operations primarily through the sale of equity securities and convertible debt securities, from which we raised \$113.4 million of net cash from our inception through September 30, 2014.

On October 8, 2014, we closed our initial public offering, or IPO, of 7,812,500 shares of our common stock, all of which were sold by us. The public offering price of the shares sold in the IPO was \$16.00 per share. The net proceeds from the IPO to us were approximately \$112.8 million, after deducting the underwriting discounts and commissions of \$8.75 million and the payment of offering expenses of approximately \$3.45 million.

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Concurrently with the IPO, we issued and sold in a private placement 468,750 shares of common stock at the public offering price of \$16.00 per share, which resulted in net proceeds of \$7.5 million, pursuant to a Common Stock Purchase Agreement by and between UCB, S.A., the parent company of UCB Pharma S.A. and us, dated September 19, 2014

We have never been profitable and, as of September 30, 2014, we had an accumulated deficit of \$75.9 million. We incurred net losses of \$7.8 million and \$25.1 million for the three and nine months ended September 30, 2014, respectively. 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 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.

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Financial Operations Overview

Revenue

To date, we have not generated any revenue. Under our development and commercialization agreement with UCB, or 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.

Research and Development Expenses

We expense both internal and external research and development expenses to operations as they are incurred. We track the external research and development costs incurred for each of our product candidates. We do not track our internal research and development costs by product candidate, as these costs are typically spread across multiple product candidates.

External research and development expenses consist primarily of costs incurred for the development of our product candidates and include:

- expenses incurred under agreements with contract research organizations, or CROs, investigative sites, and consultants to conduct our clinical trials and preclinical and non-clinical studies;
- costs to acquire, develop and manufacture supplies for clinical trials and other studies, including fees paid to contract manufacturing organizations, or CMOs;
- costs related to compliance with drug development regulatory requirements; and
- licensing fees and milestone payments incurred under product license agreements.

Internal research and development costs include:

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- salaries and related costs, including stock-based compensation and travel expenses, for personnel in our research and development functions;
- costs for consultants who advise us on multiple product candidates; and
- depreciation and other allocated facility-related and overhead expenses.

For the three months ended September 30, 2014, external costs associated with our three late-stage product candidates, Cimzia, DRM04 and DRM01, were \$0.7 million, \$2.2 million and \$0.7 million, respectively, or 12%, 37% and 12%, respectively, of our total research and development expenses. For the three months ended September 30, 2014, Cimzia external costs increased by the full \$0.7 million from none in the prior-year period as we did not acquire the rights to develop Cimzia for the treatment of moderate-to-severe psoriasis under our collaboration with UCB until 2014. For the three months ended September 30, 2014, DRM04 external costs increased by \$1.2 million from \$1.0 million in the prior-year period due to the advancement of this product candidate into two Phase 2b clinical trials beginning in the second half of 2013. For our DRM01 product candidate, external costs for the three months ended September 30, 2014 were approximately equal to those incurred in the prior-year period. For the three months ended September 30, 2014, total external costs associated with our early-stage product candidates, DRM02 and DRM05, combined, were \$0.4 million, or 6% of our total research and development expenses. For the three months ended September 30, 2013, external costs associated with our Cimzia, DRM04 and DRM01 product candidates, were 0%, 27% and 18%, respectively, of our total research and development expenses. For the same period, total external costs associated with DRM02 and DRM05, combined, were 23% of our total research and development expenses.

For the nine months ended September 30, 2014, external costs associated with Cimzia, DRM04 and DRM01 were \$0.8 million, \$8.0 million and \$2.5 million, respectively, or 4%, 41% and 13%, respectively, of our total research and development expenses. For the nine months ended September 30, 2014, Cimzia external costs increased by the full \$0.8 million from none in the prior-year period as we did not acquire the rights to develop Cimzia for the treatment of moderate-to-severe psoriasis under our collaboration with UCB until 2014. For the nine months ended September 30, 2014, DRM04 external costs increased by \$6.5 million over the prior-year period due to the advancement of the program into two Phase 2b clinical trials beginning in the second half of 2013. For our DRM01 product candidate, external costs for the nine months ended September 30, 2014 increased by \$0.4 million compared to the prior-year period due primarily to an increase in costs associated with the Phase 2a trial. For the nine months ended September 30, 2014, total external costs for DRM02 and DRM05, combined, were \$3.0 million, or 15% of our total research and development expenses. For the nine months ended September 30, 2013, external costs associated with Cimzia, DRM04 and DRM01 were 0%, 13% and 17%, respectively, of our total research and development expenses. For the same period, total external costs associated with DRM02 and DRM05, combined, were \$5.2 million, or 42% of our total research and development expenses.

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For each of the above periods, the balance of our research and development expenses were comprised primarily of internal costs.

We expect that our future research and development efforts will be focused on our late-stage clinical programs, Cimzia, DRM04 and DRM01. UCB filed an IND for Cimzia for the treatment of moderate-to-severe plaque psoriasis in September 2014, and we and UCB intend to commence Phase 3 clinical trials in the first half of 2015. For DRM04, we are currently conducting a Phase 2b clinical trial and expect data from this trial in the first half of 2015. If successful, we intend to initiate a Phase 3 clinical program in the second half of 2015. For DRM01, we have completed a Phase 2a clinical trial that demonstrated significant reductions in the signs and symptoms of acne. Based on the results of this clinical trial, we intend to file an IND and commence a Phase 2b clinical program, which would include one or more clinical trials, in the first half of 2015. We also 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.

We expect our research and development expenses to increase substantially in the future as we continue development of our product candidates. In particular, we expect to incur substantial research and development expenses associated with Cimzia beginning in the second half of 2014 to prepare for Phase 3 clinical trials that we intend to initiate in the first half of 2015.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries and related costs, including stock-based compensation and travel expenses, for personnel in our executive, finance, corporate development and other administrative functions. Other general and administrative expenses include allocated depreciation and facility-related costs, legal costs of pursuing patent protection of our intellectual property, and professional services fees for auditing, tax and general legal services.

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 SEC requirements, directors' and officers' liability insurance premiums and investor relations activities.

Interest and Other Income (Expense), Net

Interest income consists primarily of interest received or earned on our cash and cash equivalents balances. Other income (expense) primarily includes gains and losses from the remeasurement of our convertible preferred stock warrant liability and gains and losses on our foreign currency transactions.

Interest Expense

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Interest expense consists of cash and non-cash interest costs related to our bank term loan. The non-cash interest costs consist of the amortization of the fair value of the warrant that was issued to the lender in connection with our bank term loan, with the initial fair value of the warrant being amortized to interest expense over the term of the governing agreement.

Table of Contents**Results of Operations***Comparison of the Three Months Ended September 30, 2014 and 2013*

	Three Months Ended September 30,		Change	
	2014	2013	\$	%
	(in thousands, except percentages)			
Operating expenses:				
Research and development	\$ 6,028	\$ 3,619	\$ 2,409	67%
General and administrative	1,688	1,009	679	67
Total operating expenses	7,716	4,628	3,088	67
Loss from operations	(7,716)	(4,628)	(3,088)	67
Interest and other income (expense), net	(84)	(37)	(47)	*
Interest expense	(47)		(47)	*
Net loss	\$ (7,847)	\$ (4,665)	\$ (3,182)	68

* Percentage not meaningful

Research and Development. Research and development expenses increased \$2.4 million, or 67%, for the three months ended September 30, 2014 compared to the three months ended September 30, 2013. This increase was primarily due to \$1.3 million and \$0.7 million increases in external costs related to our DRM04 and Cimzia product candidates, respectively, and a \$0.7 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 combined \$0.5 million decrease in external costs associated with our DRM02 and DRM05 product candidates.

General and Administrative. General and administrative expenses increased \$0.7 million, or 67%, for the three months ended September 30, 2014 compared to the three months ended September 30, 2013. This increase was primarily due to a \$0.6 million increase in personnel-related expenses related primarily to headcount growth and incentive compensation expenses.

Interest and Other Income (Expense), Net. Amounts recorded in interest and other income (expense), net for both periods were primarily related to foreign currency exchange gains relating to our Canadian subsidiary and payments made to non-U.S. third-party service providers and the revaluation change associated with our series B convertible preferred stock warrant for the three months ended September 30, 2014.

Interest Expense. The increase in interest expense was due to interest incurred on borrowings of \$2.0 million under the bank term loan we entered into in December 2013 and amended in September 2014.

Comparison of the Nine Months Ended September 30, 2014 and 2013 (unaudited)

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	Nine Months Ended September 30,		Change	
	2014	2013	\$	%
(in thousands, except percentages)				
Operating expenses:				
Research and development	\$ 19,676	\$ 12,397	\$ 7,279	59%
General and administrative	5,240	3,214	2,026	63
Total operating expenses	24,916	15,611	9,305	60
Loss from operations	(24,916)	(15,611)	(9,305)	60
Interest and other income (expense), net	(118)	(25)	(93)	*
Interest expense	(114)		(114)	*
Net loss	\$ (25,148)	\$ (15,636)	\$ (9,512)	61

* Percentage not meaningful

Research and Development. Research and development expenses increased \$7.3 million, or 59%, for the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013. This increase was primarily due to a \$6.5 million increase in external costs related to our DRM04 product candidate, a \$1.8 million increase in internal costs related primarily to headcount growth, a \$0.8 million increase in external costs related to our Cimzia product candidate and a \$0.5 million increase in external costs related to our DRM01 and DRM02 product candidates. These increases in research and development expenses were partially offset by a \$2.5 million decrease in external costs associated with our DRM05 product candidate.

General and Administrative. General and administrative expenses increased \$2.0 million, or 63%, for the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013. This increase reflects a \$1.3 million increase in personnel-related expenses due to increased headcount and incentive compensation expenses, \$0.8 million of legal and consulting services incurred in the evaluation, due diligence and negotiations associated with the UCB collaboration transaction in the first quarter of 2014, and a \$0.4 million increase in audit and accounting consultation expenses. These increases in general and administrative expenses were partially offset by a transaction advisory fee of \$0.5 million incurred in the first quarter of 2013 in connection with the agreement we entered into with Maruho.

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Interest and Other Income (Expense), Net. Amounts recorded in interest and other income (expense), net for both periods were primarily related to foreign currency exchange gains relating to our Canadian subsidiary and payments made to non-U.S. third-party service providers and the revaluation charge associated with our Series B convertible preferred stock warrant for the nine months ended September 30, 2014.

Interest Expense. The increase in interest expense was due to interest incurred on borrowings of \$2.0 million under the bank term loan we entered into in December 2013 and amended in September 2014.

Liquidity and Capital Resources

Since our inception through September 30, 2014, we have financed our operations primarily with \$113.4 million in net proceeds from the issuance and sale of equity securities and convertible debt securities. In addition, we received \$10.0 million related to our agreement with Maruho entered into in March 2013, and \$2.0 million in bank financing under a \$7.5 million bank loan agreement entered into in December 2013. As of September 30, 2014, we had \$50.8 million of cash and cash equivalents. Our cash and cash equivalents are held in a variety of interest-bearing instruments, including repurchase agreements and obligations of U.S. government agencies. 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 March 31, 2014, we had an accumulated deficit of \$59.3 million and there was substantial doubt about our ability to continue as a going concern if we did not secure additional financing. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our 2013 consolidated financial statements with respect to this uncertainty. However, as described more fully below, since March 31, 2014, we have raised approximately \$174.1 million in net proceeds from additional equity financings.

As of September 30, 2014, we had an accumulated deficit of \$75.9 million. In October 2014, we completed our initial public offering and concurrent private placement of shares of common stock, pursuant to which we issued 8,281,250 shares of common stock and received net proceeds of approximately \$120.3 million, after deducting underwriting discounts, commissions and estimated offering expenses. In addition, beginning in September 2014, we are entitled to borrow \$5.5 million under our Term Loan B of our credit facility with Square 1 Bank. We believe that our existing cash resources are sufficient to meet our cash needs for at least the next 12 months. However, 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.

Cash Flows

The following table shows a summary of our cash flows for the nine months ended September 30, 2014 and 2013 (in thousands):

**Nine Months Ended
September 30,**

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	2014		2013
Net cash (used in) provided by:			
Operating activities	\$ (25,085)	\$	(6,738)
Investing activities	(47)		(30)
Financing activities	53,833		24,499
Net increase in cash and cash equivalents	\$ 28,701	\$	17,731

Operating Activities. 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. Net cash used in operating activities was \$6.7 million for the nine months ended September 30, 2013 and consisted primarily of our net loss of \$15.6 million and a \$1.1 million decrease in accounts payable and accrued liabilities primarily due to higher disbursements, partially offset by a \$10 million increase in deferred revenue related to our agreement with Maruho.

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Investing Activities. Net cash used in investing activities for the nine months ended September 30, 2014 and 2013 was \$47,000 and \$30,000, respectively. The amounts were for purchases of property and equipment.

Financing Activities. Net cash provided by financing activities was \$53.8 million for the nine months ended September 30, 2014 and consisted of net proceeds of \$48.8 million 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 March 2014. Net cash provided by financing activities was \$24.5 million for the nine months ended September 30, 2013 and related to the net proceeds from the sale of shares of our Series B convertible preferred stock in March 2013.

Operating and Capital Expenditure Requirements

We have incurred losses since our inception. We anticipate that we will continue to generate losses for the foreseeable future, and 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 our existing cash and cash equivalents, including net proceeds from the initial public offering and concurrent private placement of our common stock that closed in October 2014, will be sufficient to meet our anticipated cash requirements for at least the next 12 months. 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 cannot assure you that we will 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 Prospectus.

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, 2014, we had cash and cash equivalents of \$50.8 million, which consisted of bank deposits, repurchase agreements and obligations of U.S. government agencies. These interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant. All of our outstanding debt obligations carry fixed interest rates.

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 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 our Canadian 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 losses were \$15,000 and \$39,000 for the three months ended September 30, 2014 and 2013, respectively, and \$55,000 and \$31,000 for the nine months ended September 30, 2014 and 2013, respectively, are included in interest and other income (expense), net in our condensed consolidated statements of operations and comprehensive loss. 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 have had an insignificant effect on our 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 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 on-going 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 financial statements and in Note 2 to our audited financial statements contained in the Prospectus.

During the nine months ended September 30, 2014, there were no material changes to our critical accounting policies. Our critical accounting policies are described under *Management's Discussion and Analysis of Financial Condition and Results of Operations* in the Prospectus.

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 disclosures controls and procedures as of September 30, 2014. 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

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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, 2014, 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, 2014 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;

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- 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 and efficacy 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 \$20.3 million, \$22.4 million and \$25.1 million for the years ended December 31, 2012 and 2013 and for the nine months ended September 30, 2014, respectively. As of September 30, 2014, we had an accumulated deficit of \$75.9 million.

We have financed our operations primarily through the sale of equity securities and convertible debt securities. Since our inception, most of our resources have been dedicated to the 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, 2014, we had capital resources consisting of cash and cash equivalents of \$50.8 million and in October 2014, we issued shares of our common stock in our initial public offering and a concurrent private placement and received net proceeds of \$120.3 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

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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.

We believe that our existing cash and cash equivalents, including the net proceeds from our initial public offering and the concurrent private placement, together with interest thereon, will be sufficient to fund our operations through 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 of our lead product candidates, Cimzia, DRM04 and DRM01, exceed our existing cash and cash equivalents, including the net proceeds from our initial public offering and the concurrent private placement. 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.

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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;
- costs associated with prosecuting or defending any litigation that we are or 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,

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make certain investments and engage in certain merger, consolidation or asset sale transactions. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe that we have sufficient funds for our current or future operating plans.

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

If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, scale back or discontinue one or more of our product development programs or 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.

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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:

- regulatory requirements prior to commencing a clinical trial;
- 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.

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:

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- 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;
- insufficient data to support regulatory approval;
- inability or unwillingness of medical investigators to follow our clinical protocols; or
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data.

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

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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.

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.

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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 and clinical 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 our Phase 2 clinical trial for Cimzia in moderate-to-severe plaque psoriasis, a six-point physical global assessment, or PGA, scale was used, and we intend to use a five-point PGA scale in the Phase 3 clinical trials. As a result, data from our Phase 2 clinical trial may not accurately predict Phase 3 results. In addition, for DRM04, the results of our Phase 2a and Phase 2b clinical trials may not accurately predict results in our Phase 3 clinical trials that will have larger numbers of patients. 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;
- the FDA or the applicable foreign regulatory body may not find the data from preclinical studies and clinical trials 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, 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;

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- 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 give us marketing clearance of a device intended to be used in combination with our product candidate DRM05, or any other future product candidates; 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.

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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.

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 conducted a Phase 3 clinical trial before, 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 conducted a Phase 3 clinical trial before, and as a result may require more time and incur greater costs than we anticipate. For example, we intend to commence Phase 3 clinical trials for Cimzia in the first half of 2015. Failure to

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commence or complete, or delays in, our planned 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, which would adversely impact our financial performance.

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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, and 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;
- 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.

Enbrel, Humira and Stelara, injectable biologics for the treatment of moderate-to-severe plaque psoriasis, achieved aggregate sales of \$4.0 billion in 2012 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 us. 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.

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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., Actavis plc, Allergan, Inc., Amgen Inc., Anacor Pharmaceuticals, Inc., Astellas Pharma US, Inc., Bayer HealthCare AG (formerly Intendis, Inc.), Eisai Co., Ltd., Galderma S.A., GlaxoSmithKline LLC, or GSK, Janssen Biotech, Inc., Johnson & Johnson, LEO Pharma A/S, Maruho Co., Ltd., Merck & Co., Inc., Miramar Labs, Inc., Mitsubishi Tanabe Pharma Corporation, Mylan Inc., 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.

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 injected products such as 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, 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 a lower price and may offer greater efficacy or a better safety profile.

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

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application 12 years after the time of approval of the innovative biological product. 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. 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 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 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, PROs will have an important role in the development and regulatory approval of our DRM04 product candidate. 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, and from patient to patient and site to site within a clinical trial. Furthermore, we intend to use a new PRO in our Phase 2 clinical program and pursue the use of the new PRO to measure efficacy in our planned Phase 3 clinical program for DRM04. It is possible that the FDA will not accept the new PRO or will require changes in the PRO, potentially delaying clinical development of DRM04, increasing our costs and making additional clinical trials necessary.

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 a 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.

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

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

The regulations, policies or guidance of the FDA and other applicable government agencies may change and new or additional statutes or government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government 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 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 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, our Phase 3 clinical trials for Cimzia that we intend to commence in the first half of 2015 will be conducted in multiple countries. Although the FDA or applicable foreign regulatory authority may accept data from clinical trials conducted outside the United States

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

Our product candidates may cause undesirable side effects or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in post-approval regulatory action.

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 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. The 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.

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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;
- termination of clinical trial sites or entire trial programs;
- the inability to commercialize our product candidates;
- decreased demand for our product candidates;
- impairment of our business reputation;

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- 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.

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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 cleared 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, as a result, the FDA may not permit us to use this approach to regulatory approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, 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 was 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 are 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

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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.

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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. 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.

More recently, the Protecting Access to Medicare Act of 2014, signed into law in April 2014, provides for a 0.5% change from 2013 federal payment rates under the Medicare Physician Fee Schedule through 2014 and a 0% update from January 1 until April 1, 2015. Congressional failure to intervene to prevent these changes in payment rates may adversely affect our revenue and operating results.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures.

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual or in return for the purchase, lease, or order of any good, facility item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, including, for example, the federal civil False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

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- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which impose obligations on covered entities, including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal physician sunshine requirements under the Affordable Care Act, which require manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and

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- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be provided to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

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

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

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

Our employees, independent contractors, principal investigators, consultants, vendors, CROs and any partners with which we may collaborate may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

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

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Risks Related to Our Collaboration with UCB

The UCB agreement is terminable by UCB if we consummate a change of control with a significant number of competitor companies, which may adversely impact the likelihood that we will be acquired.

If we consummate a change of control with a third party that is clinically developing or commercializing a biologic TNF inhibitor, UCB has the right to terminate the UCB agreement. If such termination occurs prior to the grant of regulatory approval for Cimzia for the treatment of psoriasis, we would be obligated to pay the remaining costs for which we would be responsible under the agreed development plan reduced by the amount of development milestone payments that would have been payable upon achievement of applicable development milestones if and when such milestones are achieved. This could make an acquisition of us by any such company economically unattractive, potentially prohibitively so. Among the companies that we are aware are currently clinically developing or commercializing biologic TNF inhibitors are AbbVie, Actavis, Amgen, Baxter International Inc., Boehringer Ingelheim, Biogen Idec Inc., Eisai, GSK, Hospira, Inc., Johnson & Johnson, Merck, Mitsubishi Tanabe Pharma Corporation, Mylan, Novartis AG, Pfizer, Ranbaxy Laboratories Limited, Sandoz Inc., Stiefel Laboratories, Inc., a GSK Company, Takeda and Teva. Additional companies may develop or commercialize a biologic TNF inhibitor in the future. The resulting unlikelihood of an acquisition of us by these companies may reduce our future strategic options and the likelihood of our stockholders participating in a company sale transaction that could be financially attractive to them.

In addition, UCB has the right to terminate the UCB agreement with the same economic consequences if we consummate a change of control with a company that is not clinically developing or commercializing a biologic TNF inhibitor but that otherwise does not meet all of the following requirements:

- the company either (1) is engaged in the development or commercialization of a pharmaceutical product or (2) will maintain us as an operating entity and will maintain at least 50% of our executive management team for at least 12 months;
- the company has sufficient working capital to continue and complete our development obligations under the UCB agreement (taking into consideration any milestone payments to be made by UCB) and has the ability to obtain sufficient funding to perform the commercial and medical affairs activities and other obligations for which we are responsible under the UCB agreement; and
- if the change of control occurs prior to the date of the grant of first regulatory approval for Cimzia for the treatment of psoriasis in the United States, Canada or the European Union, the company agrees in writing to complete such development obligations.

It is therefore possible that other potential acquirers, even though not developing or commercializing a biologic TNF inhibitor, would not meet one or more of these criteria, making an acquisition of us by such a company unlikely, further reducing the ability of our stockholders to participate in a transaction that could be financially attractive to them.

We could have significant disputes with UCB over our collaboration, which could adversely impact our ability to obtain any of its intended benefits.

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We cannot ensure that UCB will fulfill its obligations under the UCB agreement. We may assert that UCB has not fulfilled its obligations, which UCB may dispute. UCB may assert that we have not fulfilled our obligations under the UCB agreement, which we may dispute. If UCB asserts that we have materially breached the UCB agreement and seeks to terminate the UCB agreement, our ability to realize the anticipated or any benefits from this collaboration would be adversely affected. Any disputes we have with UCB could lead to delays in, or termination of, the development and commercialization of Cimzia for the treatment of psoriasis and time-consuming and expensive arbitration. In any such dispute, UCB will have considerably more resources than we will to pursue such dispute, which may make it less likely that we will prevail in any such dispute, regardless of the relative merit of our position.

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We are dependent on UCB for product supply.

Under the UCB agreement, UCB is solely responsible for supplying sufficient quantities of Cimzia as well as the comparator drugs and placebo to be used in our planned Phase 3 clinical trials and any post-approval studies that are conducted. We are not permitted to obtain these materials from any other source. If we experience any interruption in product supply, potentially due to UCB's own dependencies on its suppliers, or due to damage to or destruction of its or its suppliers' facilities or equipment or noncompliance with regulatory requirements, or if we incorrectly forecast our product supply requirements or UCB incorrectly plans its manufacturing production, or if UCB were to allocate supplies of Cimzia to its commercial sales rather than to our development program, it could impact our ability to timely supply our clinical sites, and cause potentially serious delays in the timing of our clinical studies and substantially increased costs if studies need to be adjusted or re-performed.

UCB is also solely responsible for and controls all aspects of the manufacture, distribution and supply of Cimzia for commercialization, including providing any product samples that we may use in our marketing and promotion activities as well as the product that will be sold from which we would derive royalties and any sales-based milestone payments. If UCB experiences any interruption in product supply for any of the reasons described in the prior paragraph, or if UCB were to allocate its supplies of Cimzia to commercial sales attributable to physicians other than dermatologists, it could adversely impact the sales from which we derive such royalties and payments, and our financial results.

We have agreed with UCB to a scope of exclusivity that will prevent us from developing and commercializing a material category of products, which could harm our current and future business prospects, including the likelihood that we will be acquired.

We have agreed that, during the term of the UCB agreement, except in limited circumstances, we and our affiliates will not clinically develop, seek regulatory approval for or commercialize a biologic TNF inhibitor other than Cimzia, or promote any other biologic TNF inhibitor to any dermatologist in the United States or Canada. If, during the term of the UCB agreement, we acquire or are acquired by a third party that is clinically developing or commercializing a biologic TNF inhibitor, in addition to UCB's termination rights described above, we have agreed to either cease such clinical development or commercialization or divest such product candidate. These exclusivity obligations may inhibit our business opportunities by excluding an important class of products, TNF inhibitors, from potential development or commercialization by us. In addition, any acquirer of us would also be subject to these exclusivity obligations, which will potentially exclude companies that are or would consider developing or commercializing TNF inhibitors from acquiring us, which may reduce the likelihood of our being acquired in a transaction that could be beneficial to our stockholders.

UCB may determine that further development of Cimzia for the treatment of psoriasis poses a significant safety risk and terminate the UCB agreement, which would adversely affect our business.

The UCB agreement is terminable by UCB if it determines that a validated safety signal is established, the magnitude of which UCB determines constitutes a significant patient risk so that the development or commercialization of Cimzia should cease. In such event, while UCB would be obligated to reimburse us for certain costs we have incurred by paying to us royalties on sales of Cimzia in the United States and Canada, such reimbursement will likely take years, and if sales of Cimzia cease in all indications, we will likely never recoup such costs. In any event, if the UCB agreement were to be terminated for safety reasons, we would not be able to develop a dermatology-focused sales force using Cimzia as our initial commercial product or realize any royalties or sales-based milestones, and therefore our principal strategic and financial objectives in pursuing this collaboration would not be achieved.

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UCB has made very limited representations, warranties and indemnities to us regarding its ownership of and the validity of the intellectual property related to Cimzia, and that its and our activities in our collaboration will not infringe the intellectual property rights of third parties.

In the UCB agreement, UCB has made very limited representations, warranties and indemnities to us that the development of Cimzia for the treatment of psoriasis and the sale and promotion of Cimzia for the treatment of psoriasis and psoriatic arthritis will not infringe a patent or other intellectual property right of a third party, or that UCB's intellectual property related to Cimzia is valid. If third parties bring claims that the intellectual property relevant to the collaboration and Cimzia infringes the intellectual property rights of such third party, we or UCB could be enjoined from performing our activities under the UCB agreement, exposed to substantial damages or required to pay royalties to such third party, or any combination of these adverse effects. Any third-party royalties that would need to be paid in connection with the activities under our collaboration would be included in our cost of goods and therefore could reduce the financial benefits that we receive from sales of Cimzia. In addition, if a claim is made against us in connection with our collaboration, UCB may control the defense of such claim, and may make different decisions than we would make, potentially exposing us to increased liability.

Risks Related to Our Dependence on Third Parties other than UCB

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

We have in the past relied and expect to continue to rely on third-party CROs to conduct and oversee our clinical trials and other aspects of product development. We also rely upon various medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA's regulations and GCPs, which are an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, and state regulations governing the handling, storage, security and recordkeeping for drug and biologic products. These CROs and other third parties play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. We rely heavily on these parties for the execution of our clinical trials and preclinical studies, and control only certain aspects of their activities. We and our CROs and other third-party contractors are required to comply with GCP and GLP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCP and GLP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP and GLP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authority may require us to perform additional clinical trials before approving our or our partners marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical or preclinical trials complies with applicable GCP and GLP requirements. In addition, our clinical trials must generally be conducted with product produced under cGMP regulations. Our failure to comply with these regulations and