UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2016

or

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

For the transition period from to

Commission File Number 001-36668

DERMIRA, INC.
(Exact name of registrant as specified in its charter)

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

275 Middlefield Road, Suite 150
Menlo Park, CA 94025
(Address of principal executive offices) (Zip Code)

(650) 421-7200
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically 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	☐	Accelerated filer	☒
Non-accelerated filer	☐ (do not check if a smaller reporting company)	Smaller reporting company	☐

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

As of October 31, 2016, the registrant had 35,603,622 shares of common stock outstanding.

Dermira, Inc.
Quarterly Report on Form 10-Q
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PART I. FINANCIAL INFORMATION

ITEM 1. Financial Statements

DERMIRA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	September 30, 2016 (unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 55,656	$ 107,242
Short-term investments	186,266	107,451
Collaboration and license receivable	25,000	—
Prepaid expenses and other current assets	6,586	2,540
Total current assets	273,508	217,233
Property and equipment, net	413	386
Long-term investments	34,722	1,019
Intangible assets	1,126	1,126
Goodwill	771	771
Other assets	961	1,397
Total assets	$ 311,501	$ 221,932
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,226	$ 9,230
Accrued liabilities	19,175	16,666
Deferred revenue, current	3,298	—
Total current liabilities	28,699	25,896
Long-term liabilities:		
Deferred revenue, non-current	31,583	10,000
Deferred tax liability	194	194
Other long-term liabilities	156	367
Total liabilities	60,632	36,457
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock	—	—
Common stock	36	30
Additional paid-in capital	493,681	346,590
Accumulated other comprehensive loss	(99)	(97)
Accumulated deficit	(242,749)	(161,048)
Total stockholders' equity	250,869	185,475
Total liabilities and stockholders' equity	$ 311,501	$ 221,932

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

DERMIRA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Collaboration and license revenue	$ 119	$ 7,300	$ 119	$ 7,300
Operating expenses:				
Research and development	17,784	18,890	62,306	42,473
General and administrative	8,276	4,684	20,550	12,678
Total operating expenses	26,060	23,574	82,856	55,151
Loss from operations	(25,941)	(16,274)	(82,737)	(47,851)
Interest and other income, net	431	259	1,036	718
Interest expense	—	(39)	—	(115)
Net loss	$ (25,510)	$ (16,054)	$ (81,701)	$ (47,248)
Net loss per share, basic and diluted	$ (0.72)	$ (0.58)	$ (2.54)	$ (1.84)
Weighted-average common shares used to compute net loss per share, basic and diluted	35,429,586	27,553,952	32,178,234	25,645,246

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

DERMIRA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss	$ (25,510)	$ (16,054)	$ (81,701)	$ (47,248)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	(142)	77	(2)	189
Total comprehensive loss	$ (25,652)	$ (15,977)	$ (81,703)	$ (47,059)

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

DERMIRA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2016	**2015**
Cash flows from operating activities		
Net loss	$ (81,701)	$ (47,248)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	88	55
Stock-based compensation	7,920	3,668
Amortization of premiums on available-for-sale securities	1,267	1,515
Common stock issued in connection with license agreement	1,453	—
Changes in assets and liabilities:		
Collaboration and license receivable	(25,000)	—
Prepaid expenses and other current assets	(3,154)	(628)
Other assets	164	794
Accounts payable	(3,014)	1,164
Accrued liabilities	2,509	5,998
Other long-term liabilities	(211)	575
Deferred revenue	24,881	—
Net cash used in operating activities	(74,798)	(34,107)
Cash flows from investing activities		
Purchases of available-for-sale securities	(194,710)	(41,618)
Maturities of available-for-sale securities	80,031	36,155
Purchase of property and equipment	(105)	(80)
Net cash used in investing activities	(114,784)	(5,543)
Cash flows from financing activities		
Net proceeds from issuances of common stock	137,996	104,568
Net cash provided by financing activities	137,996	104,568
Net increase (decrease) in cash and cash equivalents	(51,586)	64,918
Cash and cash equivalents at beginning of year	107,242	55,358
Cash and cash equivalents at end of period	$ 55,656	$ 120,276

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

1. Organization

We are a biopharmaceutical company dedicated to identifying, developing and commercializing innovative, differentiated therapies to improve the lives of patients with dermatologic diseases. Our portfolio includes three late-stage product candidates that target significant unmet needs and market opportunities: Cimzia (certolizumab pegol), in Phase 3 development in collaboration with UCB Pharma S.A. ("UCB") for the treatment of moderate-to-severe chronic plaque psoriasis; DRM04, in Phase 3 development for the treatment of primary axillary hyperhidrosis, or excessive underarm sweating; and DRM01, in Phase 2b development for the treatment of acne vulgaris, or acne. Our corporate headquarters are located in Menlo Park, California.

On June 13, 2016, we closed an underwritten public offering pursuant to a registration statement on Form S-3 ("Shelf Offering") of 5,175,000 shares of our common stock sold by us, including 675,000 shares sold upon full exercise of the underwriters' option to purchase additional shares of common stock, at a price to the public of $28.00 per share. The gross proceeds to us from the Shelf Offering were $144.9 million, and the net proceeds to us, after deducting underwriting discounts and commissions of $8.7 million and offering expenses of $0.6 million, were $135.6 million.

2. Summary of Significant Accounting Policies

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

Basis of Presentation

Our condensed consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("U.S. GAAP") and applicable rules and regulations of the U.S. Securities and Exchange Commission ("SEC") for interim reporting. As permitted under those rules and regulations, certain footnotes or other financial information normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These condensed consolidated financial statements have been prepared on the same basis as our annual consolidated financial statements and, in the opinion of our management, reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair presentation of our financial information. The results of operations for the three- and nine-month periods ended September 30, 2016 are not necessarily indicative of the results to be expected for the full year ending December 31, 2016 or any other future period. The condensed consolidated balance sheet as of December 31, 2015 has been derived from audited consolidated financial statements at that date but does not include all of the information required by U.S. GAAP for complete financial statements.

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

The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with our audited consolidated financial statements and the related notes thereto for the year ended December 31, 2015 included in our Annual Report on Form 10-K, filed with the SEC on March 3, 2016.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the condensed consolidated financial statements and reported amounts of revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, investments, accrued research and development expenses, goodwill, intangible assets, other long-lived assets, stock-based compensation and the valuation of deferred tax assets. We base our estimates on our historical experience and also on assumptions that we believe are reasonable; however, actual results could significantly differ from those estimates.

Revenue Recognition

We generate revenue from collaboration and license agreements related to the development and commercialization of our product candidates. We recognize revenue when persuasive evidence of an arrangement exists, services have been performed or products have been delivered, the fee is fixed and determinable and collection is reasonably assured. Collaboration and license agreements may include non-refundable upfront payments or reimbursement of research and development costs, contingent

consideration payments based on achievement of defined milestones, and royalties on sales of commercialized products. Performance obligations under collaboration and license agreements may include the transfer of intellectual property rights, such as licenses, obligations to provide research and development services, product supply and regulatory approval services, and to participate on certain development and commercialization committees. Upfront payments are generally recorded as deferred revenue in the consolidated balance sheet and recognized as revenue over the estimated period of performance that is consistent with the terms of the obligations contained in the collaboration and license agreements. We regularly review the estimated periods of performance based on the progress made under each arrangement. The estimated performance period may change over the course of an arrangement's term. Such a change could have a material impact on the amount of revenue recorded in future periods.

Multiple Element Arrangements

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

Milestones and Other Contingent Payments

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

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

Risks and Uncertainties

Our product candidates 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 our current and future product candidates will receive the necessary approvals. If we are denied approval or approval is delayed, it may have a material adverse impact on our business and our financial condition.

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

Concentration of Credit Risk

Financial instruments that potentially subject us to a concentration of credit risk consist primarily of cash and cash equivalents, investments and receivables under our collaboration and license agreements. We invest our excess cash in money market funds, commercial paper, repurchase agreements, corporate debt and U.S. Government agency securities. Bank deposits are held primarily by a single financial institution and these deposits may exceed insured limits. We are exposed to credit risk in the event of a default by the financial institution holding our cash and cash equivalents and issuers of investments to the extent recorded on the condensed

consolidated balance sheets. Our investment policy limits investments to money market funds, certain types of debt securities issued by the U.S. Government and its agencies, repurchase agreements, commercial paper, municipal bonds and corporate debt and places restrictions on the credit ratings, maturities and concentration by type and issuer.

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

Fair Value of Financial Instruments

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

We measure 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 our cash and cash equivalents, investments, collaboration and license receivable, prepaid expenses, accounts payable and accrued liabilities approximate fair value due to their short maturities.

Our non-financial assets, such as intangible assets and property, plant and equipment, are recorded at fair value and adjusted if an impairment charge is recognized.

Offering Costs

Offering costs, consisting of legal, accounting, filing and other directly related fees from each public offering of shares of our common stock, are offset against proceeds from such public offering. Offering costs incurred prior to the completion of an offering are initially recorded in other assets, evaluated each period for likelihood of completion and subsequently reclassified to additional paid-in capital upon completion of the offering.

Research and Development Expenses

We expense research and development costs as they are incurred. Our research and development expenses consist primarily of costs incurred for the development of our 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; (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 or data license agreements.

Accrued Research and Development Expenses

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

Our CRO for the Cimzia Phase 3 program (“Cimzia CRO”) can earn bonuses or incur penalties based on the Cimzia CRO’s achievement of certain milestones specified in the agreement. If, in any period, it becomes probable that the Cimzia CRO would earn a bonus and the amount is estimable, we would recognize the full amount of such bonus in that same period as an expense, even if the bonus would not be earned by and paid to the Cimzia CRO until the milestone is achieved. If the Cimzia CRO incurs a penalty, it has the right to recoup such penalty if it achieves a subsequent milestone. In this case, we would continue to maintain the full amount owed to the Cimzia CRO until the right of recoupment has expired.

We make significant judgments and estimates in determining the accrual balance in each reporting period. As actual costs become known, we adjust our accruals. Although we do not expect our estimates to be materially different from amounts actually incurred, such estimates for the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any particular period. Our accrual is dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. To date, there have been no material differences between our accrued estimated expenses and the actual clinical trial expenses. However, variations in the assumptions used to estimate accruals including, but not limited to, the number of patients enrolled, the rate of patient enrollment and the actual services performed, may vary from our estimates, resulting in adjustments to clinical trial expenses in future periods. Changes in these estimates that result in material changes to our accruals could materially affect our condensed consolidated financial condition and results of operations.

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.

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

	Outstanding as of September 30,	
	2016	2015
Options to purchase common stock	4,460,024	3,718,828
Restricted stock units	147,634	—
Estimated shares issuable under the employee stock purchase plan	82,972	110,463
	4,690,630	3,829,291

Recent Accounting Pronouncements

In August 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"), which will make eight targeted changes to how cash receipts and cash payments are presented and classified in the statement of cash flows. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017. ASU 2016-15 will require adoption on a retrospective basis. Early adoption is permitted. We are currently evaluating the impact that the adoption of ASU 2016-15 will have on our consolidated financial statements and related disclosures.

In June 2016, the FASB issued Accounting Standards Update 2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), which requires measurement and recognition of expected credit losses for financial assets held. ASU 2016-13 modifies the other-than-temporary impairment model for available-for-sale debt securities and requires an estimate of expected credit losses when the fair value is below the amortized cost of the asset. ASU 2016-13 is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. Early adoption is permitted. We are currently evaluating the impact that the adoption of ASU 2016-13 will have on our consolidated financial statements and related disclosures.

In March 2016, the FASB issued Accounting Standards Update 2016-09, *Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"), which amends Accounting Standards Codification Topic 718, *Compensation — Stock Compensation*. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016 and interim periods within those fiscal years. Early adoption is permitted. We are currently evaluating the impact that the adoption of ASU 2016-09 will have on our consolidated financial statements and related disclosures.

In February 2016, the FASB issued Accounting Standards Update 2016-02, *Leases* ("ASU 2016-02"). ASU 2016-02 is aimed at making leasing activities more transparent and comparable, and requires lessees to recognize substantially all leases on their balance sheet as a right-of-use asset and a corresponding lease liability, including leases currently accounted for as operating leases. ASU 2016-02 is effective for interim and annual reporting periods during the year ending December 31, 2019 and all interim and annual reporting periods thereafter. Early adoption is permitted. We are currently evaluating the impact that the adoption of ASU 2016-02 will have on our consolidated financial statements and related disclosures.

In January 2016, the FASB issued Accounting Standards Update 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities* ("ASU 2016-01"). ASU 2016-01 made modifications to how certain financial instruments should be measured and disclosed, including using the exit price notion when measuring the fair value, separating the presentation of financial assets and financial liabilities by measurement category on the balance sheet and eliminating the requirement to disclose the method and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet. ASU 2016-01 is effective for interim and annual reporting periods during the year ending December 31, 2018 and all interim and annual reporting periods thereafter. We are currently evaluating the impact that the adoption of ASU 2016-01 will have on our consolidated financial statements and related disclosures.

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 was initially effective for the fiscal years and interim reporting periods beginning after December 15, 2016; however, in July 2015, the FASB deferred the effective date to annual reporting periods beginning after December 15, 2017 (including interim periods within those periods). Early adoption is permitted to the original effective date of December 15, 2016 (including interim periods within those periods). ASU 2014-09 will be effective for the first fiscal quarter of 2018, using one of two retrospective application methods. We have not selected a transition method and are currently assessing the future impact of ASU 2014-09 on our consolidated financial statements and related disclosures.

3. Fair Value Measurements

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

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

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

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

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

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

	As of September 30, 2016			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 8,879	$ —	$ —	$ 8,879
Corporate debt	—	163,840	—	163,840
Repurchase agreements	—	22,000	—	22,000
U.S. Government agency securities	—	39,479	—	39,479
Commercial paper	—	41,664	—	41,664
Total financial assets	$ 8,879	$ 266,983	$ —	$ 275,862

	As of December 31, 2015			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 203	$ —	$ —	$ 203
Corporate debt	—	108,470	—	108,470
Repurchase agreements	—	106,635	—	106,635
Total financial assets	$ 203	$ 215,105	$ —	$ 215,308

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

See Note 4 for further details on the financial instruments that were measured at fair value.

4. Investments

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

	As of September 30, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Financial assets:				
Money market funds	$ 8,879	$ —	$ —	$ 8,879
Corporate debt	163,945	13	(118)	163,840
Repurchase agreements	22,000	—	—	22,000
U.S. Government agency securities	39,473	8	(2)	39,479
Commercial paper	41,664	—	—	41,664
Total investments	$ 275,961	$ 21	$ (120)	$ 275,862

	As of December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Financial assets:				
Money market funds	$ 203	$ —	$ —	$ 203
Corporate debt	108,567	17	(114)	108,470
Repurchase agreements	106,635	—	—	106,635
Total investments	$ 215,405	$ 17	$ (114)	$ 215,308

As of September 30, 2016, we did not hold any investments with a maturity exceeding two years. Unrealized losses related to investments in a continuous loss position for 12 months or more were insignificant. We do not intend to sell the securities and it is more likely than not that the investments will be held until recovery of the amortized cost bases. There were no realized gains or losses on the available-for-sale securities during the three or nine months ended September 30, 2016 or 2015.

5. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
Accrued outside research and development services	$ 13,864	$ 12,373
Accrued compensation	4,468	3,848
Accrued professional and consulting services	766	297
Other	77	148
Total accrued liabilities	$ 19,175	$ 16,666

6. Commitments and Contingencies

Facility Lease

We lease our corporate headquarters in Menlo Park, California under a non-cancelable operating lease agreement initially entered into in July 2014 and amended in September 2014 ("Initial Lease"). Pursuant to the Initial Lease, we leased 18,651 square feet of space in a multi-suite building. Rent payments under the Initial Lease included base rent of $97,918 per month during the first year of the Initial Lease with an annual increase of three percent, and additional monthly fees to cover our share of certain facility expenses, including utilities, property taxes, insurance and maintenance, which were $22,381 per month during the first year of the Initial Lease.

The Initial Lease was amended in December 2015 to provide for our lease of an additional 26,541 square feet of space in the building, commencing December 2016 ("Amended Lease"). Rent payments for the additional space included base rent of $135,426 per month during the first year of the Amended Lease period with an annual increase of three percent, and additional monthly fees to cover our share of certain facility expenses, including utilities, property taxes, insurance and maintenance, which are estimated to be $30,954 per month during the first year of the Amended Lease period.

The Amended Lease was further amended to accelerate our lease commencement date for the additional space, subject to certain conditions, from December 2016 to (1) May 2016 with respect to 2,882 square feet of the additional space, and (2) October 2016 with respect to 23,659 square feet of the additional space (as further amended, "Lease"). The Lease will expire on December 31, 2021, subject to our option to renew the Lease for an additional five-year term.

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

Rent expense was $0.5 million and $0.4 million for the three months ended September 30, 2016 and 2015, respectively, and $1.3 million and $1.1 million for the nine months ended September 30, 2016 and 2015, respectively. The terms of the Lease provide for rental payments on a monthly basis on a graduated scale. We recognize rent expense on a straight-line basis over the lease period and have accrued for rent expense incurred but not paid.

CRO Agreement

Per the terms of our agreement with our CRO for the Cimzia Phase 3 program, the Cimzia CRO can earn bonus payments or incur penalties (which are adjusted from the total amount payable pursuant to the agreement) based on the achievement of milestones specified in the agreement. The Cimzia CRO can earn a maximum aggregate bonus of $3.6 million and incur a maximum aggregate penalty of $3.2 million. If, in any period, it becomes probable that the Cimzia CRO would earn a bonus and the amount is estimable, we would recognize the full amount of such bonus in that same period as an expense, even if the bonus would not be earned by and paid to the Cimzia CRO until the milestone is achieved. If the Cimzia CRO incurs a penalty, it has the right to recoup the applicable amount if it achieves a subsequent milestone, and the Cimzia CRO would adjust subsequent billings as necessary to reflect such penalty and any recouped amount. If the Cimzia CRO incurs a penalty prior to the expiration of the right of recoupment, we would maintain the full amount owed to the Cimzia CRO in either accrued liabilities or other long-term liabilities, as appropriate, in our condensed consolidated balance sheet until (1) the right of recoupment has expired, at which time we would reflect the amount as a reduction in operating expenses and eliminate the liability, or (2) the Cimzia CRO has recouped the penalty, at which time we would increase the payment to the Cimzia CRO by the recouped amount and eliminate the liability. As of September 30, 2016, we have not

recognized an increase in expense for a bonus earned, or a decrease in expense for a penalty incurred, under the agreement in our condensed consolidated statements of operations.

Contingencies

Pursuant to a development and commercialization agreement we entered into with UCB, a related party, in March 2014 ("UCB Agreement"), we are responsible for paying all development costs specified under the UCB Agreement and incurred in connection with the development plan up to a specified amount that is greater than $75.0 million and less than $95.0 million, plus our internal development costs. Development costs include the costs of Cimzia, etanercept and placebo clinical trial materials used in the Phase 3 clinical program. UCB is responsible for providing these clinical trial materials and we reimburse UCB for such costs. In addition to clinical trial materials used in the study, we are financially responsible for unused clinical drug supplies at the conclusion of the study. We cannot determine the exact amounts of unused clinical drug supplies until all patients have completed treatment. Based on currently available data, we estimate that the additional loss contingency related to unused clinical drug supplies is $0.1 million. As a result, we recorded a charge of $0.1 million to research and development expense for the three months ended September 30, 2016 for the loss contingency related to unused clinical drug supplies. For the nine months ended September 30, 2016, we recorded a charge of $1.6 million to research and development expense for the loss contingency related to unused clinical drug supplies. There were no contingency losses related to unused clinical drug supplies recorded in the three and nine months ended September 30, 2015.

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

Indemnification

We enter into standard indemnification agreements in the ordinary course of business. Pursuant to these arrangements, we indemnify, hold harmless and agree 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 our technology. The term of these indemnification agreements is generally perpetual after the execution of the agreement. The maximum potential amount of future payments we could be required to make under these agreements is not determinable because it involves claims that may be made against us in the future, but have not yet been made. We have not incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

We have entered into indemnification agreements with our directors and officers that may require us to indemnify our 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.

7. Technology and Financing Agreements

Maruho Agreements

In March 2013, we entered into a Right of First Negotiation Agreement with Maruho Co., Ltd. ("Maruho Right of First Negotiation Agreement"). Under the terms of the agreement, we provided Maruho Co., Ltd. ("Maruho") with certain information and the right to negotiate an exclusive license to develop and commercialize certain of our product candidates in specified territories. In connection with the entry into the Maruho Right of First Negotiation Agreement, Maruho paid us a non-refundable upfront payment of $10.0 million, which will be credited against certain payments payable by Maruho to us if we and Maruho enter into an exclusive license for any of our products. If we do not enter into such an arrangement with Maruho, we will be entitled to keep the funds without further obligation. As of September 30, 2016 and December 31, 2015, we recorded the $10.0 million related to the Maruho Right of First Negotiation Agreement as deferred revenue in our condensed consolidated balance sheets related to this agreement. 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 September 2016, we entered into an Exclusive License Agreement with Maruho, which grants Maruho an exclusive license to develop and commercialize DRM04 for the treatment of hyperhidrosis in Japan ("Maruho DRM04 Agreement"). Pursuant to the terms of the Maruho DRM04 Agreement, we received an upfront payment of $25.0 million from Maruho in October 2016 and are eligible to receive additional payments totaling up to $70.0 million, contingent upon the achievement of certain milestones associated with submission and approval of a marketing application in Japan and certain sales thresholds, as well as royalty payments based on a percentage of net product sales in Japan. The Maruho DRM04 Agreement further provides that Maruho will be responsible for funding all development and commercial costs for the program in Japan and, until such time, if any, as Maruho elects to establish its own source of supply of drug product, Maruho will purchase product supply from us for development and, if applicable, commercial

purposes at cost. The Maruho DRM04 Agreement is unrelated to, and the exclusive license of DRM04 in Japan to Maruho was not subject to the terms of, the existing Maruho Right of First Negotiation Agreement.

We identified the following non-contingent deliverables under the Maruho DRM04 Agreement: (1) the transfer of intellectual property rights (the "license"), and (2) the supply of drug materials for clinical development purposes. We concluded that the license is not a separate unit of accounting because Maruho cannot obtain benefit from the use of the license rights for their intended purpose without the product supplied by us. Even if Maruho elects to establish its own supply of drug product, it must rely upon us to supply the drug substance necessary for Maruho's development because Maruho does not have the right to manufacture the drug substance. We determined that neither of the deliverables has standalone value and, therefore, the deliverables are accounted for as one combined unit of accounting, with the upfront payment recognized as revenue on a straight-line basis over the estimated period of performance of approximately eight years.

Milestone payments under the Maruho DRM04 Agreement could total up to $70.0 million. The achievement of any and all milestones is dependent solely upon the results of Maruho's activities and, therefore, the milestones are not deemed to be substantive. If regulatory approval for DRM04 is achieved and the product is commercialized in Japan, we would recognize any royalty revenue received from Maruho based on Maruho's net sales of the drug product in Japan.

Unless earlier terminated, the Maruho DRM04 Agreement will remain in effect until the later of: (1) expiration or abandonment of the last valid claim of the applicable patent rights in Japan; (2) expiration of any market exclusivity in Japan granted by the applicable regulatory authority; and (3) 15 years following the date of the first commercial sale of the drug product in Japan.

For both the three and nine months ended September 30, 2016, we recognized collaboration and license revenue of $0.1 million related to the $25.0 million upfront payment received in connection with the Maruho DRM04 Agreement. In addition, as of September 30, 2016, we recorded a collaboration and license receivable of $25.0 million and deferred revenue of $24.9 million.

Rose U Agreement

In April 2013, we entered into an exclusive license agreement with Rose U, LLC to license certain patents, patent applications and know-how related to our DRM04 program. This agreement includes a sublicense and assignment of certain know-how licensed and assigned to Rose U by Stiefel Laboratories, Inc., a GSK company ("Stiefel"), the prior licensee of such patents. In connection with this agreement, we also entered into a letter agreement with Stiefel. As of September 30, 2016, we have paid license and other fees of $0.5 million to Rose U and are required to pay additional amounts totaling up to $4.4 million upon the achievement of specified development, commercialization and other milestones under these agreements to Rose U and Stiefel. In addition, we are also obligated to pay Rose U low-to-mid single-digit royalties on net product sales and low double-digit royalties on sublicense fees and certain milestone, royalty and other contingent payments received from sublicensees, to the extent such amounts are in excess of the milestone and royalty payments we are obligated to pay Rose U directly upon the events or sales triggering such payments.

UCB (a Related Party) Agreement

In March 2014, we entered into the UCB Agreement which provides that we will develop Cimzia for the treatment of psoriasis in order for UCB to seek regulatory approval from the FDA, European Medicines Agency ("EMA") and the Canadian federal department for health ("Health Canada"), and upon the grant of regulatory approval in the United States and Canada, for us 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.

We have 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. We are responsible for development costs under the development plan up to a specified cap that is greater than $75.0 million and less than $95.0 million, plus our internal development costs. Development costs under the development plan include the costs of clinical trial materials, which are supplied by UCB and paid by us. Any development costs in excess of the specified 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. We incurred expenses related to clinical materials supplied by UCB totaling $0.7 million and $0.9 million for the three months ended September 30, 2016 and 2015, respectively, and $5.1 million and $1.1 million for the nine months ended September 30, 2016 and 2015, respectively. As of September 30, 2016, we recorded $2.6 million in prepaid expense and other current assets and $0.7 million in accounts payable related to UCB. As of December 31, 2015, we recorded $0.9 million and $2.4 million in accounts payable and accrued liabilities, respectively, due to UCB.

UCB is obligated to pay us 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. The UCB Agreement has two deliverables that represent two units of accounting, which are (1) the delivery of services related to the development of Cimzia for the treatment of moderate-to-severe chronic plaque psoriasis and (2) the marketing services needed to commercialize Cimzia in the United States and Canada. At the date of execution of the UCB Agreement, potential future payments eligible to be received upon the achievement of development and regulatory milestones were all considered to be substantive. As such, any milestone payment would be recognized in its entirety in the period in which the milestone event is achieved and collectability is reasonably assured. Any royalties and sales-based milestone payments would be recognized as revenue when earned and realizable.

In December 2014, we earned the first development milestone of $7.3 million for dosing of the first patient in the Phase 3 clinical program for Cimzia and recorded the amount as collaboration and license revenue in the consolidated statements of operations for the year ended December 31, 2014. In September 2015, we earned the second development milestone of $7.3 million for the completion of patient enrollment in a Phase 3 clinical trial for Cimzia and recorded the amount as collaboration and license revenue in the consolidated statements of operations for the three and nine months ended September 30, 2015. As a result of achieving these milestones, there is $21.4 million in remaining development milestone payments that we are eligible to receive. No collaboration and license revenue from UCB was recognized for the three or nine months ended September 30, 2016.

Under the terms of the UCB Agreement, we 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 us 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 us 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 us receiving the balance, of such annual gross profits. In addition, UCB is obligated to pay us up to an aggregate of $40.0 million upon the achievement of tiered milestones based on annual net sales of Cimzia attributed to dermatologists in the United States and Canada.

As of September 30, 2016, UCB beneficially owned 1,841,234 shares of our outstanding common stock. Pursuant to the UCB Agreement, UCB is entitled to designate one member to our board of directors, subject to the terms of the UCB Agreement. Mark McDade, who most recently served as an Executive Vice President and the Chief Operating Officer of UCB S.A., is currently serving as UCB's designee to our board of directors.

8. Stock-Based Compensation

In 2010, we adopted the 2010 Equity Incentive Plan ("2010 Plan"), which provided for the granting of stock options to our employees, directors and consultants. In September 2014, our board of directors approved the 2014 Equity Incentive Plan ("2014 EIP"), which became effective on October 1, 2014. As of the effective date of the 2014 EIP, the 2010 Plan was terminated and no further stock awards will be granted pursuant to the 2010 Plan. Outstanding stock options granted under the 2010 Plan will continue to be governed by the provisions of the 2010 Plan until the earlier of the stock option's expiration or exercise. In September 2014, our board of directors approved the 2014 Employee Stock Purchase Plan ("2014 ESPP"), which became effective on October 2, 2014. As of September 30, 2016, we had 1,206,496 and 758,176 shares reserved and available for future issuance under the 2014 EIP and 2014 ESPP, respectively.

The following table reflects a summary of stock option activity and related information for the period from December 31, 2015 through September 30, 2016:

	Outstanding Options	Weighted-Average Exercise Price Per Share
Options outstanding at December 31, 2015	3,814,342	$ 9.19
Options granted	1,042,390	26.60
Options exercised	(342,771)	4.95
Options forfeited	(53,937)	21.60
Options outstanding at September 30, 2016	4,460,024	13.44

During the nine months ended September 30, 2016, we granted certain employees 161,985 restricted stock units ("RSUs"). The fair value of RSUs is determined based on the value of the underlying common stock on the date of grant. The expenses relating to

these RSUs will be recognized over their respective vesting periods. The following table reflects a summary of RSU activity under our 2014 EIP and related information for the period from December 31, 2015 through September 30, 2016:

	Outstanding RSUs	Weighted-Average Grant Date Fair Value per Share
RSUs outstanding at December 31, 2015	—	—
RSUs granted	161,985	$ 27.14
RSUs vested and settled	(13,641)	26.37
RSUs forfeited	(710)	26.37
RSUs outstanding at September 30, 2016	147,634	27.21

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development	$ 1,020	$ 541	$ 2,964	$ 1,401
General and administrative	1,845	920	4,956	2,267
Total stock-based compensation expense	$ 2,865	$ 1,461	$ 7,920	$ 3,668

There were no capitalized stock-based compensation costs or recognized stock-based compensation tax benefits during the three or nine months ended September 30, 2016 or 2015.

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

The interim financial statements included in this Quarterly Report on Form 10-Q and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the consolidated financial statements and notes thereto for the year ended December 31, 2015, included as part of our Annual Report on Form 10-K for the year ended December 31, 2015, and our unaudited Condensed Consolidated Financial Statements for the three- and nine-month periods ended September 30, 2016 and other disclosures (including the disclosures under "Part II — Other Information, Item 1A. Risk Factors") included in this Quarterly Report on Form 10-Q. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended ("Exchange Act"). These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "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. Except as may be required by law, we disclaim any obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

We are a biopharmaceutical company dedicated to identifying, developing and commercializing innovative, differentiated therapies to improve the lives of patients with dermatologic diseases. Our management team has extensive experience in product development and commercialization, having served in leadership roles at several leading dermatology companies. Our portfolio includes three late-stage product candidates that target significant unmet needs and market opportunities: Cimzia (certolizumab pegol), in Phase 3 development in collaboration with UCB Pharma S.A. ("UCB") for the treatment of moderate-to-severe chronic plaque psoriasis; DRM04, in Phase 3 development for the treatment of primary axillary hyperhidrosis, or excessive underarm sweating; and DRM01, in Phase 2b development for the treatment of acne vulgaris, or acne.

Since our founding in 2010, we have executed three transactions resulting in our portfolio of product candidates. In August 2011, we acquired Valocor Therapeutics, Inc., which gave us rights to a portfolio of intellectual property and product candidates to treat acne and inflammatory skin diseases. In April 2013, we entered into agreements with Rose U, LLC and Stiefel Laboratories, Inc., a GSK company ("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 ("UCB Agreement").

Our three late-stage product candidates are:

- Cimzia, an injectable biologic tumor necrosis factor-alpha inhibitor that is currently approved and marketed by UCB for the treatment of numerous inflammatory diseases spanning multiple medical specialties in multiple countries, including the United States. In March 2014, we entered into the UCB Agreement to develop Cimzia for the treatment of moderate-to-severe chronic plaque psoriasis in the United States, Canada and the European Union and, upon regulatory approval, to market Cimzia to dermatologists in the United States and Canada. We commenced a Phase 3 clinical program for Cimzia in moderate-to-severe chronic plaque psoriasis in December 2014. We completed patient enrollment in the three clinical trials comprising the Phase 3 program in September 2015, November 2015 and December 2015. In October 2016, we announced positive topline results for CIMPASI-2, the first of the three clinical trials to complete patient enrollment. In the CIMPASI-2 trial, Cimzia demonstrated statistically significant improvements for both co-primary endpoints compared to placebo at both treatment doses. We expect to announce topline results from the remaining two Phase 3 trials on a sequential basis by the end of the first quarter of 2017.
- DRM04, a small-molecule anticholinergic product for topical application that we are developing for the treatment of primary axillary hyperhidrosis. We commenced a Phase 3 clinical program for DRM04 in patients with primary axillary hyperhidrosis in July 2015. We completed patient enrollment in the two pivotal clinical trials, ATMOS-1 and ATMOS-2, comprising the Phase 3 program in February 2016 and announced positive topline results from these trials in June 2016. The ATMOS-1 and ATMOS-2 trials enrolled a total of 697 adult and adolescent patients (ages nine and older). In the ATMOS-2 trial, DRM04 demonstrated statistically significant improvements for both co-primary endpoints and both secondary endpoints compared to vehicle. In the ATMOS-1 trial, DRM04 demonstrated statistically significant improvements for one of the co-primary endpoints and both secondary endpoints. These results were based on the overall dataset from the intent-to-treat population. For the second co-primary endpoint in the ATMOS-1 trial, when extreme outlier data from one analysis center were excluded in accordance with the pre-specified statistical analysis plan submitted to the U.S. Food and Drug Administration ("FDA"), DRM04 demonstrated statistically significant results compared to vehicle. Consistent with the results of an earlier Phase 2b trial, DRM04 was generally well-tolerated with side effects that were primarily mild to moderate in severity. Based on these results, we plan to submit a New Drug Application ("NDA") to the FDA for potential approval of DRM04. The NDA submission is targeted for the second half of 2017 and is subject to the completion of the open-label ARIDO Phase 3 trial expected by the end of 2016, other registration-enabling activities and a pre-NDA meeting with the FDA.
- DRM01, a novel, small molecule designed to inhibit sebum production following topical application that we are developing for the treatment of acne. In April 2015, we commenced a Phase 2b dose-ranging clinical trial to evaluate the safety and efficacy of DRM01 in adult patients with moderate-to-severe facial acne vulgaris. In January 2016, we completed patient enrollment in this study and in May 2016 we announced positive topline results. In the Phase 2b dose-ranging trial, which enrolled a total of 420 patients, DRM01 demonstrated statistically significant improvements in all primary endpoints compared to vehicle at the highest dose and in most primary endpoints at the other doses. DRM01 was well-tolerated with adverse events primarily mild or moderate in severity. Based on these results and an end-of-Phase 2 meeting with the FDA, we plan to initiate a Phase 3 program to evaluate the safety and efficacy of DRM01 as a potential treatment for acne in adult and adolescent patients (ages nine and older) in the first half of 2017.

Key Developments

Following is a summary of selected key developments affecting our business that have occurred since December 31, 2015.

- *Presented data from DRM01 and DRM04 clinical programs.* In October 2016, data were presented from our Phase 2b dose-ranging study for DRM01 in patients with facial acne vulgaris and our Phase 3 clinical program for DRM04 in patients with primary axillary hyperhidrosis.
- *Announced topline results from the first of three Phase 3 trials for Cimzia in patients with psoriasis.* In October 2016, we announced positive topline results from CIMPASI-2, a Phase 3, multi-center, placebo-controlled clinical trial evaluating the efficacy and safety of Cimzia in adult patients with moderate-to-severe chronic plaque psoriasis and one of three Phase 3 trials comprising the Cimzia Phase 3 program. In the trial, CIMPASI-2 demonstrated statistically significant improvements for both co-primary endpoints compared to placebo at both treatment doses.
- *Licensed DRM04 to Maruho for hyperhidrosis in Japan.* In September 2016, we entered into a license agreement pursuant to which we granted Maruho Co., Ltd. ("Maruho") an exclusive license to develop and commercialize DRM04 for the treatment of hyperhidrosis in Japan ("Maruho DRM04 Agreement"). Maruho is responsible for

funding all development and commercial costs for the program in Japan. In connection with this agreement, we received an upfront payment of $25.0 million. We are eligible to receive potential additional payments totaling up to $70.0 million contingent on the achievement of certain milestones associated with submission and approval of a marketing application and certain sales thresholds, as well as royalty payments representing up to a low double-digit percentage of net product sales, in Japan.

- *Acquired option to license exclusive rights for up to three early-stage programs from Takeda.* In September 2016, we announced an agreement with Takeda Pharmaceutical Company Limited ("Takeda") pursuant to which we acquired the right to evaluate and conduct research on Takeda compounds directed to each of three biological targets and an option to license exclusive worldwide rights to selected compounds from each of these three programs ("Takeda Agreement"). In exchange for these rights, we paid Takeda an upfront fee of $1.5 million, issued in the form of shares of our common stock. If we exercise our option for any program, we would obtain an exclusive, worldwide license to develop and commercialize selected compounds from that program for the topical treatment of dermatologic diseases and be obligated to pay Takeda an option exercise fee and potential milestone and royalty payments.
- *Completed end-of-Phase 2 meeting for DRM01.* In September 2016, we held an end-of-Phase 2 meeting with the FDA for our DRM01 program based on the results of our Phase 2b study and in advance of initiation of a Phase 3 program.
- *Closed public offering of common stock.* In June 2016, we closed an underwritten public offering pursuant to a registration statement on Form S-3 ("Shelf Offering") of 5,175,000 shares of our common stock sold by us, including 675,000 shares sold upon full exercise of the underwriters' option to purchase additional shares of common stock, at a price to the public of $28.00 per share. The gross proceeds to us from the Shelf Offering were $144.9 million, and the net proceeds to us, after deducting underwriting discounts and commissions of $8.7 million and offering expenses of approximately $0.6 million, were approximately $135.6 million.
- *Announced topline Phase 3 pivotal clinical trial results for DRM04 in patients with hyperhidrosis.* In June 2016, we announced topline results from our Phase 3 ATMOS-1 and ATMOS-2 pivotal trials for DRM04, a topical anticholinergic product candidate in development for patients with primary axillary hyperhidrosis. The clinical trials evaluated the safety and efficacy of DRM04 compared to vehicle. Consistent with the results of an earlier Phase 2b trial, DRM04 was generally well-tolerated with side effects that were primarily mild to moderate in severity.
- *Announced topline Phase 2b clinical trial results for DRM01 in patients with acne.* In May 2016, we announced topline results for our Phase 2b dose-ranging study for DRM01 in patients with facial acne vulgaris. The clinical study evaluated the safety and efficacy of DRM01 and demonstrated statistically significant improvements in all primary endpoints compared to vehicle at the highest dose and in most primary endpoints at the other doses. DRM01 was well-tolerated with adverse events primarily mild or moderate in severity.
- *Completed patient enrollment for DRM04 Phase 3 pivotal clinical trials in patients with hyperhidrosis.* In February 2016, we completed patient enrollment in the ATMOS-1 and ATMOS-2 Phase 3 pivotal clinical trials of DRM04 in patients with primary axillary hyperhidrosis. The ATMOS-1 and ATMOS-2 Phase 3 trials were designed as identical, randomized, double-blind, vehicle-controlled studies to assess the safety and efficacy of DRM04 compared to vehicle to support a potential New Drug Application submission to the FDA. A total of 697 patients were enrolled in the two trials.
- *Completed patient enrollment for DRM01 Phase 2b clinical program in patients with acne.* In January 2016, we completed patient enrollment in the DRM01 Phase 2b clinical trial. The DRM01 Phase 2b trial was a randomized, multi-center, double-blind, parallel-group, vehicle-controlled study that enrolled 420 patients. The study was designed to assess the safety and efficacy of DRM01 compared to vehicle and to establish the optimal dose for a potential Phase 3 program.

Financial Overview

For the three months ended September 30, 2016, net loss increased 59% to $25.5 million from $16.1 million for the three months ended September 30, 2015. We recognized collaboration and license revenue of $0.1 million related to the Maruho DRM04 Agreement for the three months ended September 30, 2016 and $7.3 million for the achievement of a substantive milestone pursuant to the UCB Agreement for the three months ended September 30, 2015. Research and development expenses decreased 6% to $17.8 million for the three months ended September 30, 2016 compared to the same period in 2015, driven primarily by a reduction in clinical trial activities for our product candidates, partially offset by growth in internal costs and other research and development expenses. General and administrative expenses increased 77% to $8.3 million for the three months ended September 30, 2016

compared to the same period in 2015, driven primarily by headcount growth and associated expenses and a transaction advisory fee paid in connection with the Maruho DRM04 Agreement.

For the nine months ended September 30, 2016, net loss increased 73% to $81.7 million from $47.2 million for the nine months ended September 30, 2015. We recognized collaboration and license revenue of $0.1 million related to the Maruho DRM04 Agreement for the nine months ended September 30, 2016 and $7.3 million for the achievement of a substantive milestone pursuant to the UCB Agreement for the nine months ended September 30, 2015. Research and development expenses increased 47% to $62.3 million for the nine months ended September 30, 2016 compared to the same period in 2015, driven primarily by the advancement of our Cimzia and DRM04 product candidates. General and administrative expenses increased 62% to $20.6 million for the nine months ended September 30, 2016 compared to the same period in 2015, driven primarily by headcount growth and associated expenses.

As of September 30, 2016, we had cash and cash equivalents and investments of $276.6 million.

Since our inception, we have devoted substantially all of our efforts to developing our product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. We have financed our operations primarily through the sale of equity securities and convertible debt securities, including the sale of common stock in our initial public offering and subsequent public offerings. We do not have any approved products and have never generated any revenue from product sales. Other than the revenue we may generate in connection with our agreements with UCB and Maruho, we do not expect to generate any revenue from any product candidates that we develop unless and until we obtain regulatory approval and commercialize our products or enter into other collaboration or license agreements with third parties for the development or license of those product candidates.

We have never been profitable and may never be profitable. As of September 30, 2016, we had an accumulated deficit of $242.7 million. We expect to continue to incur net losses for the foreseeable future as we advance our current and potential additional product candidates through clinical development, seek regulatory approval for them and prepare for and proceed to commercialization. We expect to incur significant commercialization costs in advance of any of our product candidates receiving regulatory approval. As a result, we will need substantial additional funding to support our operating activities. Adequate funding may not be available to us on acceptable terms, or at all. We currently anticipate that we will seek to fund our operations through public or private equity or debt financings or other sources, such as potential collaboration or license agreements. Our failure to obtain sufficient funds on acceptable terms as and when needed could have a material adverse effect on our business, results of operations and financial condition.

Results of Operations

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2016	2015	$	%	2016	2015	$	%
	(in thousands, except percentages)							
Collaboration and license revenue	$ 119	$ 7,300	$ (7,181)	*	$ 119	$ 7,300	$ (7,181)	*
Operating expenses:								
Research and development	17,784	18,890	(1,106)	(6)	62,306	42,473	19,833	47
General and administrative	8,276	4,684	3,592	77	20,550	12,678	7,872	62
Total operating expenses	26,060	23,574	2,486	11	82,856	55,151	27,705	50
Loss from operations	(25,941)	(16,274)	(9,667)	59	(82,737)	(47,851)	(34,886)	73
Interest and other income, net	431	259	172	66	1,036	718	318	44
Interest expense	—	(39)	39	*	—	(115)	115	*
Net loss	$ (25,510)	$ (16,054)	$ (9,456)	59%	$ (81,701)	$ (47,248)	$ (34,453)	73%

* Percentage not meaningful

Revenue. Our revenue has been comprised of upfront and milestone payments in connection with the UCB Agreement and the Maruho DRM04 Agreement.

We recognized $0.1 million in collaboration and license revenue for the three and nine months ended September 30, 2016 related to the $25.0 million upfront payment pursuant to the Maruho DRM04 Agreement. We recognized $7.3 million in collaboration and license revenue for the three and nine months ended September 30, 2015 for the achievement of a milestone, the completion of patient enrollment in the first Phase 3 clinical trial for Cimzia, pursuant to the UCB Agreement.

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

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

	Development as of September 30, 2016	Three Months Ended September 30,			Nine Months Ended September 30,		
		2016	2015	$ Change	2016	2015	$ Change
				(in thousands)			
External costs incurred by product candidate:							
Cimzia (1)	Phase 3	$ 5,668	$ 7,775	$ (2,107)	$ 22,915	$ 16,845	$ 6,070
DRM04 (2)	Phase 3	3,526	4,672	(1,146)	15,507	9,093	6,414
DRM01 (3)	Phase 2b	1,066	2,492	(1,426)	5,563	6,149	(586)
Other research and development expenses (4)		1,464	19	1,445	1,548	78	1,470
Internal costs		6,060	3,932	2,128	16,773	10,308	6,465
Total research and development expenses		$ 17,784	$ 18,890	$ (1,106)	$ 62,306	$ 42,473	$ 19,833

(1) In December 2014, we commenced a Phase 3 clinical program for Cimzia. In October 2016, we announced topline results for CIMPASI-2, the first of the three clinical trials in the Phase 3 program to complete patient enrollment. We expect to announce topline results from the remaining two Phase 3 trials on a sequential basis by the end of the first quarter of 2017.

(2) In June 2016, we announced topline results from the pivotal trials of the Phase 3 program and plan to submit an NDA to the FDA for potential approval of DRM04 in the second half of 2017, subject to the completion of the open-label ARIDO Phase 3 trial expected by the end of 2016, other registration-enabling activities and a pre-NDA meeting with the FDA.

(3) In May 2016, we announced topline results from the DRM01 Phase 2b study and plan to initiate a Phase 3 program in the first half of 2017.

(4) The amounts for the three and nine months ended September 30, 2016 consist primarily of $1.5 million in upfront consideration related to the Takeda Agreement.

Research and development expenses decreased $1.1 million, or 6%, for the three months ended September 30, 2016 compared to the three months ended September 30, 2015. This decrease was due to a $4.7 million decrease in external costs resulting from the reduction in clinical trial activities for our product candidates, partially offset by a $2.1 million increase in internal costs related to headcount growth and associated expenses and a $1.5 million increase in other research and development costs related to the upfront payment pursuant to the Takeda Agreement.

Research and development expenses increased $19.8 million, or 47%, for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015. This increase was due to an $11.9 million increase in external costs primarily to advance our Cimzia and DRM04 product candidates, a $6.5 million increase in internal costs related primarily to headcount growth and associated expenses and a $1.5 million increase in other research and development costs related to the upfront payment pursuant to the Takeda Agreement.

We expect our research and development expenses to increase as we continue to advance our existing product candidates and due to our goal to continue to add to our portfolio of product candidates. The timing and amount of expenses incurred will depend largely upon the outcomes of current or future clinical studies for our product candidates, related regulatory requirements and manufacturing costs, and the timing and cost of potential additions to our portfolio of product candidates.

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

General and administrative expenses increased $3.6 million, or 77%, for the three months ended September 30, 2016 compared to the three months ended September 30, 2015. This increase was due to headcount growth and associated expenses and a transaction advisory fee paid in connection with the Maruho DRM04 Agreement.

General and administrative expenses increased $7.9 million, or 62%, for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015. This increase was due to headcount growth and associated expenses and a transaction advisory fee paid in connection with the Maruho DRM04 Agreement.

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 and increase our headcount.

Liquidity and Capital Resources

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

On November 2, 2015, we filed a shelf registration on Form S-3 with the U.S. Securities and Exchange Commission ("SEC") for the issuance and sale of up to an aggregate offering of $300.0 million of shares of our common stock, preferred stock, debt securities, warrants to purchase our common stock, preferred stock or debt securities, subscription rights to purchase our common stock, preferred stock or debt securities and/or units consisting of some or all of these securities. On June 13, 2016, we sold 5,175,000 shares of our common stock in our Shelf Offering pursuant to a registration statement on Form S-3 and received gross proceeds of $144.9 million and net proceeds, after deducting underwriting discounts and commissions of $8.7 million and offering expenses of approximately $0.6 million, of approximately $135.6 million. The shelf registration also provides that we may issue and sell up to an aggregate offering of $75.0 million of our common stock through an at-the-market sales agreement with Cowen and Company, LLC. As of September 30, 2016, no sales had been made under this at-the-market sales agreement and $75.0 million of common stock remained available to be sold, subject to certain conditions as specified in the sales agreement.

As of September 30, 2016, we had $276.6 million of cash and cash equivalents and investments. Our cash and cash equivalents and investments are held in a variety of interest-bearing instruments, including money market funds, corporate debt, repurchase agreements, U.S. Government agency securities, and commercial paper. Cash in excess of immediate requirements is invested with a view toward liquidity and capital preservation, and we seek to minimize the potential effects of concentration and degrees of risk.

Our primary use of cash is to fund our operating expenses. As of September 30, 2016, we had an accumulated deficit of $242.7 million. We expect to incur additional losses in the future as we conduct research and development and pre-commercialization activities, and potential commercialization and marketing activities, and to support the administrative and reporting requirements of a public company.

Cash Flows

The following table shows a summary of our cash flows for the nine months ended September 30, 2016 and 2015 (in thousands):

	Nine Months Ended September 30,	
	2016	2015
Net cash (used in) provided by:		
Operating activities	$ (74,798)	$ (34,107)
Investing activities	(114,784)	(5,543)
Financing activities	137,996	104,568
Net increase (decrease) in cash and cash equivalents	$ (51,586)	$ 64,918

Operating Activities. Net cash used in operating activities was $74.8 million for the nine months ended September 30, 2016 and consisted of a net loss of $81.7 million and a $3.8 million increase in net operating assets, partially offset by $10.7 million in non-cash charges. The increase in net operating assets consisted primarily of a $25.0 million increase in collaboration and license receivable pursuant to the Maruho DRM04 Agreement, a $3.2 million increase in prepaid expenses and other current assets and a $3.0 million decrease in accounts payable, partially offset by a $24.9 million increase in deferred revenue and a $2.5 million increase in accrued liabilities. Non-cash charges included $7.9 million of stock-based compensation expense, $1.5 million of common stock issued in connection with the Takeda Agreement and $1.3 million of amortization of premiums on available-for-sale securities. Net cash used in operating activities was $34.1 million for the nine months ended September 30, 2015 and consisted primarily of a net loss of $47.2 million, partially offset by a $7.9 million decrease in net operating assets and $5.2 million in non-cash charges. The decrease in net operating assets was driven primarily by a $6.0 million increase in accrued liabilities and a $1.2 million increase in accounts

payable related primarily to higher clinical trial accruals. Non-cash charges included $3.7 million of stock-based compensation expense and $1.5 million of amortization of premiums on available-for-sale securities.

Investing Activities. Net cash used in investing activities for the nine months ended September 30, 2016 was $114.8 million, which resulted primarily from purchases of investments of $194.7 million, partially offset by proceeds from maturities of investments of $80.0 million. Net cash used in investing activities for the nine months ended September 30, 2015 was $5.5 million, which resulted primarily from purchases of investments of $41.6 million, partially offset by proceeds from maturities of investments of $36.2 million.

Financing Activities. Net cash provided by financing activities for the nine months ended September 30, 2016 was $138.0 million, which resulted primarily from net proceeds from our Shelf Offering of $135.6 million. Net cash provided by financing activities for the nine months ended September 30, 2015 was $104.6 million and consisted primarily of $104.0 million of net proceeds from the sale of our common stock by us in our follow-on offering in August 2015.

Operating and Capital Expenditure Requirements

We have incurred losses since inception and anticipate that we will continue to generate losses for the foreseeable future. We expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. We believe that existing cash and cash equivalents and investments on hand as of September 30, 2016 are sufficient to meet our anticipated cash requirements through at least 2017. However, we expect we will need to raise substantial additional financing in the future to fund our operations. In order to meet these additional cash requirements, we may seek to sell additional equity or convertible debt securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of convertible debt securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. We cannot ensure that additional financing will be available to us in the amounts we need or that such financing will be available on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, scale back or discontinue one or more of our product development programs or other aspects of our business plan or relinquish, license or otherwise dispose of rights to products or product candidates that we would otherwise seek to commercialize or develop ourselves on terms that are less favorable than might otherwise be available, any of which could have a material adverse effect on our business, results of operations and financial condition. Please see "Part II — Other Information, Item 1A, Risk Factors" below for additional risks associated with our substantial capital requirements.

Contractual Obligations and Other Commitments

There were no material changes in our commitments under contractual obligations, as disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 3, 2016.

Off-Balance Sheet Arrangements

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

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

We are 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, 2016, we had cash and cash equivalents and investments of $276.6 million, which consisted of money market funds, corporate debt, repurchase agreements, U.S. Government agency securities and commercial paper. These interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant. We had no outstanding debt obligations as of September 30, 2016.

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

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 impact was immaterial for the nine months ended September 30, 2016 and 2015 and is included in interest and other income, net in our condensed consolidated statements of operations. We do not use currency forward exchange contracts to offset the related effect on the underlying transactions denominated in a foreign currency.

A hypothetical 10% change in foreign exchange rates during any of the preceding periods presented would have had an insignificant effect on our condensed consolidated financial statements.

Critical Accounting Policies and Significant Estimates

Our management's discussion and analysis of financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions. Our significant accounting policies are more fully described in Note 2 of the accompanying unaudited condensed consolidated financial statements and in Note 2 to our audited consolidated financial statements contained in the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 3, 2016. During the nine months ended September 30, 2016, there were no material changes to our critical accounting policies.

ITEM 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2016. 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 ("Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission'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, 2016, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the first quarter of 2016, we began using a new enterprise resource planning ("ERP") system for financial reporting and purchasing. As a result, our financial and operating transactions utilize the functionality provided by the new ERP system. The system implementation was designed, in part, to enhance the overall system of internal control over financial reporting through further automation of various business processes.

Except as otherwise described above, there have been no other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION.

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

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

Risks Related to Development, Regulatory Approval and Commercialization

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

Our portfolio includes three late-stage product candidates that target significant unmet needs and market opportunities: Cimzia (certolizumab pegol), in Phase 3 development in collaboration with UCB Pharma S.A. ("UCB") for the treatment of moderate-to-severe chronic plaque psoriasis; DRM04, in Phase 3 development for the treatment of primary axillary hyperhidrosis, or excessive underarm sweating; and DRM01, in Phase 2b development for the treatment of acne vulgaris, or 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. For more information about risks under our development and commercialization agreement with UCB ("UCB Agreement"), see "—Risks Related to Our Collaboration with UCB." In the future, we may also become dependent on other product candidates that we may in-license, acquire or develop. The clinical and commercial success of our product candidates will depend on a number of factors, including the following:

- the ability to raise additional capital on acceptable terms, or at all;
- timely completion of our clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the U.S. Food and Drug Administration ("FDA") or similar foreign regulatory agencies to conduct additional clinical trials beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, efficacy and acceptable risk to benefit profile of our product candidates or any future product candidates;
- the prevalence, duration and severity of potential side effects experienced with our product candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our product candidates or any future product candidates or approved products, if any;
- the ability of third parties with whom we contract to manufacture clinical trial and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices ("cGMP");
- a continued acceptable safety profile during clinical development and following approval of our product candidates or any future product candidates;

- our ability to successfully commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- acceptance by physicians 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 provide assurances that we will be able to generate sufficient revenue through the sale of our product candidates or any future product candidates to continue our business.

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

We are a clinical-stage biopharmaceutical company with a limited operating history upon which investors can evaluate our business and prospects. We are not profitable and have incurred losses in each year since we commenced operations in August 2010. We have incurred net losses of $81.7 million and $47.2 million for the nine months ended September 30, 2016 and 2015, respectively. As of September 30, 2016, we had an accumulated deficit of $242.7 million.

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

As of September 30, 2016, we had capital resources consisting of cash and cash equivalents and investments of $276.6 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, non-clinical studies and clinical trials, manufacturing and supply, as well as marketing and selling any products approved for sale. In particular, our Phase 3 clinical programs for our product candidates will require substantial funds to complete. We plan to finance the development and commercialization of Cimzia in part through milestone payments made by UCB under the UCB Agreement. In addition, other unanticipated costs may arise. Because the conduct and results of any clinical trial are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our current and any future product candidates.

As of September 30, 2016, we believe that existing cash and cash equivalents and investments are sufficient to meet our anticipated cash requirements for at least the next 12 months. We have based these estimates, however, on assumptions that may prove to be wrong, and we could spend our available capital resources much faster than we currently expect or require more capital to fund our operations than we currently expect. Our currently anticipated expenditures for the development and potential commercialization of all of our current product candidates, Cimzia, DRM04 and DRM01, exceed our existing cash and cash equivalents and investments. We will need to raise additional capital to fund our operations and continue to support our planned research and development and commercialization activities. We have substantial contractual obligations to UCB. In the event we are unable to raise sufficient capital to fund our development and commercialization obligations to UCB, we will face significant contractual liability.

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

- the timing, rate of progress and cost of any preclinical and clinical trials and other product development activities for our current and any future product candidates that we develop, in-license or acquire;
- the results of the clinical trials for our product candidates in the United States and any foreign countries;

- the timing of, and the costs involved in, FDA approval and any foreign regulatory approval of our product candidates, if at all;
- the number and characteristics of any additional future product candidates we develop or acquire;
- our ability to establish and maintain strategic collaborations, licensing, co-promotion or other arrangements and the terms and timing of such arrangements;
- the cost of commercialization activities if our current or any future product candidates are approved for sale, including manufacturing, marketing, sales and distribution costs;
- the degree and rate of market acceptance of any approved products;
- costs under our third-party manufacturing and supply arrangements for our current and any future product candidates and any products we commercialize;
- costs and timing of completion of any additional outsourced commercial manufacturing or supply arrangements that we may establish;
- costs of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates, including post-grant challenges or opposition to third-party patent claims;
- costs associated with prosecuting or defending any litigation that we may become involved in and any damages payable by us that result from such litigation;
- costs associated with any product recall that could occur;
- costs of operating as a public company;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing products or treatments;
- costs associated with any acquisition or in-license of products and product candidates, technologies or businesses; and
- personnel, facilities and equipment requirements.

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

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

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

The UCB Agreement requires us to pay substantial development costs in order for UCB to seek approval of Cimzia for the treatment of moderate-to-severe chronic 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 chronic plaque psoriasis from the FDA, the European Medicines Agency ("EMA") as established by Regulation (EC) 2309/93 and Regulation (EC) 726/2004, and the Canadian federal department for health ("Health Canada") up to a specified amount that is 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, patient enrollment and completion of clinical trials, including as a

result of regulatory requirements, could substantially increase our product development costs. We do not know whether our planned clinical trials will begin on time or will be completed on budget or on schedule, or at all. While UCB is obligated to pay us if certain development and regulatory approval milestones are met, these milestone payments will not increase even if our development costs increase, so we would be required to bear a greater portion of any increased costs, which would adversely impact our financial position. The costs associated with product development can increase for a variety of reasons, including:

- the terms of agreements with prospective contract research organizations ("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 ("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 patient 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. While we expect that clinical trials for these product candidates will continue for several years, these clinical trials may take significantly longer than expected to complete. In addition, we, any partner with which we currently or may in the future collaborate, the FDA, an IRB or other regulatory authorities, including state and local agencies and counterpart agencies in foreign countries, may suspend, delay, require modifications to or terminate our clinical trials at any time, for various reasons, including:

- discovery of serious or unexpected toxicities or side effects experienced by study participants or other safety issues;
- lack of effectiveness of any product candidate during clinical trials or the failure of our product candidates to meet specified endpoints;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials resulting from numerous factors, including the prevalence of other companies' clinical trials for their product candidates for the same indication, such as psoriasis, or clinical trials for indications for which patients do not as commonly seek treatment, such as hyperhidrosis;
- difficulty in retaining subjects who have initiated a clinical trial but may withdraw at any time due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason;

- difficulty in obtaining IRB approval for studies to be conducted at each site;
- delays in manufacturing or obtaining, or inability to manufacture or obtain, sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or the product formulation or method of delivery;
- changes in applicable laws, regulations and regulatory policies;
- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective CROs, clinical trial sites and other third-party contractors;
- inability to add a sufficient number of clinical trial sites;
- uncertainty regarding proper dosing;
- failure of our CROs or other third-party contractors to comply with contractual and regulatory requirements or to perform their services in a timely or acceptable manner;
- failure by us, our employees, our CROs or their employees or any partner with which we may collaborate or their employees to comply with applicable FDA or other regulatory requirements relating to the conduct of clinical trials or the handling, storage, security and recordkeeping for drug and biologic products;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or
- insufficient data to support regulatory approval.

In the case of our topical product candidates, we are seeking to deliver sufficient concentrations of the active pharmaceutical ingredient ("API") through the skin barrier to the targeted dermal tissue to achieve the intended therapeutic effect. As a result, safety and efficacy can be difficult to establish. The topical route of administration may involve new dosage forms, which can be difficult to develop and manufacture and may raise novel regulatory issues and result in development or review delays. For example, the dosage form for DRM04 is an API-saturated wipe, and we are not aware of previous FDA approvals of prescription drug wipes. In addition, it is possible that the FDA may require more short-term exposure of individuals to DRM04 than we currently anticipate collecting in our safety database. If we are required to expose additional individuals to DRM04 in order to establish a safety database sufficient for approval, approval of DRM04, if at all, could be delayed and our costs could increase.

We or any partner with which we may collaborate may suffer significant setbacks in our clinical trials similar to the experience of a number of other companies in the pharmaceutical and biotechnology industries, even after receiving promising results in earlier trials. In the event that we or our potential partners abandon or are delayed in the clinical development efforts related to our product candidates, we may not be able to execute on our business plan effectively and our business, financial condition, operating results and prospects would be harmed. In particular, for Cimzia, if we experience delays in the completion of, or if we terminate, clinical trials, our ability to receive development-, regulatory- or sales-based milestone payments and royalties under the UCB Agreement will be reduced, delayed or prevented.

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

We currently have no products approved for sale, and we may never obtain regulatory approval to commercialize any of our current or future product candidates. The research, testing, manufacturing, safety surveillance, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, sale, marketing, distribution, import, export and reporting of safety and other post-market information related to our product candidates are subject to extensive regulation by the FDA and other regulatory authorities in the United States and in foreign countries, and such regulations differ from country to country. We are not permitted to market any of our current product candidates in the United States until we receive approval of a new drug application ("NDA"), biologics license application, ("BLA") or other applicable regulatory filing from the FDA. We are also not permitted to market any of our current product candidates in any foreign countries until we receive the requisite approval from the applicable regulatory authorities of such countries.

To gain approval to market a biologic product such as Cimzia or a new drug such as DRM04 or DRM01, the FDA and foreign regulatory authorities must receive preclinical, clinical and chemistry, manufacturing and controls data that adequately demonstrate the safety, purity, potency, efficacy and compliant manufacturing of the product for the intended indication applied for in an NDA, BLA or other applicable regulatory filing. The development and approval of biologic products, including a drug such as Cimzia that has been approved for multiple indications, and new drug products involves a long, expensive and uncertain process. A delay or failure can occur at any stage in the process. A number of companies in the pharmaceutical and biopharmaceutical industry have suffered significant setbacks in clinical trials, including in Phase 3 clinical development, even after promising results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of clinical trials by other parties may not be indicative of the results in trials we or our partners may conduct. For example, in the Phase 2 clinical trial for Cimzia in moderate-to-severe chronic plaque psoriasis, a six-point physical global assessment ("PGA") scale was used, and in our Phase 3 clinical trials, we are using a five-point PGA scale similar to the scale that was used to support the approval of Cosentyx. As a result, data from our Phase 2 clinical trial may not accurately predict Phase 3 results. In addition, in one of the two DRM04 Phase 3 trials, DRM04 demonstrated statistically significant results compared to vehicle for the objective measurement of sweat production only following exclusion of extreme outlier data from one analysis center in accordance with the pre-specified statistical analysis plan submitted to the FDA. The FDA may determine that we did not achieve statistically significant results for this objective measurement in this trial and may require us to conduct an additional Phase 3 study as a result of the extreme outlier data, and approval of DRM04, if at all, could be delayed and our costs would increase. Further, as one of the primary assessments of efficacy in our DRM04 Phase 3 trials, we used a new patient-reported outcome assessment ("PRO"), the Axillary Sweating Daily Diary, which was validated in our Phase 2 clinical program to assess efficacy in a subjective manner. This PRO has not been previously used in an NDA filing to support potential approval of a product.

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

- the FDA or the applicable foreign regulatory body may disagree with the design, implementation, choice of dose, analysis plans, or interpretation of the outcome of one or more clinical trials;
- the FDA or the applicable foreign regulatory body may not deem a product candidate safe and effective for its proposed indication, or may deem a product candidate's safety or other perceived risks to outweigh its clinical or other benefits;
- the FDA or the applicable foreign regulatory body may not find the data from preclinical studies and clinical trials, including the number of subjects in the safety database, sufficient to support approval, or the results of clinical trials may not meet the level of statistical or clinical significance required by the FDA or the applicable foreign regulatory body for approval;
- the FDA or the applicable foreign regulatory body may disagree with our interpretation of data from preclinical studies or clinical trials performed by us or third parties, or with the interpretation of any partner with which we may collaborate;
- the data collected from clinical trials may not be sufficient to support the submission of an NDA, BLA or other applicable regulatory filing;
- the FDA or the applicable foreign regulatory body may require additional preclinical studies or clinical trials;
- the FDA or the applicable foreign regulatory agency may identify deficiencies in the formulation, manufacturing, quality control, labeling or specifications of our current or future product candidates;
- the FDA or the applicable foreign regulatory agency may require clinical trials in pediatric patients in order to establish pharmacokinetics or safety for this more drug-sensitive population;
- the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional post-approval clinical trials;
- the FDA or the applicable foreign regulatory agency may approve our current or any future product candidates for a more limited indication or a narrower patient population than we originally requested;
- the FDA or applicable foreign regulatory agency may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates;
- the FDA or the applicable foreign regulatory body may not approve of the manufacturing processes, controls or facilities of third-party manufacturers or testing labs with which we contract;

- the FDA or the applicable foreign regulatory body may not approve or grant marketing clearance of a device intended to be used in combination with our product candidates, such as an auto-injector with Cimzia; or
- the FDA or the applicable foreign regulatory body may change its approval policies or adopt new regulations in a manner rendering our clinical data or regulatory filings insufficient for approval.

Of the large number of drugs, including biologics, in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized. For example, the FDA may not agree with our Phase 3 clinical trial protocols for Cimzia or DRM04. 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, safety and pharmacovigilance.

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

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

We have never completed a Phase 3 clinical program or prepared, or obtained approval of, an NDA submission or equivalent foreign filing, and we may be unable to successfully do so for any of our product candidates. Failure to successfully complete any of these activities in a timely manner for any of our product candidates could have a material adverse impact on our business and financial performance.

Conducting a Phase 3 clinical program and preparing, and obtaining approval of, an NDA submission or equivalent foreign filing are complicated processes. Although our employees have conducted Phase 3 clinical programs and prepared, and obtained approvals of, NDAs and equivalent foreign filings in the past while employed at other companies, we as a company have not done so. As a result, such activities may require more time and cost more than we anticipate. We commenced the Phase 3 clinical program for Cimzia in December 2014, commenced the Phase 3 clinical program for DRM04 in July 2015 and plan to commence a Phase 3 clinical program for DRM01 in the first half of 2017. Failure to successfully complete, or delays in, our Phase 3 clinical programs would prevent us from or delay us in obtaining regulatory approval for our product candidates and could prevent us from or delay us in receiving development- or regulatory-based milestone payments. Additionally, failure to complete or obtain, or delays in completing or obtaining, our NDA submissions for DRM04 or DRM01 or approval thereof, respectively, would prevent us from or delay us in commercializing our product candidates in the United States. The occurrence of any of the foregoing could have a material adverse impact on our business and financial performance.

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

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

- the clinical indications for which the product is approved and patient demand for approved products that treat those indications;
- 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 ("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.

We are uncertain whether the market for injectable biologics for the treatment of moderate-to-severe plaque psoriasis, 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 chronic 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 chronic plaque psoriasis, we may not be able to utilize directly comparative head-to-head data on the clinical performance of Cimzia relative to other tumor necrosis factor-alpha inhibitors ("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 healthcare products competitive with those that we are developing. We face competition from a number of sources, such as pharmaceutical companies, generic drug companies, biotechnology companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, clinical trial expertise, intellectual property portfolios, experience in obtaining patents and regulatory approvals for product candidates and other resources than we do. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. In addition, certain of our product candidates, if approved, may compete with other dermatological products, including over-the-counter ("OTC") treatments, for a share of some patients' discretionary budgets and for physicians' attention within their clinical practices.

Many pharmaceutical companies currently offer products, and continue to develop additional alternative product candidates and technologies, for indications similar to those targeted by our product candidates, including: AbbVie Inc., Allergan plc, Almirall, S.A., Amgen Inc., Astellas Pharma US, Inc., Bayer HealthCare AG (formerly Intendis, Inc.), BioPharmX, Inc., Brickell Biotech, Inc., Can-Fite BioPharma Ltd., Cassiopea S.p.A., Celgene International, Celltrion Healthcare Co., Ltd., Eirion Therapeutics, Inc., Eisai Co., Ltd., Foamix Pharmaceuticals Ltd., Galderma S.A., GlaxoSmithKline LLC ("GSK"), Janssen Biotech, Inc. (a division of Johnson & Johnson), Johnson & Johnson, LEO Pharma A/S, Eli Lilly and Company, Maruho Co., Ltd., Merck & Co., Inc., MetrioPharm AG, Miramar Labs, Inc., Mitsubishi Tanabe Pharma Corporation, Mylan Inc., Novan, Inc., Novartis International AG, Pfizer Inc., Ranbaxy Pharmaceuticals Inc., Regeneron Pharmaceuticals, Inc., Revance Therapeutics, Inc., Sun Pharmaceutical Industries Ltd., Takeda Pharmaceutical Company Limited, Teva Pharmaceutical Industries Ltd., TheraVida, Inc., Torii Pharmaceutical Co. Ltd., UCB, Valeant Pharmaceuticals International, Xenon Pharmaceuticals Inc. and Ziarco Pharma Ltd. The markets for dermatological therapies are competitive and are characterized by significant technological development and new product introduction. We anticipate that, if we obtain regulatory approval of our product candidates, we will face significant competition from other approved therapies. If approved, our product candidates may also compete with unregulated, unapproved and off-label treatments. Certain of our product candidates, if approved, would present novel therapeutic approaches for the approved indications and would have to compete with existing therapies, some of which are widely known and accepted by physicians and patients. To compete successfully in this market, we will have to demonstrate that the relative cost, safety and efficacy of our approved products, if any, provide an attractive alternative to existing and other new therapies. The competition we face could lead to reduced market share for our product candidates and contribute to downward pressure on the pricing of our product candidates, which could harm our business, financial condition, operating results and prospects.

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

Cimzia faces intense competition. Most of our competitors have significantly greater resources than we do and we may not be able to successfully compete.

If approved for the treatment of psoriasis, Cimzia will face direct competition from numerous other injectable products such as Cosentyx, Enbrel, Humira, Remicade, Stelara and Taltz, which may limit the market size for Cimzia.

In addition, Cimzia will compete against oral systemic treatments for psoriasis, which include acitretin, apremilast, methotrexate and cyclosporine, and against a number of approved topical treatments for psoriasis, including branded drugs and generic versions where available. There are a number of other treatments used for psoriasis, including light-based treatments, topical corticosteroids and non-prescription topical treatments. Certain alternative treatments offered by competitors may be available at lower prices and may offer greater efficacy or better safety profiles.

Additional products and treatments, including numerous injectable biological products currently in clinical trials, may also receive regulatory approval in one or more territories in which we compete, and these existing and new products may be more effective, more widely used and less costly than ours, which may reduce the sales on which we receive royalties and sales-based milestone payments under the UCB Agreement. Even if a generic product or an OTC product is less effective than our product candidates, a less effective generic or OTC 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 ("BPCIA") created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar," or "biosimilar," to or "interchangeable" with an FDA-approved biological product. This pathway allows competitors to reference the FDA's prior determinations regarding innovative biological products and to obtain approval of a biosimilar application 12 years after the time of approval of the innovative biological product. The 12-year exclusivity period runs from the initial approval of the innovator product and not from approval of a new indication. In addition, the 12-year exclusivity period does not prevent another company from developing a product that is highly similar to the innovative product, generating all the data necessary for a full BLA and seeking approval. Exclusivity only assures that another company cannot rely on the FDA's prior determinations in approving a BLA for an innovator's biological product to support the biosimilar product's approval. Further, under the FDA's current interpretation, it is possible that a biosimilar applicant could obtain approval for one or more of the indications approved for the innovator product by extrapolating clinical data from one indication to support approval for the other indications.

The BPCIA is complex and only beginning to be interpreted and implemented by the FDA. In April 2016, Celltrion was granted marketing approval by the FDA for Inflextra, an infliximab biosimilar referencing Remicade. In August 2016, Sandoz was granted marketing approval by the FDA for Erelzi, an etanercept biosimilar referencing Enbrel. In addition, biosimilar product candidates in Phase 3 development by other companies include biosimilar versions of adalimumab, a biosimilar version of etanercept and biosimilar versions of infliximab. If Cimzia receives marketing approval for the treatment of moderate-to-severe chronic plaque psoriasis, we expect competition from potential future biosimilars. We cannot predict to what extent the entry of biosimilars or other competing products will impact future sales of Cimzia. 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.

We expect to face generic competition for our product candidates, which could adversely affect our business, financial condition, operating results and prospects.

Upon the expiration or loss of any patent protection for any of our product candidates that are approved, or upon the "at-risk" launch, despite pending patent infringement litigation against the generic product, by a generic competitor of a generic version of any of our product candidates that are approved, which may be sold at significantly lower prices than our approved product candidates, we could lose a significant portion of sales of that product in a short period of time, which would adversely affect our business, financial condition, operating results and prospects. In particular, our DRM04 product candidate faces competition from currently marketed generic oral and compounded topical anticholinergic agents. In addition, we may be subject to additional competition from third parties pursuing topical formulations of other anticholinergic agents for hyperhidrosis.

Any product candidates that we commercialize, or that any partner with which we may collaborate commercializes, will be subject to ongoing and continued regulatory review. Failure to comply with applicable regulatory requirements could have a material adverse impact on our business.

Even after we or our partners achieve U.S. regulatory approval for a product candidate, if any, we or our partners will be subject to continued regulatory review and compliance obligations. For example, with respect to our product candidates, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. A product candidate's approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials or other REMS, to monitor the safety and efficacy of the product. We will also be subject to ongoing FDA obligations and continued regulatory review with respect to, among other things, the manufacturing, processing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for our product candidates. These requirements include submissions of safety and other post-marketing information and reports and registration, as well as continued compliance with cGMP requirements and with the FDA's good clinical practice ("GCP") requirements and good laboratory practice ("GLP") requirements, which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical development, and for any clinical trials that we conduct post-approval. To the extent that a product candidate is approved for sale in other countries, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries.

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

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

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

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

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

We have conducted, are conducting and may in the future choose to conduct, one or more of our clinical trials outside the United States, including in Canada and Europe. For example, our Phase 3 clinical programs for Cimzia and DRM04 are being conducted in multiple countries. Although the FDA or applicable foreign regulatory authority may accept data from clinical trials conducted outside the United States or the applicable jurisdiction, acceptance of such study data by the FDA or applicable foreign regulatory authority may be subject to certain conditions. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan.

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

Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. Undesirable side effects caused by product candidates could cause us, any partners with which we may collaborate or regulatory authorities to interrupt, modify, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities. For example, if we obtain

regulatory approval for Cimzia for the treatment of moderate-to-severe chronic plaque psoriasis, we expect that regulatory authorities will require us to include the same box warning regarding increased risk of serious infections that may lead to hospitalization or death and a potential association with increased cancer risk in TNF inhibitors, of which Cimzia is one, that is currently included in labeling for Cimzia for the treatment of other indications. Results of clinical trials could reveal a high and unacceptable severity and prevalence of one or more of these side effects. In such an event, trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us, or our potential partners, to cease further development of or deny approval of product candidates for any or all targeted indications. In addition, the FDA recently created a Tracked Safety Issue ("TSI") for all TNF inhibitors, including Cimzia, based on a potential signal of psychiatric and nervous system disorders including: anxiety, hallucination, paranoia, psychotic disorder, cognitive impairment, depression, and suicide/suicidal ideation. This TSI may have an impact on our development program or the labeling for Cimzia. Any drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in product liability claims. Any of these occurrences may harm our business, financial condition, operating results and prospects.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by our product candidates after obtaining U.S. or foreign regulatory approval or other products with the same or related active ingredients, a number of potentially negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require a recall of the product or we or our potential partners may voluntarily recall a product;
- regulatory authorities may require the addition of warnings or contraindications in the product labeling, narrowing of the indication in the product label or field alerts to physicians and pharmacies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or institute a REMS;
- we may have limitations on how we promote the product;
- we may be required to change the way the product is administered or modify the product in some other way;
- the FDA or applicable foreign regulatory authority may require additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- sales of the product may decrease significantly;
- we could be sued and held liable for harm caused to patients; and
- our brand and reputation may suffer.

Any of the above events resulting from undesirable side effects or other previously unknown problems could prevent us or our potential partners from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

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

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

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

- withdrawal of clinical trial participants;
- decreased enrollment rates of clinical trial participants;

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

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

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

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about drug and biologic products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling and comparative safety or efficacy claims cannot be made without direct comparative clinical data. For example, if Cimzia is approved for use in the United States for the treatment of moderate-to-severe chronic 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 off-label promotion and have enjoined several companies from engaging in off-label promotion.

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

We cannot, however, prevent a physician from using our product candidates outside of those indications for use when in the physician's independent professional medical judgment he or she deems appropriate. Physicians may also misuse our product candidates or use improper techniques, potentially leading to adverse results, side effects or injury, which may lead to product liability claims. If our product candidates are misused or used with improper technique, we may become subject to costly litigation by

physicians or their patients. Furthermore, the use of our product candidates for indications other than those approved by the FDA may not effectively treat such conditions, which could harm our reputation among physicians and patients.

We may choose not to continue developing or commercializing any of our product candidates 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 the 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 manufacturing, labeling, promotion, sale or distribution. Any recall, withdrawal or seizure in the future could materially and adversely affect consumer confidence in our brand and lead to decreased demand for our approved products. In addition, a recall, withdrawal or seizure of any of our approved products would require significant management attention, would likely result in substantial and unexpected expenditures and would harm our business, financial condition and operating results.

If the FDA concludes that our DRM04 product candidate does not satisfy the requirements under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("Section 505(b)(2)"), or if the requirements for our DRM04 product candidate under Section 505(b)(2) are not as we expect, the approval pathway for our DRM04 product candidate will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, any of which may adversely impact our business, financial condition, operating results and prospects.

We are currently developing our DRM04 product candidate and we currently 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 either does not own or has not obtained a right of reference. Reliance on certain findings made by the FDA in approving the anticholinergic agent we intend to reference in our NDA could expedite the DRM04 development program by potentially decreasing the amount of non-clinical or clinical data that we would need to generate in order to obtain FDA approval.

DRM04 differs from the approved product we intend to reference in chemical structure, route of administration, dosage form and indication, and if we are unable to demonstrate an acceptable clinical bridge through comparative pharmacokinetic data between DRM04 and the approved product, the FDA may not permit us to use the Section 505(b)(2) pathway for regulatory approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, or if the Section 505(b)(2) regulatory pathway fails to significantly decrease the amount of testing we must conduct, we may need to conduct additional non-clinical or clinical trials, provide additional data and information and meet additional standards for regulatory approval, which would substantially increase the time and financial resources required to obtain FDA approval for DRM04 and entail significantly greater complications and risks than anticipated. If this were to occur, our business, financial condition, operating results and prospects may be adversely impacted.

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

Notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain competitors and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its Section 505(b)(2) policies and practices, which

could delay or even prevent the FDA from approving any NDA that we submit under 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. In addition, Section 505(b)(2) NDAs are subject to potential data or marketing exclusivity rights that reward certain research performed by the sponsors of previously approved drugs. The exercise of such exclusivity rights can delay FDA approval of a Section 505(b)(2) NDA, or certain proposed product uses, for a period ranging from three to seven years, depending on the type of exclusivity earned. It is not uncommon for a manufacturer of an approved referenced product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to faster product development or earlier approval.

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

For any of our product candidates that become available only by prescription, successful sales by us or by any partners with which we may collaborate depend on the availability of coverage and adequate reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. The availability of coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and private third-party payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If any of our product candidates do not demonstrate attractive efficacy profiles, they may not qualify for coverage and reimbursement. In addition, certain currently approved therapies for the treatment of hyperhidrosis have received limited or no reimbursement coverage by insurers and, accordingly, coverage for DRM04, if approved, may not be available. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients may be unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

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

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, although private third-party payors tend to follow Medicare, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

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

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

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future revenue and profitability and the future revenue and profitability of any partner with which we may collaborate. Federal and state lawmakers regularly propose and, at times, enact legislation that results in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, in March 2010, President Obama signed one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, "Affordable Care Act"). It contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which 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.

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual or in return for the purchase, lease, or order of any good, facility item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, including, for example, the federal civil False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which impose obligations on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal physician sunshine requirements under the Affordable Care Act, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be provided to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

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

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

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

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

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

Risks Related to Our 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, Amgen, Baxter International Inc., Boehringer Ingelheim, Biogen Idec Inc., Celltrion, Eisai, GSK, Hospira, Inc., Johnson & Johnson, Merck, Mitsubishi Tanabe Pharma Corporation, Mylan, Novartis AG, Pfizer, Ranbaxy Laboratories Limited, 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 acquirors, 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.

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.

We are dependent on UCB for product supply and any interruption in our product supply may cause serious delays in the timing of our clinical studies, increase our costs and adversely impact our financial results.

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 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 acquiror 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 such 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.

UCB has made very limited disclosures, representations, warranties and indemnities to us regarding its ownership of and the validity of the intellectual property related to Cimzia. If a third party claims that the intellectual property related to Cimzia infringes the intellectual property rights of such third party, we could be enjoined from performing our activities and/or exposed to substantial liability, either of which would have an adverse effect on our business.

In the UCB Agreement, UCB has made very limited disclosures, 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 provide assurances that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical or preclinical trials complies with applicable GCP and GLP requirements. In addition, our clinical trials must generally be conducted with products produced under cGMP regulations. Our failure to comply with these regulations and policies may require us to repeat clinical trials, which would delay the regulatory approval process.

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

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

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

We do not have direct control over the ability of our contract suppliers and manufacturers to maintain adequate capacity and capabilities to serve our needs, including quality control, quality assurance and qualified personnel. Although we are ultimately responsible for ensuring compliance with regulatory requirements such as cGMPs, we are dependent on our contract suppliers and manufacturers for day-to-day compliance with cGMPs for production of both APIs and finished products. Facilities used by our contract suppliers and manufacturers to produce the APIs and other substances and materials or finished products for commercial sale must pass inspection and be approved by the FDA and other relevant regulatory authorities. Our contract suppliers and manufacturers must comply with cGMP requirements enforced by the FDA through its facilities inspection program and review of submitted technical information. If the safety of any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize or obtain regulatory approval for the affected product or product candidate, and we may be held liable for injuries sustained as a result. Any of these factors could cause a delay or termination of preclinical studies, clinical trials or regulatory submissions or approvals of our product candidates, and could entail higher costs or result in our being unable to effectively commercialize our approved products on a timely basis, or at all.

We also rely and will continue to rely on certain third parties as the sole source of the materials they supply or the finished products they manufacture. UCB is solely responsible for and controls all aspects of the manufacture, distribution and supply of Cimzia. For more information about risks related to the manufacture of Cimzia, see "—Risks Related to Our Collaboration with UCB." Some of the APIs and other substances and materials used in our product candidates are currently available only from one or a limited number of domestic or foreign suppliers and foreign manufacturers and certain of our finished product candidates are manufactured by one or a limited number of contract manufacturers. In the event an existing supplier fails to supply product on a timely basis or in the requested amount, supplies product that fails to meet regulatory requirements, becomes unavailable through business interruption or financial insolvency or loses its regulatory status as an approved source or if we or our manufacturers are unable to renew current supply agreements when such agreements expire and we do not have a second supplier, we likely would incur added costs and delays in identifying or qualifying replacement manufacturers and materials and there can be no assurance that

replacements would be available to us on a timely basis, on acceptable terms or at all. In certain cases we may be required to obtain regulatory approval to use alternative suppliers, and this process of approval could delay production of our products or development of product candidates indefinitely. In particular, we are dependent on our current suppliers of the nonwoven material and foil in our DRM04 finished product, and any need to find and qualify new suppliers for these materials would adversely affect our business. We and our manufacturers do not currently maintain inventory of these APIs and other substances and materials. Any interruption in the supply of an API or other substance or material or in the manufacture of a finished product could have a material adverse effect on our business, financial condition, operating results and prospects.

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

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

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

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

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

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

In addition, the manufacturing facilities of certain of our suppliers are located outside of the United States. This may give rise to difficulties in importing our products or product candidates or their components into the United States or other countries as a result of, among other things, regulatory agency approval requirements or import inspections, incomplete or inaccurate import documentation or defective packaging.

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

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

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

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

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

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

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

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

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

Risks Related to Our Business and Financial Operations

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

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

Our need to manage our operations, growth and various projects effectively requires that we:

- continue to improve our operational, financial, management and regulatory compliance controls and reporting systems and procedures;
- attract and retain sufficient numbers of talented employees;
- develop a marketing, sales and distribution capability;
- manage our commercialization activities for our product candidates effectively and in a cost-effective manner;
- establish and maintain relationships with development and commercialization partners;
- manage our preclinical and clinical trials effectively;
- manage our third-party supply and manufacturing operations effectively and in a cost-effective manner, while increasing production capabilities for our current product candidates to commercial levels; and
- manage our development efforts effectively while carrying out our contractual obligations to partners and other third parties.

In addition, historically, we have utilized and continue to utilize the services of part-time outside consultants to perform a number of tasks for us, including tasks related to preclinical and clinical testing. Our growth strategy may also entail expanding our use of consultants to implement these and other tasks going forward. We rely on consultants for certain functions of our business and will need to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. There can be no assurance that we will be able to manage our existing consultants or find other competent outside consultants, as needed, on economically reasonable terms, or at all. If we are not able to effectively manage our growth and expand our organization by hiring new employees and expanding our use of consultants, we might be unable to implement successfully the tasks necessary to execute effectively on our planned research, development and commercialization activities and, accordingly, might not achieve our research, development and commercialization goals.

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

Our ability to compete in the highly competitive pharmaceuticals industry depends upon our ability to attract and retain highly qualified managerial, scientific, medical, sales and marketing and other personnel. We are highly dependent on our management and scientific personnel, including: our Chief Executive Officer and Chairman of the Board, Thomas G. Wiggans; our Chief Medical Officer and a member of our board of directors, Eugene A. Bauer, M.D.; our Chief Operating Officer and Chief Financial Officer, Andrew L. Guggenhime; our Chief Development Officer, Luis C. Peña; and our Vice President, Corporate Development and Strategy, Christopher M. Griffith. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in-licensing or acquisition of new assets and could negatively impact our ability to successfully implement our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. We employ all of our executive officers and key personnel on an at-will basis and their employment can be terminated by us or them at any time, for any reason and without notice. In order to retain valuable employees at our company, in

addition to salary and cash incentives, we provide stock options and restricted stock units that vest over time. The value to employees of stock options and restricted stock units that vest over time will be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract offers from other companies.

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

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

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

We currently have limited marketing capabilities and no sales organization. To commercialize our product candidates, if approved, in the United States, Canada, the European Union and other jurisdictions we seek to enter, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. Any failure or delay in the development of our sales, marketing and distribution capabilities would adversely impact the commercialization of our product candidates. Although our employees have experience in the marketing, sale and distribution of pharmaceutical products from prior employment at other companies, we as a company have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. To commercialize Cimzia, we also intend to leverage the commercial infrastructure of our partner UCB in selected areas such as managed care and patient access, which will provide us with resources and expertise in these areas that are greater than we could initially build ourselves. If we are unable to utilize UCB's resources and expertise in this way, the cost, time and complexity involved in developing our own commercial infrastructure will likely increase. We may choose to collaborate with additional third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates. The inability to successfully commercialize our product candidates, either on our own or through collaborations with one or more third parties, would harm our business, financial condition, operating results and prospects.

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

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

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales and other resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

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

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

Our strategy is to in-license and acquire product candidates and we may in-license and acquire commercial-stage products or engage in other strategic transactions. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions entail numerous potential operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- substantial acquisition and integration costs;
- write-downs of assets or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers, partners or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain our key employees or those of any acquired businesses.

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

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

Our operations to date have been primarily limited to researching and developing our product candidates and undertaking preclinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market. From time to time, we may enter into collaboration agreements and license agreements with other companies that include development funding and significant upfront and milestone expenditures and payments, and we expect that amounts earned from or paid pursuant to these agreements will be a significant source of our capital expenditures and an important source of our revenue. Accordingly, our revenue and profitability will depend on development funding and the achievement of development and clinical milestones under the UCB Agreement, the achievement of milestones under a license agreement with Maruho Co., Ltd. pursuant to which we granted Maruho an exclusive license to develop and commercialize DRM04 in Japan, as well as any potential future collaboration and license agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next. In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- delays in the commencement, patient enrollment and the timing of clinical testing for our product candidates;
- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review and approval of product candidates in clinical development;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on FDA guidelines and requirements, and the quantity of production;
- our ability to obtain additional funding to develop our product candidates;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the level of demand for our product candidates, should they receive approval, which may vary significantly;
- potential side effects of our product candidates that could delay or prevent commercialization or cause an approved drug to be taken off the market;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our product candidates, if approved;
- our dependency on third-party manufacturers to supply or manufacture our product candidates;
- our ability to establish an effective sales, marketing and distribution infrastructure in a timely manner;
- market acceptance of our product candidates, if approved, and our ability to forecast demand for those product candidates;
- our ability to receive regulatory approval and commercialize our product candidates;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability and third parties' abilities to protect intellectual property rights;
- costs related to and outcomes of potential litigation or other disputes;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively;
- potential liabilities associated with hazardous materials;
- our ability to maintain adequate insurance policies; and
- future accounting pronouncements or changes in our accounting policies.

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

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

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

As of December 31, 2015, we had NOL carryforwards available to reduce future taxable income, if any, for federal, California and Canadian income tax purposes. If not utilized, the federal and California NOL carryforwards will begin expiring during the year ending December 31, 2030 and the Canadian NOL carryforwards will begin expiring during the year ending December 31, 2028. Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We have experienced at least one ownership change since inception and our utilization of NOL carryforwards will therefore be subject to annual limitation. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

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

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

Our business and operations would suffer in the event of failures in our internal computer systems.

Despite the implementation of security measures, our internal computer systems and those of our current and any future partners, contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our manufacturing activities, development programs and our business operations. For example, the loss of manufacturing records or clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further commercialization and development of our product candidates could be delayed.

Risks Related to Our Intellectual Property

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

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

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

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

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

Competitors in the field of dermatologic therapeutics have created a substantial amount of prior art, including scientific publications, patents and patent applications. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Although we believe that our technology includes certain inventions that are unique and not duplicative of any prior art, we do not have outstanding issued patents covering all of the recent developments in our technology and we are unsure of the patent protection that we will be successful in obtaining, if any. Even if the patents do successfully issue, third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. In particular, due to the extensive prior art relating to anticholinergic agents to control hyperhidrosis and because DRM04 is a form of a generic anticholinergic agent, the patent protection available for DRM04 may not prevent competitors from developing and commercializing similar products. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our product candidates is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our product candidates.

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

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

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

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Without patent protection for our product candidates, we may be open to competition from generic versions of our product candidates. Further, the extensive period of time between patent filing and regulatory approval for a product candidate limits the time during which we can market a product candidate under patent protection, which may particularly affect the profitability of our early-stage product candidates. The issued U.S. patents relating to DRM01 and DRM04 will expire between 2020 and 2034. The issued U.S. patents relating to Cimzia will expire in 2024.

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

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

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

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

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

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

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

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

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

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

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

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

We are a party to certain license agreements that impose various diligence, milestone, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the respective licensors may have the right to terminate the license, in which event we may not be able to develop or market the affected product candidate. The loss of such rights could materially adversely affect our

business, financial condition, operating results and prospects. For example, any dispute with UCB relating to compliance with the terms of the UCB Agreement 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. See also "—Risks Related to Our Collaboration with UCB."

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

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

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

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

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

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

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could

harm our ability to raise additional funds or otherwise adversely affect our business, financial condition, operating results and prospects.

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

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

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

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

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

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

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

As is common in the biotechnology and pharmaceutical industries, certain of our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants to assist us in the development of our product candidates, many of whom were previously employed at or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees and consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims. Even if we are successful in defending against any such claims, any such litigation could be protracted, expensive, a distraction to our management team, not viewed favorably by investors and other third parties and may potentially result in an unfavorable outcome.

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

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

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

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

- other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events; and
- any other factors discussed herein.

In addition, the stock markets, and in particular The NASDAQ Global Select Market, have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many pharmaceutical companies. Stock prices of many pharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were involved in securities litigation, we could incur substantial costs and our resources and the attention of management could be diverted from our business.

For the period from January 1, 2015 through September 30, 2016, the closing sale price of our common stock on The NASDAQ Global Select Market ranged from $14.34 to $35.57 per share. Because our stock price has been volatile, investing in our common stock is risky.

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

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

As of September 30, 2016, we had 35,568,998 shares of common stock outstanding, and stockholders holding 5% or more of our stock, individually or with affiliated persons or entities, collectively beneficially owned or controlled approximately 42% of such shares. If stockholders holding a significant number of our shares sell, indicate an intention to sell, or if it is perceived that they will sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline and our ability to raise future capital may be adversely affected.

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

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. Ineffective internal control could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. In addition, any future testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we furnished a report by management on, among other things, the effectiveness of our internal control over financial reporting for the fiscal year ending December 31, 2015 in our Annual Report on Form 10-K filed with the SEC on March 3, 2016. While we are currently an "emerging growth company" as defined in Section 2(a) of the Securities Act of 1933, as amended, as modified by the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"), because the market value of our common stock held by non-affiliates exceeded $700 million as of June 30, 2016, we will be deemed a "large accelerated filer" under the Securities Exchange Act of 1934, as amended ("Exchange Act") and will lose emerging growth company status as of December 31, 2016. As such, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

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

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

We incur significantly increased costs as a result of and devote substantial management time to operating as a public company.

As a public company, we incur significant legal, accounting and other expenses that we did not previously incur as a private company. For example, we are subject to the reporting requirements of the Exchange Act and are required to comply with the applicable requirements of the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the SEC and The NASDAQ Stock Market, including the establishment and maintenance of effective disclosure and financial controls, changes in corporate governance practices and required filing of annual, quarterly and current reports with respect to our business and operating results. Compliance with these requirements has increased and will continue to increase our legal and financial compliance costs and has made and will increasingly make some activities more time-consuming and costly. In addition, our management and other personnel need to divert attention from operational and other business matters to devote substantial time to these public company requirements. We will continue to need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge.

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

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

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

On November 2, 2015, we filed a shelf registration statement on Form S-3 for the potential offering, issuance and sale by us of up to $300.0 million of our common stock, preferred stock, debt securities, warrants to purchase our common stock, preferred stock and debt securities, subscription rights to purchase our common stock, preferred stock and debt securities, and units consisting of all or some of these securities. Our shelf registration statement was declared effective by the SEC on November 24, 2015. In June 2016, we sold 5,175,000 shares of our common stock in an underwritten public offering pursuant to the shelf registration statement. Furthermore, pursuant to a sales agreement between us and Cowen and Company, LLC (''Cowen''), common stock with an aggregate offering price of up to $75.0 million may be issued and sold pursuant to an ''at-the-market'' offering for sales of our common stock. Subject to certain limitations in the sales agreement and compliance with applicable law, we have the discretion to deliver a sales notice to Cowen at any time throughout the term of the sales agreement, which has a term equal to the term of the registration statement on Form S-3 unless otherwise terminated earlier by us or Cowen pursuant to the terms of the sales agreement. The number of shares that are sold by Cowen after delivering a sales notice will fluctuate based on the market price of our common stock during the sales period and limits we set with Cowen. Because the price per share of each share sold will fluctuate based on the market price of our common stock during the sales period, it is not possible at this stage to predict the number of shares that will be ultimately issued. As of the date hereof, no shares of our common stock have been sold pursuant to the sales agreement. If we sell additional common stock, preferred stock, convertible securities and other equity securities in future transactions pursuant to our shelf registration statement on Form S-3, existing investors may be materially diluted by such subsequent sales and new investors could gain rights superior to our existing stockholders.

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

As of September 30, 2016, our directors and executive officers beneficially owned (determined in accordance with the rules of the SEC), in the aggregate, approximately 16% of our outstanding common stock. As a result, these stockholders, acting together,

would have the ability to exert significant influence on matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, have the ability to significantly influence the management and affairs of our company. Accordingly, this concentration of ownership could harm the market price of our common stock by:

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

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

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

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

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

We are an "emerging growth company" as defined in the JOBS Act and cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including certain reduced financial statement reporting obligations, reduced disclosure obligations about our executive compensation arrangements, exemptions from the requirement that we solicit non-binding advisory votes on executive compensation or golden parachute arrangements and exemption from the auditor's attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." Because the market value of our common stock held by non-affiliates exceeded $700 million as of June 30, 2016, we will be deemed a "large accelerated filer" under the Exchange Act and will lose emerging growth company status as of December 31, 2016.

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

Our management will have considerable discretion over the use of proceeds from our previous and future sales of securities and could spend the proceeds in ways that do not necessarily improve our operating results or enhance the value of our common stock, or

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

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

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

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

Unregistered Sales of Equity Securities

During the three months ended September 30, 2016, we did not make any sales of unregistered securities other than the sale of 46,413 shares of our common stock to Takeda Pharmaceutical Company Limited ("Takeda") pursuant to an exclusive option and license agreement dated August 29, 2016 under which we paid Takeda an upfront fee of $1.5 million, issued in the form of shares of our common stock, in exchange for the right to evaluate and conduct research on Takeda compounds directed to three biological targets and an option to license exclusive worldwide rights to selected compounds from each of these three programs. The shares were sold in reliance on the exemption from the registration requirements of the Securities Act of 1933, as amended ("Securities Act"), set forth in Rule 506(b) of Regulation D promulgated under the Securities Act, based on the sale of securities to an accredited investor in a transaction not involving any public offering.

Use of Proceeds from Initial Public Offering

On October 2, 2014, the Securities and Exchange Commission ("SEC") declared our registration statement on Form S-1 (File No. 333-198410) effective for our initial public offering, which closed on October 8, 2014, pursuant to which we sold an aggregate of 7,812,500 shares of our common stock at a price to the public of $16.00 per share. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on October 3, 2014.

Issuer Purchases of Equity Securities

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS

Number	Exhibit Title	Incorporated by Reference			Filed Herewith
		Form	File No.	Filing Date	
10.1†	Exclusive License Agreement, dated September 19, 2016, by and between the Registrant and Maruho Co., Ltd.				X
31.1	Certification of Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*				X
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*				X
101.INS	XBRL Instance Document.				X
101.SCH	XBRL Taxonomy Extension Schema Document.				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				X

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

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in Menlo Park, California, on November 7, 2016.

DERMIRA, INC.

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

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

EXHIBIT INDEX

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

Exhibit 10.1

CONFIDENTIAL TREATMENT REQUESTED

EXCLUSIVE LICENSE AGREEMENT

THIS EXCLUSIVE LICENSE AGREEMENT ("**Agreement**") is made effective as of the 19th day of September, 2016 (the "**Effective Date**"), by and between Maruho Co., Ltd., a corporation organized and existing under the laws of Japan with offices at 1-5-22, Nakatsu, Kita-ku, Osaka, 531-0071, Japan ("**Maruho**") and Dermira, Inc., a corporation organized and existing under the laws of Delaware with offices at 275 Middlefield Rd., Suite 150, Menlo Park, CA 94025, U.S.A. ("**Dermira**"). Maruho and Dermira may, from time-to-time, be individually referred to as a "**Party**" and collectively referred to as the "**Parties**".

RECITALS

WHEREAS, Dermira owns or controls the Licensed IP Rights (hereinafter defined) that cover [*****] ("**DRM04**"); and

WHEREAS, Maruho wishes to obtain, and Dermira wishes to grant, certain licenses under the Licensed IP Rights on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein and other good and valuable consideration, the receipt and sufficiency of which the Parties hereby acknowledge, the Parties, intending to be legally bound hereby, agree to the foregoing and as follows:

1. DEFINITIONS

1.1. "**Adverse Drug Experience**" means any serious, non-serious or unexpected adverse event associated with the use of a drug in humans, whether or not considered drug-related, that may come to the attention of either of the Parties or their respective Affiliates or Third Party subcontractors with regard to the Product including but not limited to those that are of such a nature and magnitude that they are required under Applicable Law to be reported to the FDA or the Regulatory Authority.

1.2. "**Affiliate**" means, with respect to a Party, any Person that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, "**control**" shall refer to: (a) the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities, by contract or otherwise, or (b) the ownership, directly or indirectly, of fifty percent (50%) or more of the voting securities of such entity.

1.3. "**Applicable Laws**" means all applicable laws, statutes, rules, regulations and guidelines of any jurisdiction, including, without limitation, all good clinical practices, all good laboratory practices, all good manufacturing practices and all applicable standards or guidelines promulgated by the appropriate regulatory agency such as the FDA or the Regulatory Authority.

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.4. "**Business Day**" means any day other than a Saturday, a Sunday or a day on which commercial banks located in San Francisco, California, or Osaka, Japan are authorized or required by law to remain closed.

1.5. "**Calendar Quarter**" means each three (3) month period commencing on January 1st, April 1st, July 1st and October 1st.

1.6. "**Calendar Year**" means the twelve (12) month period commencing on each January 1st.

1.7. "**Commercialize**" or "**Commercialization**" means to manufacture for sale, market, promote, distribute, and sell.

1.8. "**Commercially Reasonable Efforts**" means the carrying out of Development or Commercialization activities with respect to the Product in a sustained manner using good faith and diligent efforts, using the efforts that a company within the pharmaceutical industry of a similar size to Maruho would reasonably devote to a product.

1.9. "**Control**" or "**Controlled**" means, with respect to any Intellectual Property Rights, the legal authority or right (whether by ownership, license or otherwise) of a Party to grant a license or a sublicense of or under such Intellectual Property Rights to the other Party without breaching the terms of any agreement with a Third Party.

1.10. "**Dermira FTE Rate**" means, as of the Effective Date, USD $[*****] per annum for the time of an employee for a full-time equivalent person year (consisting of a total of 1800 hours per annum) of work ($[*****] per day), to be pro-rated on a daily basis provided that if less than eight (8) hours are worked in a day, then the FTE Rate shall be pro-rated on an hourly basis. The FTE Rate shall be increased or decreased each year on the anniversary of the Effective Date by a percentage equal to the increase or decrease of [*****].

1.11. "**Dermira Other IP**" has the meaning as set forth in Section 8.4.

1.12. "**Dermira Product IP**" has the meaning as set forth in Section 8.3.

1.13. "**Develop**" or "**Development**" means to conduct any and all research and development activities necessary to obtain Regulatory Approval to commercialize a drug candidate.

1.14. "**Developed IP**" has the meaning as set forth in Section 8.2.

1.15. "**Development Plan**" means a development plan written in English for the Development of the Product in the Territory and includes without limitation (a) all non-clinical and clinical studies to be conducted for Regulatory Approval of the Product in the Territory, (b) quantities and timing of DRM04 drug substance or Product required to support the planned non-clinical and clinical studies, (c)

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

regulatory requirements for the drug substance and drug product for the Product in the Territory, and (d) Dermira's support and assistance for the Development of the Product in the Territory (as Dermira has agreed in writing or approved by the Steering Committee).

1.16. "**Exploit**" or "**Exploitation**" means to develop, register, make, have made, manufacture, have manufactured, use, sell, offer for sale, distribute and import.

1.17. "**FDA**" means the Food and Drug Administration of the United States, or the successor thereto.

1.18. "**Field**" means the topical treatment or prevention of hyperhidrosis in human patients for [*****].

1.19. "**First Commercial Sale**" means the first sale for use or consumption by the general public of the Product in the Territory following receipt of Regulatory Approval for such Product in the Territory.

1.20. "**GAAP**" means Japanese generally accepted accounting principles.

1.21. "**Generic Competitor**" means a pharmaceutical product with the same active ingredient, therapeutic dosage, dosing schedule, safety profile, and administration route as the Product, and which has been approved by the Regulatory Authority in the Territory with the Product as the reference product.

1.22. "**Incremental Cost**" means the costs described on Schedule E.

1.23. "**IND**" means an investigational new drug application filed with the Regulatory Authority for authorization for the investigation of the Product in the Field.

1.24. "**Intellectual Property Rights**" means all trade secrets, copyrights, patents and other patent rights, trademarks, moral rights, and any and all other intellectual property or proprietary rights now known or hereafter recognized in any jurisdiction.

1.25. "**Know-How**" means all confidential and proprietary information and data Controlled by Dermira (a) as of the Effective Date and which: (i) Dermira [*****] into the Product prior to the Effective Date of this Agreement, and (ii) [*****] for Maruho to Exploit the Product, (b) which is included within the Developed IP, or (c) which is included within the Dermira Product IP.

1.26. "**Licensed IP Rights**" means collectively, the Patent Rights and Know-How.

1.27. "**Losses and Claims**" means collectively, any and all Third Party demands, claims, actions and proceedings (whether criminal or civil, in contract, tort or otherwise) for losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees).

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.28. "**Maruho Other IP**" has the meaning as set forth in Section 8.5.

1.29. "**NDA**" means a new drug application filed with the Regulatory Authority for authorization for marketing the Product in the Field.

1.30. "**Net Sales**" means the gross sales amount recognized by Maruho, its Affiliates and their respective sublicensees for sales of the Product (other than sales by Maruho, its Affiliates or sublicensees for subsequent resale in which case the final sale to the end user shall be used for calculation of Net Sales), less deductions calculated in accordance with GAAP. If the calculation of "Net Sales" in accordance with the foregoing would be less than the amount determined in accordance with the "Net Sales" definition under the Rose U Agreement, then upon Dermira's written request, the definition of "Net Sales" shall convert to the definition set forth in the Rose U Agreement.

1.31. "**Patent Rights**" means: (a) the patents and patent applications listed in Schedule A and any patents and patent applications within the Developed IP and Dermira Product IP, (b) all divisionals and continuations in the Territory that claim priority to the patents or patent applications described in subsection (a), (c) all patents that have issued or in the future issue from any of the foregoing patent applications described in subsections (a) and (b) in the Territory, including utility, model and design patents and certificates of invention, and (d) any reissues, renewals, extensions or additions of any of the foregoing in the Territory.

1.32. "**Person**" means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

1.33. "**Phase 1/2b Clinical Study**" means a human clinical trial in the Territory that is intended to initially evaluate the effectiveness of the Product for a particular indication or indications in patients with the disease or indication under study.

1.34. "**Phase 3 Clinical Study**" means a human clinical trial in the Territory, which are performed after Phase 1/2b Clinical Study, the results of which could be used to establish safety and efficacy, and to determine warnings, precautions, and adverse reactions of the Product as a basis for an NDA.

1.35. "**Product**" means a drug product that incorporates DRM04 [*****].

1.36. "**Product Trademarks**" means all registered and unregistered trademarks, service marks, trade dress, trade names, logos, insignias, domain names, symbols, designs, and combinations thereof, in each case that are developed and used by Maruho, its Affiliates or its sublicensees in the Development or Commercialization of the Product in the Field and Territory and identifies the Product. The "Product Trademarks" will not include a trademark registered and maintained by Dermira in the Territory ("Dermira Trademark(s)"). For the avoidance of doubt if a trademark

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used by Maruho comprises a Dermira Trademark, then such trademark is not a Product Trademark and is owned by Dermira.

1.37. "**Regulatory Approval**" means, with respect to the Product, any approval (including where required, pricing and reimbursement approvals), registration, license or authorization that is required by the Regulatory Authority to market and sell the Product in the Field and Territory.

1.38. "**Regulatory Authority**" means Koseirodosho, the Japanese Ministry of Health, Labour and Welfare, Pharmaceuticals and Medical Devices Agency and any successor agency thereto responsible for granting Regulatory Approvals for the Product in the Territory.

1.39. "**Regulatory Filings**" means, with respect to the Product, any submission to the Regulatory Authority of any appropriate regulatory application, including, without limitation, any IND, NDA, any submission to a regulatory advisory board, any marketing authorization application, and any supplement or amendment thereto.

1.40. "**Report Due Date**" means February 1st for the reporting period from October 1st to December 31st in the preceding year, May 1st for the reporting period from January 1st to March 31st , August 1st for the reporting period from April 1st to June 30, and November 1st for the reporting period from July 1st to September 30.

1.41. "**Royalty Term**" means the period commencing on the Effective Date and expiring upon the later of: (a) expiration or abandonment of the last Valid Claim of the Patent Rights in the Territory, (b) expiration of any market exclusivity in the Territory granted by the Regulatory Authority, and (c) fifteen (15) years following the date of First Commercial Sale of the Product in the Territory.

1.42. "**Steering Committee**" has the meaning as set forth in Section 3.1.

1.43. "**Term**" has the meaning as set forth in Section 13.1.

1.44. "**Territory**" means Japan.

1.45. "**Third Party**" means any Person other than a Party or an Affiliate of a Party.

1.46. "**Valid Claim**" means either: (a) a claim of an issued and unexpired patent included within the Patent Rights, which has not been permanently revoked or declared unenforceable or invalid by an unreversed and unappealable or unreversed and unappealed decision of a court or other appropriate body of competent jurisdiction, or (b) a claim of a pending patent application included within the Patent Rights, which claim was filed in good faith and has not been abandoned or finally disallowed without the possibility of appeal or refiling of such application.

2. LICENSE GRANT

2.1. **License Grant**. Subject to the terms and conditions of this Agreement, Dermira hereby grants to Maruho an exclusive, sublicensable (subject to Section 2.2, and to the extent applicable, to Section 2.3), royalty-bearing right and license under the Licensed IP Rights to Exploit the Product in the Field and Territory.

2.2. **Sublicense Rights**. Maruho may sublicense the rights granted to it by Dermira under this Agreement to any of its Affiliates without obtaining Dermira's prior written approval, or to any Third Party upon Dermira's prior written approval, which approval shall not be unreasonably withheld or delayed. Any and all sublicenses shall be subject to the following conditions:

2.2.1. All sublicenses shall be subject to and consistent with the terms and conditions of this Agreement and shall: (a) preclude the assignment of such sublicense without the prior written approval of Dermira, (b) include Dermira as a third party beneficiary under the sublicense with the right to enforce the terms of such sublicense, and (c) preclude the granting of further sublicenses in contravention with the terms and conditions of this Agreement. In no event shall any sublicense relieve Maruho of any of its obligations under this Agreement.

2.2.2. Maruho shall furnish to Dermira a true and complete copy of each sublicense agreement and each amendment thereto within thirty (30) days after the sublicense or amendment has been executed, provided that Maruho may redact confidential provisions of the sublicense agreement and each amendment that are not reasonably required by Dermira to confirm Maruho's compliance with this Agreement. In addition, if the executed sublicense agreement or amendment is [*****] to provide to Dermira with [*****] the document.

2.2.3. Dermira agrees that Maruho's obligation set forth in this Section 2.2 will not apply to the agreements between Maruho or its Affiliates and contract research organizations, contract manufacturing organizations and similar Third Parties in each case performing services for the benefit of Maruho or its Affiliates or a Maruho sublicensee.

2.3. **Rose U Rights**. Dermira has obtained certain intellectual property and data rights (the "**Rose U Rights**") from Rose U LLC ("**Rose U**") and Stiefel Laboratories, Inc. ("**Stiefel**") pursuant to that certain Exclusive License Agreement dated April 26, 2013 (the "**Rose U Agreement**"), the redacted version of which has been provided to Maruho prior to the Effective Date. If during the Development of the Product it is necessary to utilize the Rose U Rights, then the following shall apply:

2.3.1. For purposes of the license grant under Section 2.1, the Licensed IP Rights shall include the Rose U Rights to the extent necessary for the Exploitation of the Product in the Field and in the Territory.

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

2.3.2. If Maruho further sublicenses the Rose U Rights (as included within the license grant under Section 2.1) to a Third Party (a "**Rose U Sublicensee**"), then Maruho's sublicense agreement with the Rose U Sublicensee (the "**Rose U Sublicense**") shall be within the scope of the license granted under the Rose U Agreement and shall be consistent with the terms of the Rose U Agreement in all respects. For clarity, Maruho or Rose U Sublicensee will not be under the obligation other than the obligation described in this Agreement and the Rose U Agreement.

2.3.3. Maruho shall (and shall cause each Rose U Sublicensee to) (a) indemnify Rose U and its Affiliates (as defined in the Rose U Agreement) as provided in Section 11.1 of the Rose U Agreement and indemnify Stiefel and its Affiliates (as defined in the Rose U Agreement) as provided in the Stiefel Side Letter (as defined in the Rose U Agreement and attached thereto), in each case as Dermira's sublicensee in the Field in the Territory, subject to conditions and procedures substantially equivalent to those contained in Section 11.2 of the Rose U Agreement and the Stiefel Side Letter, and (b) maintain the Stiefel Data (as defined in the Rose U Agreement) under confidentiality obligations no less protective than those set forth in Article 9 of the Rose U Agreement.

2.3.4. All information provided by Dermira to Maruho that constitutes Patent Rights and Technology (as defined in the Rose U Agreement) shall be governed by the terms of Article 9 of the Rose U Agreement.

2.3.5. Stiefel and its Affiliates (as defined in the Rose U Agreement) shall be intended third party beneficiaries of this Agreement and Maruho shall include in each Rose U Sublicense an express statement that Stiefel and its Affiliates (as defined in the Rose U Agreement) are intended third party beneficiaries of the Rose U Sublicense.

2.4. **Exclusivity**. During the Term, and except with respect to the Product under this Agreement, neither Maruho nor any of its Affiliates (nor any sublicensee of Maruho as provided under Section 2.2 of this Agreement) shall Develop or Commercialize in the Field and in the Territory a product that contains [*****], provided that, with respect to this Section 2.4 only, the term "Develop" as applied to Maruho, its Affiliates or its sublicensees does not include basic, non-clinical research activities (but still includes clinical research activities such as clinical trials and other non-clinical registration enabling research such as toxicology studies). During the Term, neither Dermira nor any of its Affiliates shall itself (and neither shall grant a license to any Third Party to) Develop or Commercialize in the Field and in the Territory a product that contains DRM04 (alone or in combination with another drug substance).

2.5. **No Additional Rights**. Nothing in this Agreement shall be construed to confer any rights upon Maruho by implication, estoppel, or otherwise as to any technology or Intellectual Property Rights of Dermira or its Affiliates other than the Licensed IP Rights.

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

3. GOVERNANCE

3.1. Establishment of Steering Committee. No later than thirty (30) days after the Effective Date, the Parties will establish a committee to oversee and monitor the Development and Commercialization of the Product in the Territory (the "**Steering Committee**").

3.1.1. The Steering Committee will be composed of three (3) representatives of each Party, who shall be appointed (and may be replaced at any time) by such Party on written notice to the other Party in accordance with this Agreement. Any member of the Steering Committee may designate a substitute to attend and perform the functions of that member at any meeting of the Steering Committee.

3.1.2. The Steering Committee will be held [*****] during the Term, or more frequently as agreed by the Steering Committee provided that the minimum frequency will be decreased to once each year after the first anniversary of the First Commercial Sale of the Product. The location of regularly scheduled in-person Steering Committee meetings shall alternate between the offices of the Parties, unless otherwise agreed. Meetings may be held telephonically, provided that at least one meeting in a Calendar Year is an in-person meeting.

3.1.3. The Party hosting any Steering Committee meeting shall appoint one person (who need not be a member of the Steering Committee) to attend the meeting and record the minutes of the meeting. Such minutes shall be circulated to the Parties promptly following the meeting for review, comment and distribution. A final copy of the minutes of each meeting, clearly describing any formal actions taken by the Steering Committee, shall be approved and signed by a representative from each Party within thirty (30) days after the meeting.

3.1.4. The Steering Committee will operate by unanimous consent, with each Party having a single vote.

3.1.5. At any time during the Term and for any reason, Dermira shall have the right to withdraw from participation in the Steering Committee effective immediately upon written notice to Maruho.

3.2. Steering Committee Responsibilities. In addition to and without limiting the general oversight functions described above, the Steering Committee shall perform the following functions specific to Maruho's Development and Commercialization of Product in the Field and Territory (other than the function described in 3.2.9 which is specific to Dermira's development and Commercialization):

3.2.1. [*****] the Development Plan and any proposed amendments to the Development Plan;

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

3.2.2. [*****] the following, for which Maruho will prepare summaries, each with sufficient detail regarding, as applicable, general strategy, dosing, efficacy, safety, and inclusion and exclusion criteria: (a) any non-clinical studies and protocols and any non-clinical study report conclusions; (b) any clinical trial protocols and any clinical study report conclusions, (c) any Regulatory Filing, and (d) any scientific publication or public presentation regarding DRM04 drug substance or Product. With respect to the approval process under Section 3.2.2, at Maruho's discretion, the applicable summary may be sent directly to Dermira's Steering Committee members and if such Steering Committee members have not responded within [*****] Business Days, then the applicable approval shall be deemed given by Dermira's Steering Committee members. Maruho shall provide the summaries in English, but shall not be obligated to translate the underlying protocols and documents identified in Section 3.2.2, provided Maruho shall continue to be obligated to maintain and make available such protocols and documents in accordance with Section 4.3.;

3.2.3. [*****], provided that the Steering Committee approval shall no longer be required if Maruho and not Dermira supplies the DRM04 drug substance in the Territory;

3.2.4. [*****], provided that the Steering Committee approval shall no longer be required if Maruho and not Dermira supplies the Product in the Territory;

3.2.5. [*****] Maruho's non-binding forecast for supply requirements of Product and Dermira's plans for providing such supply, provided that the Steering Committee review shall no longer be required if Maruho and not Dermira supplies the Product in the Territory;

3.2.6. [*****] the commercialization plan and proposed amendments to the commercialization plan;

3.2.7. [*****] requests by Dermira for including certain costs as Incremental Cost and amending Schedule E accordingly;

3.2.8. [*****] requests by Maruho for Dermira support and assistance in connection with the Development or supply of the Product in the Territory and associated budget to the extent such support and assistance is not [*****];

3.2.9. [*****] Dermira's progress of its development and the Commercialization of the Product outside the Territory.

3.2.10. establishing working committees and delegate authority of the Steering Committee thereto as the Steering Committee deems necessary; and

3.2.11. serve as the first forum for settlement of disputes or disagreements arising from the Development or Commercialization of the Product in the Territory, unless otherwise indicated in this Agreement.

3.3. **Decision Making**. Decisions of the Steering Committee shall be made by unanimous vote, with each Party having one vote. If the votes required to approve a decision cannot be reached within the Steering Committee, then the Parties shall refer the matter, within [*****] Business Days after the matter was first considered by the Steering Committee, to their respective Chief Executive Officers ("CEOs") or a representative designated by CEOs ("Designee") for discussion and attempted resolution in good faith. Such resolution, if any, of a referred matter by the CEOs or Designees shall be final and binding upon the Parties and shall be considered a decision of the Steering Committee for purposes of this Agreement. If [*****] Business Days after the matter was first submitted to the CEOs, the CEOs or Designees are unable to reach consensus, then (i) Dermira shall have the deciding vote on any matter that could potentially result in a negative impact on the development or Commercialization of the Product outside of the Territory (ii) Maruho shall have the deciding vote on any matter substantially related to Development, manufacture or Commercialization of the Product in the Field and Territory, provided that is also not a matter within Section 3.3(i). For any disputed matters at the Steering Committee that are not resolved by the CEOs or Designees and do not fall within subclauses (i) or (ii), the Parties shall submit the matter to arbitration in accordance with Section 16.3. The Steering Committee, the CEOs, Designees, or the arbitrators shall be guided in resolving any potential future dispute that Maruho explicitly agreed to reimburse Dermira for the Incremental Cost.

4. DEVELOPMENT AND COMMERCIALIZATION

4.1. **Development Efforts**. Within sixty (60) days following the Effective Date, Maruho shall prepare and provide to Dermira the proposed initial Development Plan. As soon as practicable, the Parties shall hold a Steering Committee meeting to review and approve the Development Plan as provided by Section 3.2. Maruho shall itself, or through its Affiliates or sublicensees, use Commercially Reasonable Efforts to Develop the Product in the Field and Territory in accordance with the approved Development Plan and in accordance with all Applicable Laws. In connection with its efforts to Develop the Product, Maruho shall bear all responsibility and expense for filing Regulatory Filings in Maruho's name and obtaining Regulatory Approval for the Product in the Field and Territory. Maruho will undertake such activities at its sole expense. Without the prior written consent of Dermira, Maruho shall not contact any Third Party, or otherwise engage in discussions with a Third Party, regarding access to such Third Party's data that may be used in connection with the Development or the Regulatory Approval of the Product in the Field and Territory.

4.2. **Commercialization**. Subject to Dermira's obligation under the Development Supply Agreement and the Commercial Supply Agreement, Maruho shall itself, or through its Affiliates or sublicensees, use Commercially Reasonable Efforts to Commercialize the Product in the Territory. Maruho will undertake such activities at its sole expense.

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

4.3. **Records**. Maruho shall maintain records of the Development or Commercialization of the Product in the Territory in sufficient detail and in good scientific manner as shall reflect, to the reasonable extent, work done by Maruho or by a Third Party on Maruho's behalf and results achieved (the "**Records**"), including data in the form required under any applicable governmental regulations. For avoidance of doubt, Records include all correspondences between Maruho (or a Third Party on Maruho's behalf) and any government agency including but not limited to the Regulatory Authority. For clarity, the Relevant Records defined in Section 7.1.1 are not included in the definition of the Records.

4.3.1. Maruho shall maintain the Records during the Term and for a period equal to the longer of (a) [*****] years or (b) the period of time required by Applicable Laws.

4.3.2. Within [*****] of the Effective Date, Maruho shall establish an electronic repository reasonably acceptable and accessible to Dermira. Maruho shall maintain such repository and ensure to a reasonable extent that the Records are placed therein no later than [*****] Business Days after creation of such Records. For avoidance of doubt, other than the Records necessary for the Steering Committee review and approval as enumerated in Section 3.2, Maruho has [*****] any of the other Records or any other documents [*****] that are deposited in the electronic repository.

4.4. **Reports**. No later than the Report Due Date, Maruho shall provide to Dermira a written report, in the English language, that contains the results of the Development or Commercialization of the Product for such Calendar Quarter, including status of any non-clinical or clinical study, study findings, summary of discussions with the Regulatory Authority, total monthly sales calculation of Net Sales of Product (with explicit enumeration of all Deductions) and all royalty due (including explicit enumeration of any foreign exchange rates employed), and invention disclosure ("**Reports**"). Maruho shall also provide Dermira with such additional information as Dermira may reasonably request, at such times as Dermira reasonably requests, in order for Dermira to comply with its reporting obligations or to verify Maruho's compliance with its obligations under this Agreement.

4.5. **Safety Reporting.** Maruho acknowledges that Dermira has certain reporting obligations to the FDA regarding the Product. Maruho shall cooperate with Dermira and shall ensure that Dermira is provided with all information in a timely manner to enable Dermira to comply with its reporting obligations to the FDA or its equivalent outside of the Territory. As promptly as possible following the Effective Date and at least before the start of the first non-clinical study or clinical trial conducted by Maruho with DRM04 drug substance or the Product, the Parties shall enter into a safety agreement governing the Parties' respective responsibilities with respect to Adverse Drug Experiences, complaints and other safety-related matters relating to the Product.

4.5.1. Dermira shall own and maintain the global safety database with respect to the Product [*****].

4.5.2. Any Adverse Drug Experience known by a Party or its Affiliates or Third Party subcontractors must be reported to the other Party in writing in accordance with the timelines and procedures set forth in the Safety Agreement.

4.5.3. Maruho shall cooperate with Dermira to ensure the collection, reporting and follow-up of any safety data in the Territory.

4.5.4. Dermira shall have the final decision on any drug safety or pharmacovigilance matters from the global perspective; provided that Maruho shall have the responsibility to conduct pharmacovigilance activities in the Territory.

4.5.5. Maruho shall not, and shall ensure that each of its Affiliates, agents or Third Party subcontractors shall not, make any public statement or give any public opinion on drug safety or pharmacovigilance matters, whether orally or in writing, without first having received Dermira's express written consent to do so, provided that Dermira shall not withhold, delay or condition such consent in a manner that would result in Maruho's non-compliance with Applicable Law and further provided that once Dermira has provided its consent for a particular statement or opinion then Maruho shall be able to freely release such statement or opinion without the need for additional consent.

5. MANUFACTURE OF PRODUCT

5.1. **Development Supply Agreement**. Pursuant to the Development Supply Agreement (as defined below), Dermira shall be responsible for the supply of DRM04 drug substance and supply of Product for Maruho's non-clinical and clinical Development meeting the specifications provided to Maruho prior to the Effective Date ([*****], the "Specifications") and if [*****] for the Development in the Territory, the Parties will [*****] as provided by Section 3.2. For avoidance of doubt, the Parties have explicitly agreed that Maruho shall reimburse Dermira for all [*****] incurred by Dermira, in support of Maruho's Development of Product, including all costs specific only for the Territory.

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Dermira's baseline costs are based on the [*****] (meeting Dermira's then-current specifications (the "**Dermira Specifications**"), manufacturing processes, in-process tests, and in-process specifications for Product for Dermira's development and Commercialization) [*****]. Dermira will notify Maruho of any changes to the Dermira Specifications as soon as reasonably practicable. In addition, the Parties have explicitly agreed that the transfer price of the Product will be Dermira's [*****] the Product. The Parties will make reasonable effort to execute the supply agreement of supply of DRM04 drug substance and the Product for non-clinical and clinical Development containing the terms set for the on Schedule B (the "**Development Supply Agreement**"). If the Parties are unable to reach agreement on the terms of the Development Supply Agreement by [*****] days after the Effective Date, then within [*****] days following the end of such period the Parties shall submit the matter to a neutral arbitrator located in London, England as follows: (a) the arbitrator will be selected by the Parties and shall have expertise in pharmaceutical manufacturing and supply agreements (if the Parties are unable to reach mutual agreement on an arbitrator, then each Party will select its neutral arbitrator and the two selected arbitrators shall select the arbitrator), (b) each Party shall deliver to the arbitrator and the other Party its proposed draft of the Development Supply Agreement based on the terms set forth on Schedule B, (c) the arbitrator shall give each Party the opportunity to explain to the arbitrator why its draft of the Development Supply Agreement is more appropriate than the other Party's, which may include conducting an oral argument or an evidentiary hearing if the arbitrator determines that it would assist the arbitrator's decision of which draft of the Development Supply Agreement to select, (d) the arbitrator shall, within [*****] Business Days after receipt of the two draft Development Supply Agreements and having heard each Party's rationale for its proposal, select one draft Development Supply Agreement from the two (2) submitted, that fully reflects the terms set forth on Schedule B and (e) the draft Development Supply Agreement selected by the arbitrator shall be executed by both Parties and binding on the Parties and the arbitrator may not modify or alter the terms of the Development Supply Agreement.

5.2. **Commercial Supply Agreement**. Pursuant to the Commercial Supply Agreement (as defined below), Dermira shall be responsible for the commercial supply of Product meeting the Specifications for Maruho's Commercialization of Product in the Territory. For avoidance of doubt, the Parties have explicitly agreed that Maruho shall reimburse Dermira for the [*****]. Dermira's baseline costs are based on the [*****] meeting the Dermira Specifications, manufacturing processes, in-process tests, and in-process specifications) [*****]. Dermira will notify Maruho of any changes to the Dermira Specifications as soon as reasonably practicable. In addition, the Parties have explicitly agreed that the transfer price of the Product will be Dermira's [*****] the Product. The Parties will commence negotiations at the time of NDA filing and make reasonable effort to execute the supply agreement for commercial supply of the Product at least [*****] months prior to the anticipated First Commercial Sale of the Product in the Territory (the "**Commercial Supply Agreement**"). The Commercial Supply Agreement shall

contain the terms set forth on Schedule C. If the Parties are unable to reach agreement on the terms of the Commercial Supply Agreement by [*****] days after the commencement of negotiations, then within [*****] days following the end of such period the Parties shall submit the matter to a neutral arbitrator located in London, England as follows: (a) the arbitrator will be selected by the Parties and shall have expertise in pharmaceutical manufacturing and supply agreements (if the Parties are unable to reach mutual agreement on an arbitrator, then each Party will select its neutral arbitrator and the two selected arbitrators shall select the arbitrator), (b) each Party shall deliver to the arbitrator and the other Party its proposed draft of the Commercial Supply Agreement based on the terms set forth on Schedule C, (c) the arbitrator shall give each Party the opportunity to explain to the arbitrator why its draft of the Commercial Supply Agreement is more appropriate than the other Party's, which may include conducting an oral argument or an evidentiary hearing if the arbitrator determines that it would assist the arbitrator's decision of which draft of the Commercial Supply Agreement to select, (d) the arbitrator shall, within [*****] Business Days after receipt of the two draft Commercial Supply Agreements and having heard each Party's rationale for its proposal, select one draft Commercial Supply Agreement from the two (2) submitted, that fully reflects the terms set forth on Schedule C and (e) the draft Commercial Supply Agreement selected by the arbitrator shall be executed by both Parties and binding on the Parties and the arbitrator may not modify or alter the terms of the Commercial Supply Agreement.

6. PAYMENT TERMS

6.1. Payment Terms.

6.1.1. **Upfront Payment**. In partial consideration of the licenses and rights granted to Maruho hereunder, within fifteen (15) Business Days following the Effective Date, Maruho shall pay to Dermira a one-time upfront, non-refundable and non-creditable payment of twenty five million dollars (USD $25,000,000).

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

6.1.2. **Milestone Payments**. In further consideration of the licenses and rights granted to Maruho hereunder, upon achievement of each Milestone set forth below, the corresponding non-creditable and non-refundable Milestone Payment shall be payable by Maruho to Dermira. Maruho shall notify Dermira as soon as practicable upon achievement of each Milestone, but no later than [*****] Business Days after Maruho's determination of achievement and Dermira shall submit an invoice for the applicable Milestone Payment within [*****] Business Days after such notice. Maruho shall pay to Dermira each applicable Milestone Payment within [*****] days after such Milestone is achieved.

MILESTONE	MILESTONE PAYMENT
(1)Upon [*****] for the Product [*****]	USD $[*****]
(2)Upon [*****] for the Product [*****]	USD $[*****]
(3)Upon [*****]	USD $[*****]
(4)Upon [*****]	USD $[*****]
(5)Upon [*****]	USD $[*****]
(6)Upon [*****]	USD $[*****]
(7)Upon [*****]	USD $[*****]

For the avoidance of doubt (a) a Milestone achieved by a sublicensee or assignee of, or Third Party retained by, Maruho or its Affiliates shall be deemed to have been achieved by Maruho for purposes of this Section 6.1.2, and (b) if more than one Milestone is achieved at the same time, then each applicable Milestone Payment will be due and payable (by way of example, if during Maruho's first fiscal year after First Commercial Sale, there are [*****], then Milestone Payment 3 and Milestone Payment 4 would both be due and payable.)

6.1.3. **Royalty Payments**.

(a) In further consideration of the licenses and rights granted to Maruho hereunder, during the Royalty Term, Maruho shall pay to Dermira [*****] percent ([*****]%) of Net Sales of Product in the Territory. After the First Commercial Sale, the Net Sales and the royalty due shall be part of the Reports in accordance with Section 4.4. The applicable royalty payment shall be due no later than the Report Due Date.

(b) If a Generic Competitor is [*****] in the Field and Territory during the Royalty Term, then the royalty rate in Section 6.1.3(a) shall be lowered from [*****] percent ([*****]%) to [*****] percent ([*****]%) effective at the beginning of the [*****].

6.1.4. **Other Payments**. For payments other than Milestone Payments or royalty payments, each Party shall pay to the other party any other amounts due under this Agreement (that is not disputed in good faith) within [*****] days following receipt of invoice, which shall include sufficient detail and description regarding the invoiced amount. If any portion of the invoiced amount is disputed, the Parties shall discuss in good faith to resolve the matter. For clarity, Dermira has the right to invoice Maruho in advance of incurring certain Incremental Cost as specified in Schedule E subject to Maruho's prior approval for such advance payment.

6.1.5. **Late Payments**. Any late payments shall bear interest, to the extent permitted by law, at [*****] percent ([*****]%) per month.

6.2. Payment Method.

6.2.1. Any payments under Section 6 that are initially calculated in currencies other than the US dollar shall be converted into US dollars at the average of the daily foreign exchange rates published in the online version of the Wall Street Journal (currently located www.wsj.com) for the Calendar Quarter for which such payments apply, or for periods less than a Calendar Quarter, the average of the daily rates published in the Wall Street Journal for such period .

6.2.2. All payments from Maruho to Dermira shall be made by wire transfer in US Dollars to the credit of such bank account as may be designated by Dermira in writing to Maruho. Any payment which falls due on a date which is not a Business Day may be made on the next succeeding Business Day.

6.3. Taxes.

6.3.1. It is understood and agreed between the Parties that any amounts payable by Maruho to Dermira hereunder are exclusive of any and all applicable sales, use, value-added tax, general sales tax, excise, property, and other taxes, levies, duties or fees in the Territory (collectively, "**Taxes**"). Maruho shall be responsible for billing and collection from its customers and remitting to the appropriate taxing authority any and all Taxes which it is required to collect or remit. Each Party will be responsible for its own income and property taxes.

6.3.2. If Maruho is required to make a payment to Dermira subject to a deduction of tax or withholding tax (a "**Withholding Tax Requirement**") then the sum payable by Maruho (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that Dermira receives a sum equal to the sum which it would have received had no such Withholding Tax Requirement been applicable, and the amount required to be deducted or withheld shall be remitted by Maruho in accordance with Applicable Law in the Territory. Any such withholding taxes required under Applicable Law in the Territory to be paid or withheld shall be an expense of, and borne solely by, Maruho.

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6.3.3. The Parties agree to cooperate and produce on a timely basis any tax forms or reports, including an IRS Form W-8BEN, reasonably requested by the other Party in connection with any payment made by Maruho to Dermira under this Agreement.

7. FINANCIAL RECORDS; AUDIT RIGHTS

7.1. Relevant Records.

7.1.1. **Relevant Records**. Maruho shall maintain accurate financial books and records pertaining to the sublicensing of the Licensed IP Rights pursuant to Section 2.2 and Maruho's sale of the Product, including any and all calculations of the applicable fees (collectively, "**Relevant Records**"). Maruho shall maintain the Relevant Records for the longer of: (a) [*****] following expiration or termination of this Agreement or (b) the period of time required by Applicable Law.

7.1.2. **Audit Request**. Dermira shall have the right during the Term and for [*****] thereafter to engage, at its own expense, an independent auditor reasonably acceptable to Maruho to examine the Relevant Records from time-to-time, but no more frequently than [*****], as may be necessary to verify compliance with the terms of this Agreement. Such audit shall be requested in writing at least [*****] days in advance, and shall be conducted during Maruho's normal business hours and otherwise in manner that minimizes any interference to Maruho's business operations.

7.1.3. **Audit Fees and Expenses**. Dermira shall bear any and all fees and expenses it may incur in connection with any such audit of the Relevant Records; provided, however, in the event an audit reveals an underpayment of Maruho of more than [*****] percent ([*****]%) as to the period subject to the audit, Maruho shall reimburse Dermira for any reasonable and documented out-of-pocket costs and expenses of the audit within [*****] days after receiving invoices thereof.

7.1.4. **Payment of Deficiency**. If any audit establishes that Maruho underpaid any amounts due to Dermira under this Agreement, then Maruho shall pay Dermira any such deficiency within [*****] days after receipt of written notice thereof. For the avoidance of doubt, such payment will be considered a late payment, subject to Section 6.1.5.

8. INTELLECTUAL PROPERTY RIGHTS

8.1. Pre-existing IP. Each Party shall retain all rights, title and interests in and to any Intellectual Property Rights that are owned, licensed or sublicensed by such Party prior to the Effective Date of this Agreement.

8.2. Developed IP. Dermira shall solely own all rights, title and interests in and to any Intellectual Property Rights that are both: (a) related to the Product, and (b) conceived, developed or reduced to practice by Maruho, its Affiliates or its

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

sublicensees on or following the Effective Date (collectively, "**Developed IP**"). Maruho hereby assigns to Dermira all right, title and interest in and to the Developed IP.

8.3. **Dermira Product IP.** Dermira shall retain all rights, title and interests in and to any Intellectual Property Rights that are conceived, developed or reduced to practice by Dermira or its Affiliates after the Effective Date and are necessary to Develop or Commercialize Product (the "**Dermira Product IP**").

8.4. **Dermira Other IP.** Dermira shall retain all rights, title and interests in and to any Intellectual Property Rights that are conceived, developed or reduced to practice by Dermira or its Affiliates after the Effective Date and are not necessary to Develop or Commercialize Product (the "**Dermira Other IP**"). For avoidance of doubt, licenses granted to Maruho under this Agreement exclude Dermira Other IP.

8.5. **Maruho Other IP.** Maruho shall retain all rights, title and interests in and to any Intellectual Property Rights that are conceived, developed or reduced to practice by Maruho or its Affiliates after the Effective Date and are not Developed IP (the "**Maruho Other IP**"). For avoidance of doubt, the rights assigned to Dermira under this Agreement exclude Maruho Other IP.

8.6. **Patents**.

(a) **Patent Prosecution, Maintenance and Enforcement**. Dermira shall have the sole right and responsibility for filing, prosecuting (including in connection with any reexaminations, oppositions and the like), maintaining and enforcing the Patent Rights in the Territory in Dermira's name and at Dermira's own cost and expense. Dermira shall use Commercially Reasonable Efforts to obtain up to [*****] of patent term extension for the Patent Rights in the Territory.

(b) **Assistance**. Maruho will provide reasonable assistance to Dermira, at Dermira's expense, including but not limited to bearing the Maruho's labor cost calculated based on the same rate to the Dermira's FTE Rate, in connection with the filing, prosecution and maintenance of the Patent Rights in the Territory, where such assistance shall include providing access to relevant persons and executing all documentation reasonably requested by Dermira. As reasonably requested by Dermira in writing reasonably in advance, Maruho shall cooperate in obtaining patent term restoration, supplementary protection certificates or their equivalents, and patent term extensions with respect to the Patent Rights in the Territory.

8.7. **Product Trademarks**. Dermira shall notify Maruho of the filing of any trademark application for the Product as soon as reasonably practicable. Upon Dermira's request, Maruho shall [*****] the use of a Dermira Trademark for the Product in the Territory. If Maruho uses a Dermira Trademark for the Product, Dermira shall grant to Maruho an exclusive, sublicensable right to use such

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Dermira Trademark for the Development and Commercialization of the Product in the Field and Territory [*****] and Dermira shall prosecute and maintain such Dermira Trademark in the Territory at [*****] cost. If Maruho [*****] a Dermira Trademark, it may [*****].

9. CONFIDENTIALITY

9.1. Definition. "**Confidential Information**" means the terms and provisions of this Agreement, inventions, processes, materials, chemicals, know-how and ideas, and other business, commercial, technical and financial information, that the disclosing Party or any of its Affiliates has supplied or otherwise made available to the other Party or its Affiliates. All Know-How shall be considered Dermira's Confidential Information.

9.2. Obligations. The receiving Party will protect all Confidential Information against unauthorized disclosure to Third Parties with the same degree of care as the receiving Party uses for its own similar information, but in no event less than a reasonable degree of care for a pharmaceutical company in a major market country. The receiving Party may disclose the Confidential Information to its Affiliates, and their respective directors, officers, employees, subcontractors, sublicensees, consultants, attorneys, and accountants, banks and investors (collectively, "**Recipients**") who have a need-to-know such information for purposes related to this Agreement, provided that the receiving Party shall hold such Recipients to written obligations of confidentiality with terms and conditions at least as restrictive as those set forth in this Agreement.

9.3. Exceptions.

9.3.1. The obligations under this Section 9 shall not apply to any information to the extent the receiving Party can demonstrate by competent evidence that such information:

(a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the receiving Party or any Recipients to whom it disclosed such information;

(b) was known to, or was otherwise in the possession of, the receiving Party prior to the time of disclosure by the disclosing Party;

(c) is disclosed to the receiving Party on a non-confidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to the disclosing Party; or

(d) is independently developed by or on behalf of the receiving Party or any of its Affiliates, as evidenced by its written records, without use of the Confidential Information.

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

9.3.2. The restrictions set forth in this Section 9 shall not apply to any Confidential Information that the receiving Party is required to disclose under Applicable Laws or a court order or other governmental order, provided that the receiving Party: (a) provides the disclosing Party with prompt notice of such disclosure requirement if legally permitted, (b) affords the disclosing Party an opportunity to oppose or limit, or secure confidential treatment for such required disclosure and (c) if the disclosing Party is unsuccessful in its efforts pursuant to subsection (b), discloses only that portion of the Confidential Information that the receiving Party is legally required to disclose as advised by the receiving Party's legal counsel. If and whenever any Confidential Information of the disclosing Party is disclosed in accordance with this Section 9.3.2, such disclosure shall not cause any such information to cease to be Confidential Information, except to the extent that such disclosure results in a public disclosure of such information (otherwise than by breach of this Agreement).

9.3.3. In the event that Dermira wishes to assign, pledge or otherwise transfer its rights to receive some or all of the Milestone Payments or royalties payable hereunder, Dermira may disclose to a Third Party Confidential Information of Maruho in connection with any such proposed assignment, provided that Dermira shall provide notice to Maruho and shall hold such Third Parties to written obligations of confidentiality with terms and conditions at least as restrictive as those set forth in this Agreement.

9.4. Right to Injunctive Relief. The Parties agree that breaches of this Section 9 may cause irreparable harm to the non-breaching Party and shall entitle the non-breaching Party, in addition to any other remedies available to it (subject to the terms of this Agreement), the right to seek injunctive relief enjoining such action.

9.5. Ongoing Obligation for Confidentiality. Upon expiration or termination of this Agreement, the receiving Party shall, and shall cause its Recipients to, destroy or return (as requested by the disclosing Party) any Confidential Information of the disclosing Party. Notwithstanding the foregoing, (i) each Party may keep a copy of Confidential Information to the extent such retention is required to comply with Applicable Law, provided such Confidential Information is not used for any purpose other than compliance with such Applicable Law, and (ii) each Party's counsel may retain a copy of any Confidential Information solely for the purpose of establishing compliance with the terms of this Agreement in the event of a dispute regarding the same.

10. REPRESENTATIONS, WARRANTIES AND COVENANTS

10.1. Representations and Warranties by Each Party. Each Party represents and warrants to the other Party as of the Effective Date and during the Term that:

(a) it is a corporation duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation;

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(b) it has full corporate power and authority to execute, deliver, and perform this Agreement, and has taken all corporate action required by Applicable Law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;

(c) this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms;

(d) all consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained; and

(e) the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, and the consummation of the transactions contemplated hereby do not and shall not: (i) conflict with or result in a breach of any provision of its organizational documents, (ii) result in a breach of any agreement to which it is a party that would impair the performance of its obligations hereunder; or (iii) violate any Applicable Law.

10.2. Representations and Warranties by Dermira. Dermira represents and warrants that:

(a) to Dermira's Knowledge as of the Effective Date (a) there is no claim pending alleging that the Exploitation of the Product in the Field within the Territory infringes, misappropriates or otherwise violates the Intellectual Property Rights of a Third Party, and (b) there is no claim pending or threatened by Dermira alleging that a Third Party is or was infringing, misappropriating or otherwise violating the Licensed IP Rights in the Field within the Territory. As used herein, " **Knowledge**" means with respect to a matter, (i) the actual knowledge of such matter or (ii) the knowledge of such matter that would have been obtained [*****] in respect of such matter and [*****], or (iii) knowledge that [*****];

(b) the Rose U Agreement has been executed and delivered by Rose U and remains in full force and effect; and,

(c) Dermira shall comply with the terms of this Agreement and all Applicable Law with respect to the performance of its obligations hereunder.

10.3. Representations and Warranties by Maruho. Maruho represents and warrants to Dermira that it shall comply with the terms of this Agreement and all Applicable Law with respect to the performance of its obligations hereunder.

10.4. No Other Warranties. EXCEPT AS EXPRESSLY STATED IN THIS SECTION 10, NEITHER PARTY MAKES ANY REPRESENTATIONS OR

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EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO WARRANTIES OF TITLE, NON-INFRINGEMENT, VALIDITY, ENFORCEABILITY, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. ANY INFORMATION PROVIDED BY DERMIRA OR ITS AFFILIATES IS MADE AVAILABLE ON AN "AS IS" BASIS WITHOUT WARRANTY WITH RESPECT TO COMPLETENESS, COMPLIANCE WITH REGULATORY STANDARDS OR REGULATIONS OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER KIND OF WARRANTY WHETHER EXPRESS OR IMPLIED.

11. INDEMNIFICATION

11.1. **Indemnification by Dermira**. Dermira shall defend, indemnify and hold harmless Maruho and its Affiliates, and their respective officers, directors, employees, contractors, agents and assigns, from and against any Losses and Claims arising or resulting from: (a) infringement of a Third Party's Intellectual Property Rights by the Exploitation of the Product in the Field and in the Territory to the extent the Losses and Claims arise from DRM04 drug substance or Product in the form set forth in the Specifications as supplied by Dermira, (b) the negligence, recklessness or wrongful intentional acts or omission of Dermira, its Affiliates, subcontractors or sublicensees in the supply of DRM04 drug substance or Product to Maruho, (c) breach by Dermira of any representation, warranty or covenant as set forth in this Agreement or (d) manufacture of the DRM04 drug substance or the Product as supplied by Dermira. For avoidance of doubt, the foregoing indemnification does not include Losses and Claims that arise (i) as a result of [*****] the manufacturing processes, in-process tests, in-process specifications or Specifications, in each case that are [*****], or (ii) as a result of an allegation or finding of trademark infringement of a Third Party trademark by a Product Trademark or Maruho's use of a Dermira Trademark in the Territory.

11.2. **Indemnification by Maruho**. Maruho shall defend, indemnify and hold harmless Dermira and its Affiliates (and if applicable, Rose U and its Affiliates and/or Stiefel and its Affiliates in accordance with Section 2.3.3), and their respective officers, directors, employees, contractors, agents and assigns, from and against any Losses and Claims arising or resulting from: (a) the Development of a Product by Maruho, its Affiliates, subcontractors or sublicensees to the extent that such Losses and Claims are not the result Dermira's negligence, recklessness, or wrongful intentional acts or omissions, (b) the Commercialization of a Product by Maruho, its Affiliates, subcontractors or sublicensees, (c) the negligence, recklessness or wrongful intentional acts or omissions of Maruho, its Affiliates, subcontractors or sublicensees with respect to the performance of Maruho's obligations under this Agreement, or (d) breach by Maruho of any representation, warranty or covenant as set forth in this Agreement.

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11.3. **Indemnification Procedure**. Subject to Section 2.3.3 (if applicable), in connection with any Losses and Claims for which a Party (the "**Indemnitee**") seeks indemnification from the other Party (the "**Indemnitor**") pursuant to this Agreement, the Indemnitee shall: (a) give to Indemnitor prompt written notice of the Losses and Claims; provided, however, that failure to provide such notice shall not relieve the Indemnitor of its liability or obligation hereunder, except to the extent of any material prejudice as a direct result of such failure; (b) cooperate with the Indemnitor, at the Indemnitor's expense, in connection with the defense and settlement of the Losses and Claims; and (c) permit the Indemnitor to control the defense and settlement of the Losses and Claims; provided, however, that in the event such settlement materially adversely impacts the Indemnitee's rights or obligations, the Indemnitor may not settle the Losses and Claims without the Indemnitee's prior written consent, which shall not be unreasonably withheld or delayed. Further, the Indemnitee shall have the right to participate (but not control) and be represented in any suit or action by advisory legal counsel of its selection and at its own expense.

12. LIMITATION OF LIABILITY

12.1. **Consequential Damages Waiver**. EXCEPT FOR A BREACH OF SECTION 9 OR OBLIGATIONS ARISING UNDER SECTION 11, NEITHER PARTY SHALL BE LIABLE FOR ANY INDIRECT, CONSEQUENTIAL, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES, INCLUDING DAMAGES FOR LOST PROFITS OR LOST REVENUES REGARDLESS OF WHETHER IT HAS BEEN INFORMED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES OR THE TYPE OF CLAIM, CONTRACT OR TORT (INCLUDING NEGLIGENCE).

13. TERM; TERMINATION

13.1. **Term**. The term of this Agreement shall commence as of the Effective Date and shall expire upon the expiration of the Royalty Term.

13.2. **Termination for Cause**. Each Party shall have the right, without prejudice to any other remedies available to it at law or in equity, to terminate this Agreement in the event the other Party breaches any of its material obligations hereunder and fails to cure such breach within [*****] days of receiving notice thereof; provided, however, if such breach is capable of being cured, but cannot be cured within such [*****] day period, and the breaching Party initiates actions to cure such breach within such period and thereafter diligently pursues such actions, the breaching Party shall have such additional period as is reasonable to cure such breach, but in no event will such additional period exceed [*****] days. Any termination by a Party under this Section 13.2 shall be without prejudice to any damages or other legal or equitable remedies to which it may be entitled from the other Party. For the avoidance of doubt, Maruho's failure to use Commercially Reasonable Efforts to Develop and Commercialize the Product shall constitute a material breach by Maruho under this Agreement and Dermira's failure to supply

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the DRM04 drug substance or the Product in accordance with the Development Supply Agreement or Commercial Supply Agreement shall constitute a material breach by Dermira.

13.3. **Termination for a Bankruptcy Event**. Each Party shall have the right to terminate this Agreement in the event of a Bankruptcy Event with respect to the other Party. "**Bankruptcy Event**" means the occurrence of any of the following: (a) the institution of any bankruptcy, receivership, insolvency, reorganization or other similar proceedings by or against a Party under any bankruptcy, insolvency, or other similar law now or hereinafter in effect, including any section or chapter of the United States Bankruptcy Code, as amended or under any similar laws or statutes of the United States or any state thereof (the "**Bankruptcy Code**"), where in the case of involuntary proceedings such proceedings have not been dismissed or discharged within [*****] days after they are instituted, (b) the insolvency or making of an assignment for the benefit of creditors or the admittance by a Party of any involuntary debts as they mature, (c) the institution of any reorganization, arrangement or other readjustment of debt plan of a Party not involving the Bankruptcy Code, (d) appointment of a receiver for all or substantially all of a Party's assets, or (e) any corporate action taken by the board of directors of a Party in furtherance of any of the foregoing actions.

13.4. **Maruho Termination**. Maruho shall have the right to terminate this Agreement upon [*****] days written notice to Dermira upon the occurrence of: (a) the Product has not received Regulatory Approval in the Territory by the end of 2027, (b) the labeling for the Product obtained or expected to be obtained in the Territory will not allow for an economically-viable Commercialization of the Product, (c) the initial Japan National Health Insurance (NHI) price or that of subsequent revisions does not allow for an economically-viable Commercialization of the Product in the Territory or (d) the Development or the Commercialization of the Product could not be continued due to a safety issue related to DRM04 or the Product.

13.5. **Termination for Challenge to Licensed IP Rights**. Dermira shall have the right to immediately terminate this Agreement at any time after the Effective Date in the event Maruho or any of its Affiliates or its or their sublicensees contests or challenges, or supports or assists any Third Party to contest or challenge, in any patent office, court, regulatory agency or other forum, Dermira's ownership of or rights in, or the validity, enforceability or scope of, any of the Licensed IP Rights.

13.6. **Effect of Termination or Expiration**.

13.6.1. Upon termination or expiration of this Agreement, Maruho shall pay to Dermira all amounts due to Dermira as of the effective date of termination or expiration within [*****] days following the effective date of termination or expiration.

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

13.6.2. Upon expiration (but not termination) of this Agreement, Dermira hereby grants to Maruho a royalty-free right and license to use a Dermira Trademark used by Maruho and the Know-How for the purpose of the Development and Commercialization of the Product in the Field within the Territory.

13.6.3. Upon termination of this Agreement, Maruho shall have the right to sell its remaining inventory of Product following the termination of this Agreement so long as Maruho has fully paid, and continues to fully pay when due, any and all royalties owed to Dermira, and Maruho otherwise is not in material breach of this Agreement.

13.6.4. Upon termination of this Agreement, all licenses granted by Dermira to Maruho shall terminate. For avoidance of doubt, termination of the licenses granted by Dermira to Maruho shall terminate all sublicenses granted by Maruho hereunder.

13.6.5. Upon termination of this Agreement:

(a) Maruho shall: (i) [*****] to Dermira, transfer to Dermira all data, Regulatory Filings and Regulatory Approvals held by Maruho with respect to the Product, (ii) to the extent subsection (i) is not permitted by the Regulatory Authority, [*****] to Dermira, permit Dermira to cross-reference and rely upon any Regulatory Approvals and Regulatory Filings filed by Maruho with respect to the Product, and (iii) except as set forth in Section 13.6.3 cease the further manufacture, Development or Commercialization of Product in the Territory provided that if Maruho terminated this Agreement in accordance with 13.2 or 13.3 Dermira shall pay [*****] to Maruho for the transfer and cross reference.

(b) Except in the case of termination by Maruho under Section 13.2 or 13.3, Maruho hereby grants to Dermira a [*****] license to use the Product Trademarks for the purpose of manufacturing, marketing, distributing, selling or otherwise Exploiting the Product.

13.7. Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing hereunder prior to such expiration or termination. Without limiting the foregoing, the provisions of Sections 2.3.3, 2.3.4, 2.3.5, 4.3, 4.5, 7, 8.1, 8.6(b), 9, 11, 12, 13.6, 13.7, 15.1 and 17 shall survive expiration or termination of this Agreement.

14. PRESS RELEASES

Each Party desires to issue a press release regarding this Agreement. Both press releases are attached hereto as Schedule D. Such press releases shall be issued within three (3) Business Days after the Effective Date. Except as required by applicable laws (including disclosure requirements of the SEC or any stock exchange on which securities issued by a Party are traded), neither Party shall make any other public announcement concerning this Agreement or the

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subject matter hereof without the prior written consent of the other, which shall not be unreasonably withheld or delayed; provided that each Party may make any public statement in response to questions by the press, analysts, investors or those attending industry conferences or financial analyst calls, or issue press releases, so long as any such public statement or press release is not inconsistent with prior public disclosures or public statements approved by the other Party pursuant to this Section. In the event of such a required public announcement, to the extent practicable under the circumstances, the Party making such announcement shall provide the other Party with a copy of the proposed text of such announcement at least three (3) Business Days prior to the scheduled release to afford such other Party a reasonable opportunity to review and comment upon the proposed text.

15. MARUHO INSURANCE

15.1. **Insurance Requirements**. Maruho will maintain during the Term and until the later of: (a) [*****] after termination or expiration of this Agreement, or (b) the date that all statutes of limitation covering claims or suits that may be instituted for personal injury based on the sale or use of the Product have expired, product liability insurance with coverage limits of not less than [*****] dollars (USD $[*****]) per occurrence and [*****] dollars (USD $[*****]) in the aggregate and clinical trial insurance which reasonably covers the liabilities arising from each clinical trials. Maruho has the right to provide the total limits required by any combination of primary and umbrella/excess coverage. The minimum level of insurance set forth herein shall not be construed to create a limit on Maruho's liability hereunder.

15.2. **Policy Notification**. Upon Dermira's request, Maruho shall provide Dermira with certified copies of such policies or original certificates of insurance evidencing such insurance.

16. DISPUTE RESOLUTION

16.1. **General**. The following procedures shall be used to resolve any dispute arising out of or in connection with this Agreement except for disputes for which injunctive or other equitable relief is sought to prevent the unauthorized use or disclosure of proprietary materials or information or prevent the infringement or misappropriation of a Party's Intellectual Property Rights. Any dispute that is not otherwise resolved by the Parties as provided by Section 3.3 shall skip the procedure in Section 16.2 and go directly to Section 16.3. For avoidance of doubt, disputes relating to the terms of the Development Supply Agreement or the Commercial Supply Agreement shall be resolved as provided by Section 5.1 and 5.2 respectively and not by the procedures of this Article 16.

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16.2. **Meeting**. Promptly after the written request of either Party, each of the Parties shall appoint a designated representative to meet in person or by telephone to attempt in good faith to resolve any dispute. If the designated representatives do not resolve the dispute within [*****] Business Days of such request, then an executive officer of each Party shall meet in person or by telephone to review and attempt to resolve the dispute in good faith. The executive officers shall have [*****] Business Days to attempt to resolve the dispute.

16.3. **Arbitration**. Any disputes that are not otherwise resolved by the Parties shall be submitted to binding arbitration with the International Centre for Dispute Resolution ("**ICDR**") in San Francisco, California, U.S.A. in accordance with the then-prevailing commercial arbitration rules of the ICDR. The language of the arbitration shall be English. For avoidance of doubt, disputes relating to the terms of the Development Supply Agreement or the Commercial Supply Agreement shall be resolved as provided by Section 5.1 and 5.2 respectively.

16.3.1. There shall be three (3) arbitrators, one selected by the initiating Party in the request for arbitration, the second selected by the other Party within [*****] days of the request for arbitration, and the third (who shall act as chairperson of the arbitration tribunal) selected by the two (2) Party-appointed arbitrators within [*****] days of the selection of the second arbitrator. In the event that the respondent fails to select an arbitrator, or if the two Party-appointed arbitrators are unable or fail to agree upon the third arbitrator, the ICDR shall designate the remaining arbitrator(s) required to comprise the tribunal.

16.3.2. Each arbitrator chosen shall speak, read, and write English fluently and shall be either (i) a practicing lawyer who has specialized in business litigation with at least ten (10) years of experience, or (ii) a retired judge of a court of general jurisdiction.

16.3.3. The arbitrators shall issue an award within [*****] of the submission of the request for arbitration. This time limit may be extended by agreement of the Parties or by the tribunal if necessary. It is expressly understood and agreed by the Parties that the rulings and award of the tribunal shall be conclusive on the Parties, their successors and permitted assigns. Judgment on the award rendered by the tribunal may be entered in any court having jurisdiction thereof.

16.3.4. The cost of the arbitration, including the fees and expenses of the arbitrator, will be shared equally by the Parties. The prevailing Party shall be entitled to recover from the losing Party the prevailing Party's attorneys' fees and costs. The arbitrator shall have the right to apportion liability between the Parties, but will not have the authority to award any damages or remedies not available under the express terms of this Agreement.

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17. GENERAL PROVISIONS

17.1. **Assignment**. Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that: (a) Dermira may assign to a Third Party its rights to receive some or all of the fees payable hereunder, (b) each Party may assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates without the consent of the other Party; and (c) either Party may assign this Agreement in its entirety to a successor to all or substantially all of its business to which this Agreement relates. The assigning Party shall provide the other Party with prompt written notice of any such assignment. Any permitted assignee pursuant to clauses (b) and (c) above shall assume all obligations of its assignor under this Agreement, and no permitted assignment shall relieve the assignor of liability for its obligations hereunder. Any attempted assignment in contravention of the foregoing shall be void.

17.2. **Severability**. Should one or more of the provisions of this Agreement become void or unenforceable as a matter of law, then such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement, and the Parties agree to substitute a valid and enforceable provision therefor which, as nearly as possible, achieves the desired economic effect and mutual understanding of the Parties under this Agreement.

17.3. **Governing Law; Exclusive Jurisdiction**.

17.3.1. This Agreement shall be governed by and construed under the laws in effect in the State of California, U.S.A., without giving effect to any conflicts of laws provision thereof or of any other jurisdiction that would produce a contrary result, except that issues subject to the arbitration clause and any arbitration hereunder shall be governed by the applicable commercial arbitration rules and regulations.

17.3.2. The courts located in San Francisco, California, U.S.A. shall have exclusive jurisdiction over any action brought to enforce this Agreement, and each of the Parties hereto irrevocably: (a) submits to such exclusive jurisdiction for such purpose; (b) waives any objection which it may have at any time to the laying of venue of any proceedings brought in such courts; (c) waives any claim that such proceedings have been brought in an inconvenient forum, and (d) further waives the right to object with respect to such proceedings that any such court does not have jurisdiction over such Party. Notwithstanding the foregoing, application may be made to any court of competent jurisdiction with respect to the enforcement of any judgment or award.

17.4. **Force Majeure**. Except with respect to delays or nonperformance caused by the negligent or intentional act or omission of a Party, any delay or nonperformance by such Party (other than payment obligations under this Agreement) will not be considered a breach of this Agreement to the extent such delay or nonperformance is caused by acts of God, natural disasters, acts of the government or civil or military authority, fire, floods, epidemics, quarantine, energy crises, war or riots

or other similar cause outside of the reasonable control of such Party (each, a "**Force Majeure Event**"), provided that the Party affected by such Force Majeure Event will promptly begin or resume performance as soon as reasonably practicable after the event has abated. If the Force Majeure Event prevents a Party from performing any of its obligations under this Agreement for one hundred eighty (180) days or more, then the other Party may terminate this Agreement immediately upon written notice to the non-performing Party.

17.5. Translation. [*****].

17.6. Obligation. Each Party shall bear the cost for performing its own obligations herein including but not limited to the labor cost of its own employees unless otherwise explicitly set forth in this Agreement.

17.7. Waivers and Amendments. The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver shall be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

17.8. Relationship of the Parties. Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture, or legal entity of any type between Dermira and Maruho, or to constitute one Party as the agent of the other. Moreover, each Party agrees not to construe this Agreement, or any of the transactions contemplated hereby, as a partnership for any tax purposes. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give any Party the power or authority to act for, bind, or commit the other Party.

17.9. Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

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17.10. **Notices**. All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when: (a) delivered by hand (with written confirmation of receipt), by an internationally recognized overnight delivery service (receipt requested), or (b) when received by the addressee, if sent by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses set forth below (or to such other addresses as a Party may designate by written notice):

If to Dermira:

Dermira, Inc.
275 Middlefield Rd., Suite 150
Menlo Park, CA 94025, U.S.A.
Attention: Legal Department

If to Maruho:

Maruho Co., Ltd.
1-5-22, Nakatsu
Kita-ku, Osaka, 531-0071, Japan
Attention: Business Development Department

17.11. **Further Assurances**. Maruho and Dermira hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary or appropriate to carry out the intent and purposes of this Agreement.

17.12. **No Third Party Beneficiary Rights**. Subject to Section 2.3 (and only to the extent it is applicable), this Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including, without limitation, any third party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby.

17.13. **Entire Agreement**. This Agreement, together with its Schedules, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter. In the event of any conflict between a material provision of this Agreement and any Schedule hereto, the Agreement shall control.

17.14. **Counterparts**. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

17.15. **Cumulative Remedies**. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

17.16. **Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, any rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

[Signatures on next page]

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IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

MARUHO CO., LTD.	**DERMIRA, INC.**
By: /s/ Koichi Takagi	By: /s/ Thomas Wiggans
Name: Koichi Takagi	Name: Thomas Wiggans
Title: President and Chief Executive Officer	Title: Chief Executive Officer

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

SCHEDULE A: PATENT RIGHTS

1. PATENT RIGHTS

Application or Patent Number	Country	Controlling Entity	Filing Date	Title
[*****]	JP	Dermira	[*****]	[*****]
[*****]	PCT	Dermira	[*****]	[*****]
[*****]	PCT	Dermira	[*****]	[*****]

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

SCHEUDLE B: DEVELOPMENT SUPPLY AGREEMENT TERMS

Product	Dermira shall provide the DRM04 drug substance or Product in accordance with the Specifications. The Product shall consist of wipes in pouches (labeled with lot number) that are ready for clinical labeling. Maruho shall be responsible for secondary packaging of the Product. Maruho has the right (but not the obligation) to establish its own supply of Product. If Maruho were to exercise its right (in its sole discretion) to establish its own supply of Product, "drug substance" shall be substituted for "Product" in the terms herein.
Forecasts	Maruho shall provide an initial forecast for its yearly requirements for the DRM04 drug substance and for Product during Development and the first [*****] of Commercialization as an appendix to the Development Supply Agreement. The non-binding [*****] commercial forecast will be used by Dermira for planning purposes until it is replaced by an updated commercial forecast in the Commercial Supply Agreement. Maruho shall provide Dermira with a [*****] rolling forecast on a Calendar Quarterly basis. The forecast for the first [*****] Calendar Quarters will be a "Firm Forecast" and the forecast for each remaining Calendar Quarter will represent a non-binding forecast until such time as such Calendar Quarter becomes one of the first [*****] Calendar Quarters in a delivered Forecast, at which time it becomes part of the Firm Forecast. The lead time for the first purchase order will be at least [*****] prior to the requested amount of the Product. The amount of Product in all purchase orders shall be consistent with the Firm Forecast.
Supply	Dermira shall provide the Products [*****]. Dermira shall not be obligated to supply amounts of Product that [*****] unless (a) Maruho provided sufficient notice to enable Dermira to plan and secure such [*****] and (b) Maruho paid Dermira [*****].
Cost of Product	Maruho shall pay to Dermira [*****] the Product.
Audit Rights	Maruho shall have the right to audit the manufacturing facility, subject to the rights Dermira has obtained from its manufacturer. Dermira shall have the right to accompany any audit performed by Maruho. Each Party shall bear its own costs associated with all such manufacturing audits, provided that Maruho shall reimburse Dermira for any costs actually paid to the manufacturer as a result of such audits according to the License Agreement.

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Payment	All payments for supply of Product will be paid in US Dollars and will be paid within [*****] days of receipt of the invoice.
Quality Agreement and Quality standards	Within [*****] after the execution of the Development Supply Agreement, the Parties will enter into a quality agreement with reasonable terms that are usual and customary in the pharmaceutical industry. Dermira shall provide Maruho with a certificate of release, certificate of analysis and copies of batch records. If Maruho elects to establish its own supply of Product, the quality agreement shall be amended accordingly.
Contract Duration	The duration of the Exclusive License Agreement.
Termination	Termination provisions to be consistent with the Exclusive License Agreement. The Development Supply Agreement will also include a customary provision allowing Dermira and Maruho to terminate the Development Supply Agreement for breach of the other party. If Dermira ever determines that it will no longer manufacture and sell the Product outside the Territory, Dermira will have the right to terminate the continuing supply obligation to Maruho by first providing Maruho [*****] prior written notice. Dermira shall cooperate with Maruho during the [*****] notice period to establish the alternative supply chain at Maruho's expense.
Assignment	Same as Exclusive License Agreement.
Confidentiality	Provisions to be included consistent with the terms of the Exclusive License Agreement.
Disputes, Governing Law and Jurisdiction.	Provisions to be included consistent with the terms of the Exclusive License Agreement.
Other Customary Provisions	The Development Supply Agreement shall contain reasonable and customary terms in the pharmaceutical industry with respect to a clinical and non-clinical supply agreement.

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

SCHEDULE C: COMMERCIAL SUPPLY AGREEMENT TERMS

Product	Dermira shall supply the Product in accordance with the Specifications. Dermira is responsible for the primary packaging of the Product, subject to Maruho approving the primary packaging. Maruho shall be responsible for secondary packaging of the Product. Maruho may subcontract such secondary packaging to Dermira's manufacturing site(s). Maruho has the right (but not the obligation) to establish its own supply of Product, provided that Maruho provides a [*****] written notice of its intention of establishing such supply. Following such written supply notice, Dermira shall continue to supply Product until Maruho has no amount of Product in the Firm Forecast portion of the delivered Forecast. If Maruho were to exercise its right (in its sole discretion) to establish its own supply of Product, Dermira shall supply Maruho with commercial supply of drug substance which Maruho will convert to Product for use in the Field and Territory. In such case, "drug substance" shall be substituted for "Product" in the terms herein.
Forecasts	Maruho shall provide an initial non-binding forecast for its yearly requirements for Product during the first [*****] of Commercialization as an appendix to the Commercial Supply Agreement for reference. Maruho shall provide Dermira with a [*****] rolling forecast. The forecast for the first [*****] Calendar Quarters will be a "Firm Forecast" and the forecast for each remaining Calendar Quarter will represent a non-binding forecast until such time as such Calendar Quarter becomes one of the first [*****] Calendar Quarters in a delivered Forecast, at which time it becomes part of the Firm Forecast.
Supply	Dermira shall provide the Products [*****]. Dermira shall not be obligated to supply amounts of Product that [*****] unless (a) Maruho provided sufficient notice to enable Dermira to plan and secure such [*****] and (b) Maruho paid Dermira [*****] according to the License Agreement.
Cost of Product	Maruho shall pay to Dermira [*****] the Product.

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Audit Rights	Maruho shall have the right to audit the manufacturing facility, subject to the rights Dermira has obtained from its manufacturer. Dermira has the right to accompany any audit performed by Maruho. Each Party shall bear its own costs associated with all such manufacturing audits, provided that Maruho shall reimburse Dermira for costs actually paid to the manufacturer as a result of such audits according to the License Agreement.
Payment	All payments for supply of Product will be paid in US Dollars and will be paid within [*****] days of receipt of the invoice.
Quality Agreement and Quality standards	Within [*****] after the execution of the Commercial Supply Agreement, the Parties will enter into a quality agreement with reasonable terms that are usual and customary in the pharmaceutical industry. Maruho is responsible for instructions for use, labels and secondary packaging for Product. If Maruho elects to establish its own supply of Product, the quality agreement shall be amended accordingly.
Contract Duration	The duration of the Exclusive License Agreement.
Termination	Termination provisions to be consistent with the Exclusive License Agreement. The Commercial Supply Agreement will also include a customary provision allowing Dermira and Maruho to terminate the Commercial Supply Agreement for breach of the other. If Dermira ever determines that it will no longer manufacture and sell the Product outside the Territory, Dermira will have the right to terminate the continuing supply obligation to Maruho by first providing Maruho [*****] prior written notice. Dermira shall cooperate with Maruho during the [*****] notice period to establish the alternative supply chain at Maruho's expense.
Assignment	Same as Exclusive License Agreement.
Confidentiality	Provisions to be included consistent with the terms of the Exclusive License Agreement.
Disputes, Governing Law and Jurisdiction.	Provisions to be included consistent with the terms of the Exclusive License Agreement.
Other Customary Provisions	The Commercial Supply Agreement shall contain reasonable and customary terms in the pharmaceutical industry with respect to a commercial supply agreement.

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

SCHEDULE D: PRESS RELEASES

Dermira Licenses DRM04 to Maruho for Hyperhidrosis in Japan

- *Terms include $25 million upfront license payment to Dermira*
- *Maruho to fund all development and commercial costs for DRM04 in Japan*

MENLO PARK, Calif., September 20, 2016 – Dermira, Inc. (NASDAQ: DERM), a biopharmaceutical company dedicated to identifying, developing and commercializing innovative, differentiated therapies to improve the lives of patients with dermatologic diseases, today announced it has entered into an exclusive license agreement with Maruho Co., Ltd., a Japanese company specializing in dermatology. Pursuant to the terms of the agreement, Dermira has granted Maruho an exclusive license to develop and commercialize DRM04, a topical anticholinergic product candidate currently being developed by Dermira for the treatment of primary axillary hyperhidrosis (excessive underarm sweating), in Japan.

According to a recent study, the prevalence of primary axillary hyperhidrosis in Japan is estimated to be approximately 5.75% of the population, or approximately 7.5 million people.

“Maruho is recognized as a leading dermatology company in Japan and we are pleased it has chosen to enter into this agreement with Dermira to add DRM04 to its clinical development pipeline for the Japanese market,” said Tom Wiggans, chairman and chief executive officer of Dermira. “This licensing agreement further validates the need for an effective, well-tolerated and convenient therapy for hyperhidrosis. We look forward to working with Maruho to bring this potential treatment to patients in Japan who suffer from this debilitating condition.”

Under the terms of the agreement, Dermira will receive an initial $25 million license payment. Dermira also is eligible to receive potential additional payments totaling up to $70 million, contingent on the achievement of milestones associated with submission and approval of a marketing application and certain sales thresholds, as well as royalty payments representing up to a low double-digit percentage of net product sales, in Japan. Maruho is responsible for funding all development and commercial costs for the program in Japan. Until such time, if any, as Maruho elects to establish its own source of supply, Maruho will purchase product supply from Dermira for development and, if applicable, commercial purposes at cost. Subject to discussions with Japanese regulatory authorities, Maruho plans to initiate a Phase 1 clinical trial for DRM04 in Japan.

This license agreement between Dermira and Maruho is not subject to the existing Right of First Negotiation Agreement entered into between the parties in 2013, in connection with which Maruho also made an investment in Dermira. Maruho currently owns approximately 1.2 million shares of common stock of Dermira, representing approximately 3.4% of Dermira’s total shares of common stock outstanding as of August 1, 2016.

About DRM04 and Dermira’s Phase 3 Clinical Program

DRM04 is a topical anticholinergic product candidate in development for patients with primary axillary hyperhidrosis (excessive underarm sweating). In June 2016, Dermira reported results from two DRM04 Phase 3 clinical trials, ATMOS-1 and ATMOS-2, which were designed as identical, multi-center, randomized, double-blind, vehicle-controlled trials to assess the safety and efficacy of DRM04 at a concentration of 3.75% compared to vehicle in adolescent and adult patients (ages nine and older) with primary axillary hyperhidrosis. Both clinical trials evaluated the safety and efficacy of DRM04 compared to vehicle.

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

The co-primary endpoints for the ATMOS-1 and ATMOS-2 Phase 3 trials were the proportion of patients who achieved at least a four-point improvement from baseline in sweating severity as measured by the Axillary Sweating Daily Diary (ASDD), Dermira's proprietary patient-reported outcome (PRO) instrument, and the average absolute change from baseline in gravimetrically-measured sweat production. The secondary endpoints in both trials measured the proportion of patients who had at least a two-grade improvement from baseline as measured by the Hyperhidrosis Disease Severity Scale (HDSS) and the proportion of patients with at least a 50% reduction from baseline in gravimetrically-measured sweat production. Each endpoint was measured at the end of the four-week treatment period.

The ATMOS-1 trial enrolled 344 patients at 29 sites in the United States and Germany, and the ATMOS-2 trial enrolled 353 patients at 20 sites in the United States. Inclusion criteria required that prior to the start of treatment, all patients produce at least 50 mg of sweat in each underarm over a five-minute period and rate the severity of their sweating as a four or higher on the 11-point ASDD scale and as a three or a four on the four-grade HDSS. In the ATMOS-1 trial, 229 patients were randomized to receive DRM04 and 115 patients were randomized to receive vehicle; and in the ATMOS-2 trial, 234 patients were randomized to receive DRM04 and 119 patients were randomized to receive vehicle. Patients were instructed to apply the study product to each underarm once daily for four weeks using topical wipes containing either DRM04 or vehicle only.

In the ATMOS-2 trial, DRM04 demonstrated statistically significant improvements for both co-primary endpoints and both secondary endpoints compared to vehicle. In the ATMOS-1 trial, DRM04 demonstrated statistically significant improvements for one of the co-primary endpoints and both secondary endpoints. These results were based on the overall dataset from the intent-to-treat population. For the second co-primary endpoint in the ATMOS-1 trial, when extreme outlier data from one analysis center were excluded in accordance with the pre-specified statistical analysis plan submitted to the U.S. Food and Drug Administration (FDA), DRM04 demonstrated statistically significant results compared to vehicle. Consistent with previous results, DRM04 was generally well-tolerated with side effects that were primarily mild to moderate in severity.

In addition to these trials, Dermira is also conducting ARIDO, an open-label trial assessing the long-term safety of DRM04 as part of its Phase 3 program to provide safety data for a minimum of 100 patients who have received DRM04 for at least 12 months per the International Council on Harmonization guidelines. Patients from the ATMOS-1 and ATMOS-2 trials were permitted to enroll in the ARIDO trial and continue to receive DRM04 (active treatment) for up to an additional 44 weeks from the end of the four-week treatment periods in the ATMOS-1 or ATMOS-2 trials. A total of 564 patients, more than 80%, elected to enroll in ARIDO. Dermira expects to complete the treatment period for the ARIDO trial by the end of 2016.

Based on the results of the ATMOS-1 and ATMOS-2 trials, Dermira plans to submit a New Drug Application (NDA) to the FDA for potential approval of DRM04. The NDA submission is targeted for the second half of 2017, subject to the completion of the ARIDO trial, other registration-enabling activities and a pre-NDA meeting with the FDA.

About Hyperhidrosis

Based on the most recent data available in the United States, the prevalence of hyperhidrosis in 2003 was estimated to be 2.8% of the population, or approximately 7.8 million people. Hyperhidrosis is a condition of sweating beyond what is physiologically required to maintain normal thermal regulation. Sweat is produced by glands in the skin and released to the skin surface through ducts. Sweat gland activity is controlled by the nervous system. The nervous system transmits signals to the sweat glands through acetylcholine, which is known as a neurotransmitter. Primary hyperhidrosis, which is excessive sweating without a known cause, can affect the underarms, palms of the hands, soles of the feet, face and other areas. According to published studies, approximately half of hyperhidrosis sufferers have axillary hyperhidrosis, and roughly one-third of axillary hyperhidrosis sufferers, or 1.3 million Americans, have severe disease that is barely tolerable and frequently interferes with daily activities or is intolerable and always interferes with daily activities as scored by the HDSS.

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Several studies have demonstrated that excessive sweating often impedes normal daily activities and can result in occupational, emotional, psychological, social and physical impairment.

About Dermira

Dermira is a biopharmaceutical company dedicated to identifying, developing and commercializing innovative, differentiated therapies to improve the lives of patients with dermatologic diseases. Dermira's portfolio includes three late-stage product candidates that target significant unmet needs and market opportunities: CIMZIA® (certolizumab pegol), in Phase 3 development in collaboration with UCB Pharma S.A. for the treatment of moderate-to-severe plaque psoriasis; DRM04, in Phase 3 development for the treatment of axillary hyperhidrosis (excessive underarm sweating); and DRM01, in Phase 2b development for the treatment of facial acne vulgaris. Dermira is headquartered in Menlo Park, California. For more information, please visit www.dermira.com.

In addition to filings with the Securities and Exchange Commission (SEC), press releases, public conference calls and webcasts, Dermira uses its website (www.dermira.com) and LinkedIn page (https://www.linkedin.com/company/dermira-inc-) as channels of distribution of information about its company, product candidates, planned financial and other announcements, attendance at upcoming investor and industry conferences and other matters. Such information may be deemed material information and Dermira may use these channels to comply with its disclosure obligations under Regulation FD. Therefore, investors should monitor Dermira's website and LinkedIn page in addition to following its SEC filings, press releases, public conference calls and webcasts.

Forward-Looking Statements

The information in this press release contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections. This press release contains forward-looking statements that involve substantial risks and uncertainties, including statements with respect to Maruho's plans for the development and commercialization of, including the initiation of a Phase 1 clinical trial for, DRM04 in Japan; potential payments to Dermira based upon the successful achievement of regulatory- and sales-based milestones for DRM04 and potential royalty payments for net product sales in Japan; the use of DRM04 as a safe and effective treatment for hyperhidrosis; the expected timing for completion of the treatment period for the open-label ARIDO Phase 3 trial and the results of such trial; the timing of the anticipated pre-NDA meeting with the FDA and other registration-enabling activities; and the potential NDA submission to the FDA for DRM04 and the expected timing of such submission. These statements deal with future events and involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Factors that could cause actual results to differ materially include risks and uncertainties such as those relating to the design, implementation and outcomes of Dermira's clinical trials; Dermira's anticipated pre-NDA meeting with the FDA for DRM04; Dermira's dependence on third-party clinical research organizations, manufacturers and suppliers; Dermira's ability to obtain regulatory approval for its product candidates; Dermira's ability to continue to stay in compliance with applicable laws and regulations; Maruho's plans for the development and commercialization of DRM04; and the outcome of Maruho's discussions with Japanese regulatory authorities for Maruho's Phase 1 clinical trial of DRM04 in Japan. You should refer to the section entitled "Risk Factors" set forth in Dermira's Annual Report on Form 10-K, Dermira's Quarterly Reports on Form 10-Q and other filings Dermira makes with the Securities and Exchange Commission from time to time for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, such forward-looking statements speak only as of the date of this press release. Dermira undertakes no obligation to publicly update any forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise, except as required by law.

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Contacts:

Media:
Erica Jefferson
Senior Director, Head of Corporate Communications
650-421-7216
erica.jefferson@dermira.com

Investors:
Andrew Guggenhime
Chief Operating Officer and Chief Financial Officer
650.421.7200
Investor@dermira.com

Robert H. Uhl
Westwicke Partners
Managing Director
858.356.5932
robert.uhl@westwicke.com

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maruho

News Release

October [], 2016
Maruho Co., Ltd.

Maruho enters a License Agreement with Dermira for Hyperhidrosis treatment agent DRM04

Osaka (Japan), October [], 2016 – Maruho Co., Ltd. ("Maruho", Head Office: Osaka, Japan, President and CEO: Koichi Takagi), announced that it has entered an exclusive license agreement with Dermira, Inc. (Head Office: Menlo Park, California, US, Chairman and CEO: Thomas G. Wiggans) to develop and market hyperhidrosis treatment agent DRM04 (a topical, small-molecule, anticholinergic product) in Japan.

Under the terms of this agreement, Maruho acquires an exclusive license for the development, distribution and marketing of DRM04 in Japan, and is aiming to receive manufacturing and marketing approval. Maruho will pay Dermira a license payment of $25 million and potential additional payments totaling up to $70 million, contingent on the achievement of milestones associated with submission and approval of a marketing application and certain sales thresholds, as well as royalty payments representing a fixed percentage of net product sales, in Japan.

Hyperhidrosis is a disease that causes excessive sweating in localized areas such as on the head and face, underarms, palms, and soles of feet[1]. DRM04 is a topical, small-molecule, anticholinergic product in Phase 3 clinical development by Dermira for the treatment of primary axillary (underarm) hyperhidrosis in the US. DRM04 inhibits sweat production by blocking the interaction between acetylcholine and the cholinergic receptors responsible for sweat gland activation.

Maruho hopes that by providing a new treatment option for hyperhidrosis to medical professionals it can further contribute to the health of patients in Japan suffering from skin diseases.

About Hyperhidrosis

Hyperhidrosis is classified into focal hyperhidrosis, where sweating increases on a confined part of the body, and systemic hyperhidrosis, where sweating increases over the entire body. It can affect the head and face, underarms, palms, soles of feet, and other areas regardless of the presence or absence of hyperthermia or psychological effects. In Japan, the prevalence of primary axillary (underarm) hyperhidrosis is reported to be 5.75% of the population and the average age of onset is 19.5 years[2]. The main treatment is therapy with a topical aluminum chloride solution or botulinum toxin injections.

About Dermira

Dermira is a biopharmaceutical company dedicated to identifying, developing and commercializing innovative, differentiated therapies to improve the lives of patients with dermatologic diseases. Dermira is headquartered in Menlo Park, California. For more information, please visit www.dermira.com.

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About Maruho

Maruho Co., Ltd. has its headquarters in Osaka and leads Japan in research and development, manufacturing, and commercialization of dermatological products. Founded in 1915, Maruho has 1,335 employees (as of the end of September 2015), and net sales were approximately 67.0 billion yen in the previous fiscal year. Pursuing its long-term corporate vision of "Excellence in Dermatology," Maruho is striving to improve the health and quality of life of people all over the world.

For more information about Maruho Co., Ltd., please refer to www.maruho.co.jp/english

References

1 Fujimoto T, et al: Primary focal hyperhidrosis clinical practice guidelines Revised in 2015 *Jpn J Dermatol*: 125 (7), 1379-1400,2015

2 Fujimoto T, Kawahara K, Yokozeki H: Epidemiological study and considerations of focal hyperhidrosis in Japan: From questionnaire analysis. *J Dermatol*.40:886-890,2013

Contact Information:

Maruho Co., Ltd.
Public Relations Department
Shuhei Inokuchi
Tel: +81-(0)6-6371-8831 Fax: +81-(0)6-6376-1724
Email: kouhou@mii.maruho.co.jp

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News Release

2016年10月[]日
マルホ株式会社

報道関係各位

多汗症治療薬DRM04に関する
ライセンス契約締結のお知らせ

マルホ株式会社（本社：大阪府大阪市北区、代表取締役社長：高木幸一、以下、マルホ）はDermira, Inc.（本社：米国カリフォルニア、CEO:トーマス・ウィガンス、以下、Dermira社）と多汗症治療薬DRM04（抗コリン外用製剤）の開発および販売の独占的ライセンス供与について、契約締結したことをお知らせいたします。

マルホは本契約により、日本で本剤を開発・販売する独占的実施権を取得し、製造販売承認取得を目指します。マルホはDermira社に契約一時金として20百万米ドルを支払うとともに、申請、承認および所定売上高達成の段階に応じて最大75百万米ドル、さらに日本での売上高に応じた一定のロイヤリティを支払います。

原発性多汗症は、頭部・顔面、手のひら、足の裏、腋（わき）という限られた部位から両側性に過剰な発汗をおこす疾患です[1)]。
DRM04は抗コリン外用製剤で、Dermira社が原発性腋窩多汗症を対象とした第III相臨床試験を米国で実施中です。本剤は、汗腺からの発汗に関与するアセチルコリンのコリン作動性受容体への結合を阻害することによって汗の産生を抑制します。

マルホは本症の新たな治療選択肢を医療現場に提供することで、この疾患に悩む日本の患者さんに対して更なる貢献ができるものと期待しております。

以上

多汗症について

多汗症は、全身の発汗が増加する全身性多汗症と体の一部に限局して発汗量が増加する局所性多汗症に分類されます。原発性局所多汗症は、頭部・顔面、手のひら、足の裏、腋に、温熱や精神的な負荷の有無によらず日常生活に支障をきたす程の大量の汗を生じる状態をいいます。社会的活動範囲が広く、生産性のある年代の罹患率が非常に高く、このことにより精神的な苦痛を受けているといわれています[1)]。腋におこるものを原発性腋窩多汗症といいます。原発性腋窩多汗症の日本における有病率は5.75%、平均発症年齢は19.5歳と報告[2)]されており、主な治療としては塩化アルミニウム液外用療法、ボツリヌス毒素局所注射療法などが行われています。

Dermira, Incについて

Dermira社はカリフォルニア州メンローパークに本社を置くバイオ医薬品企業で、皮膚科疾患患者さんの生活を向上させるために革新的で他とは一線を画す製品の研究・開発、販売に取り組んでいます。Dermira社の詳細については、www.dermira.comをご覧ください。

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

マルホ株式会社について

マルホ株式会社は大阪市北区に本社を置く、医療用医薬品の研究・開発・製造・販売を行う製薬企業です。創業は1915年、従業員数は1,335人（2015年9月末）です。 2015年9月期の売上高は670億円でした。“Excellence in Dermatology”を長期ビジョンとして掲げ、皮膚科学領域での卓越した貢献を目指しています。

マルホ株式会社についての詳細はwww.maruho.co.jpをご覧ください。

参考資料

1 藤本智子ら:原発性局所多汗症診療ガイドライン2015年改訂版　日皮会誌:125(7),1379-1400,2015

2 Fujimoto T, Kawahara K, Yokozeki H: Epidemiological study and considerations of focal hyperhidrosis in Japan: From questionnaire analysis. *J Dermatol*.40:886-890,2013

本件に関する問い合わせ先

マルホ株式会社　広報部

井口修平

Tel: 06-6371-8831　Fax: 06-6376-1724

Email: kouhou@mii.maruho.co.jp

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

SCHEDULE E: INCREMENTAL COST

The Incremental Costs shall mean the following costs:

Category	Item
Manufacturing and Supply Costs	✓ All out of pocket costs (including costs paid to third parties), capital costs and Dermira labor costs (calculated by Dermira's FTE Rate) for [*****] the Specifications, manufacturing processes, in-process tests and in-process specifications from Dermira's then-current Dermira Specifications, manufacturing processes, in-process tests and in-process specifications, respectively, [*****]. Incremental Cost will be calculated as the cost of [*****] the Dermira Specifications, manufacturing processes, in-process tests and in-process specifications, respectively, [*****].
	✓ All out of pocket costs (including costs paid to third parties), capital costs and Dermira labor costs (calculated by Dermira's FTE Rate) for [*****]; such anticipated out of pocket costs and capital costs may be invoiced in advance prior to Dermira actually incurring such costs and are payable as provided by Section 6.1.4. Incremental Cost will be calculated as the cost of [*****].
Other Costs	✓ Out of pocket costs, capital costs and labor costs to [*****] in the case that [*****].

The costs incurred by Dermira for performing obligations herein shall not be considered Incremental Cost unless they are described in this Schedule E. In the event Dermira desire to add an item which is not listed herein, Dermira and Maruho shall discuss in good faith in the Steering Committee, and approval of the Steering Committee is required to add such item as Incremental Cost and to amend this Schedule E accordingly.

[*****] Certain portions denoted with an asterisk have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Exhibit 31.1

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

I, Thomas G. Wiggans, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Dermira, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2016

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

Exhibit 31.2

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

I, Andrew L. Guggenhime, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Dermira, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2016

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

Exhibit 32.1

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

I, Thomas G. Wiggans, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) the Quarterly Report of Dermira, Inc. on Form 10-Q for the fiscal quarter ended September 30, 2016 (the "***Report***") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Dermira, Inc. for the periods presented therein.

Date: November 7, 2016

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

Exhibit 32.2

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

I, Andrew L. Guggenhime, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) the Quarterly Report of Dermira, Inc. on Form 10-Q for the fiscal quarter ended September 30, 2016 (the "***Report***") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Dermira, Inc. for the periods presented therein.

Date: November 7, 2016

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