Dermira, Inc.
Form 10-Q
August 07, 2017

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 June 30, 2017

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 (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

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

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

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

As of August 1, 2017, the registrant had 41,591,375 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)

	June 30, 2017 (unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$418,308	$41,793
Short-term investments	272,453	210,149
Collaboration receivables from a related party	—	21,400
Prepaid expenses and other current assets	7,949	10,649
Total current assets	698,710	283,991
Property and equipment, net	1,003	1,127
Long-term investments	5,186	24,551
Intangible assets	1,126	1,126
Goodwill	771	771
Other assets	992	1,035
Total assets	$707,788	$312,601
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$8,476	$13,500
Accrued liabilities	15,862	17,227
Deferred revenue, current	4,265	4,265
Total current liabilities	28,603	34,992
Long-term liabilities:		
Deferred revenue, non-current	27,418	29,550
Convertible notes, net	278,468	—
Deferred tax liability	194	194
Other long-term liabilities	696	495
Total liabilities	335,379	65,231
Stockholders' equity:		
Preferred stock	—	—
Common stock	42	36
Additional paid-in capital	690,785	497,718
Accumulated other comprehensive loss	(211)	(252)
Accumulated deficit	(318,207)	(250,132)
Total stockholders' equity	372,409	247,370
Total liabilities and stockholders' equity	$707,788	$312,601

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

DERMIRA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenue:				
Collaboration and license revenue	$1,066	$—	$2,132	$—
Operating expenses:				
Research and development	25,978	21,668	45,838	44,522
General and administrative	13,587	6,373	24,913	12,274
Total operating expenses	39,565	28,041	70,751	56,796
Loss from operations	(38,499)	(28,041)	(68,619)	(56,796)
Interest and other income, net	1,253	286	1,864	605
Interest expense	(1,320)	—	(1,320)	—
Net loss	$(38,566)	$(27,755)	$(68,075)	$(56,191)
Net loss per share, basic and diluted	$(0.93)	$(0.89)	$(1.73)	$(1.84)
Weighted-average common shares used to compute net loss per share, basic and diluted	41,552,784	31,088,757	39,432,973	30,534,694

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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net loss	$(38,566)	$(27,755)	$(68,075)	$(56,191)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	(36)	(5)	41	140
Total comprehensive loss	$(38,602)	$(27,760)	$(68,034)	$(56,051)

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

DERMIRA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Six Months Ended June 30,	
	2017	2016
Cash flows from operating activities		
Net loss	$(68,075)	$(56,191)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	166	54
Stock-based compensation	9,719	5,055
Net amortization of premiums on available-for-sale securities	1,342	788
Amortization of convertible note discount and issuance costs	230	—
Changes in assets and liabilities:		
Collaboration receivables from a related party	21,400	—
Prepaid expenses and other current assets	3,534	(2,812)
Other assets	43	156
Accounts payable	(5,024)	(434)
Accrued liabilities	(1,365)	(75)
Other long-term liabilities	201	(244)
Deferred revenue	(2,132)	—
Net cash used in operating activities	(39,961)	(53,703)
Cash flows from investing activities		
Purchases of available-for-sale securities	(164,601)	(33,784)
Maturities of available-for-sale securities	119,527	54,614
Purchase of property and equipment	(42)	(103)
Net cash provided by (used in) investing activities	(45,116)	20,727
Cash flows from financing activities		
Net proceeds from issuances of common stock	183,354	136,715
Net proceeds from issuance of convertible notes	278,238	—
Net cash provided by financing activities	461,592	136,715
Net increase in cash and cash equivalents	376,515	103,739
Cash and cash equivalents at beginning of year	41,793	107,242
Cash and cash equivalents at end of period	$418,308	$210,981

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

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DERMIRA, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

1. Organization

We are a biopharmaceutical company dedicated to bringing biotech ingenuity to medical dermatology by delivering differentiated, new therapies to the millions of patients living with chronic skin conditions. We are committed to understanding the needs of both patients and physicians and using our insight to identify and develop leading-edge medical dermatology clinical programs. Our pipeline includes three late-stage product candidates that could have a profound impact on the lives of patients: Cimzia (certolizumab pegol), for which marketing applications have been submitted for potential approval for the treatment of moderate-to-severe chronic plaque psoriasis, in collaboration with UCB Pharma S.A., a related party ("UCB"); glycopyrronium tosylate (formerly DRM04), which has completed a Phase 3 program for the treatment of primary axillary hyperhidrosis, or excessive underarm sweating; and olumacostat glasaretil (formerly DRM01), in Phase 3 development for the treatment of acne vulgaris, or acne. Our corporate headquarters are located in Menlo Park, California.

In March 2017, we sold 5,750,000 shares of our common stock ("2017 Public Offering") pursuant to an automatic shelf registration statement on Form S-3 and received gross proceeds of $193.8 million and net proceeds of $181.5 million, after deducting underwriting discounts and commissions of $11.6 million and offering expenses of $0.7 million.

In May 2017, we sold $287.5 million aggregate principal amount of 3.00% Convertible Senior Notes due 2022 ("Notes") in a private placement to qualified institutional buyers and received net proceeds of approximately $278.2 million, after deducting the initial purchasers' discounts of $8.6 million and estimated issuance costs of $0.7 million.

2. Summary of Significant Accounting Policies

Basis of Presentation

Our condensed consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("U.S. GAAP") and applicable rules and regulations of the U.S. Securities and Exchange Commission ("SEC") for interim reporting. As permitted under those rules and regulations, certain footnotes or other financial information normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These condensed consolidated financial statements have been prepared on the same basis as our annual consolidated financial statements and, in the opinion of our management, reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair presentation of our financial information. The results of operations for the three- and six-month periods ended June 30, 2017 are not necessarily indicative of the results to be expected for the full year ending December 31, 2017 or any other future period. The condensed consolidated balance sheet as of December 31, 2016 has been derived from audited consolidated financial statements at that date but does not include all of the information required by U.S. GAAP for complete financial statements.

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

The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with our audited consolidated financial statements and the related notes thereto for the year ended December 31, 2016 included in our Annual Report on Form 10-K, filed with the SEC on February 28, 2017.

Use of Estimates

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

Revenue Recognition

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

Multiple Element Arrangements

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

Milestones and Other Contingent Payments

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

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

Accrued Research and Development Expenses

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

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

Amortization of Debt Discount and Issuance Costs

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

Net Loss Per Share

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

The following common equivalent shares were not included in the computation of diluted net loss per share because their effect was antidilutive:

	Outstanding as of June 30,	
	2017	2016
Stock options to purchase common stock	5,682,968	4,544,787
Shares subject to outstanding restricted stock units	367,124	136,275
Estimated shares issuable under the employee stock purchase plan	133,839	85,380
Shares issuable upon conversion of Notes	8,109,771	—
	14,293,702	4,766,442

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2016-02, Leases (“ASU 2016-02”). ASU 2016-02 is aimed at making leasing activities more transparent and comparable, and requires lessees to recognize substantially all leases on their balance sheet as a right-of-use asset and a corresponding lease liability, including leases currently accounted for as operating leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early adoption is permitted. We are currently evaluating the impact that the adoption of ASU 2016-02 will have on our consolidated

financial statements and related disclosures.

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

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

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

3. Fair Value Measurements

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

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

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

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

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

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

	As of June 30, 2017			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$195,950	$—	$ —	$195,950
U.S. Treasury securities	8,045	—	—	8,045
Corporate debt	—	208,836	—	208,836
Repurchase agreements	—	150,000	—	150,000
U.S. Government agency securities	—	29,360	—	29,360

Commercial paper	—	101,102	—	101,102
Certificates of deposit	—	900	—	900
Total financial assets	$203,995	$490,198	$ —	$694,193

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

The estimated fair value of our Notes was $317.0 million as of June 30, 2017 and was based upon observable, Level 2 inputs, including pricing information from recent trades of the Notes as of June 30, 2017.

Where quoted prices are available in an active market, securities are classified as Level 1. When quoted market prices are not available for the specific security, then we estimate fair value by using quoted prices for identical or similar instruments in markets that are not active and model based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Where applicable, these models project future cash flows and discount the future amounts to a present value using market based observable inputs obtained from various third party data providers, including but not limited to benchmark yields, reported trades and broker/dealer quotes.

4. Investments

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

	As of June 30, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Financial assets:				
Money market funds	$195,950	$ —	$ —	$195,950
U.S. Treasury securities	8,054	—	(9)	8,045
Corporate debt	209,012	9	(185)	208,836
Repurchase agreements	150,000	—	—	150,000
U.S. Government agency securities	29,386	—	(26)	29,360
Commercial paper	101,102	—	—	101,102
Certificates of deposit	900	—	—	900
Total investments	$694,404	$ 9	$ (220)	$694,193

	As of December 31, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Financial assets:				
Money market funds	$5,115	$ —	$ —	$5,115
U.S. Treasury securities	6,112	1	(1)	6,112
Corporate debt	169,112	6	(240)	168,878
Repurchase agreements	22,550	—	—	22,550
U.S. Government agency securities	41,384	—	(18)	41,366

Commercial paper	30,836	—	—	30,836
Certificates of deposit	901	—	—	901
Total investments	$276,010	$ 7	$ (259)	$275,758

As of June 30, 2017, we did not hold any investments with a maturity exceeding two years or that have been in a continuous loss position for 12 months or more. We do not intend to sell the securities that are in an unrealized loss position and it is more likely than not that the investments will be held until recovery of the amortized cost bases. We have determined that the gross unrealized losses on our securities as of June 30, 2017 were temporary in nature.

5. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	June 30, 2017	December 31, 2016
Accrued outside research and development services	$7,640	$ 10,046
Accrued compensation	4,786	5,839
Accrued professional and consulting services	1,969	1,042
Accrued interest	1,090	—
Other	377	300
Total accrued liabilities	$15,862	$ 17,227

6. Convertible Notes

In May 2017, we sold $287.5 million aggregate principal amount of 3.00% Convertible Senior Notes due 2022 in a private placement. We received net proceeds of approximately $278.2 million, after deducting the initial purchasers' discounts of $8.6 million and estimated issuance costs of $0.7 million. The Notes were issued pursuant to an Indenture, dated as of May 16, 2017 (the "Indenture"), between us and U.S. Bank National Association, as trustee. The Notes are senior, unsecured obligations and bear interest at a rate of 3.00% per year, payable in cash semi-annually in arrears on May 15 and November 15 of each year, beginning on November 15, 2017. The Notes mature on May 15, 2022, unless earlier converted or repurchased in accordance with their terms.

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

As of June 30, 2017, there were unamortized issuance costs and debt discounts of $9.0 million, which were recorded as a direct deduction from the Notes on the condensed consolidated balance sheets.

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”), pursuant to which we provided Maruho with certain information and the right to negotiate an exclusive license to develop and commercialize certain of our products in specified territories. In connection with the entry into this agreement, Maruho paid us $10.0 million (“Maruho Payment”), which will be credited against certain payments payable by Maruho to us if we enter into a license agreement for any of our products. Maruho’s right of first negotiation expired in December 2016 but the right to credit the Maruho Payment against certain payments under any future license agreement for our products remains. As of June 30, 2017 and December 31, 2016, we recorded the $10.0 million payment related to the Maruho Right of First Negotiation Agreement as deferred revenue, non-current in our consolidated balance sheets. The revenue would be recognized in connection with and pursuant to a future license arrangement, if any, or at the time the parties decide not to enter into such a license, at which point the entire amount would be recognized as revenue.

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

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

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

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

For the three and six months ended June 30, 2017, we recognized collaboration and license revenue related to the Maruho G.T. Agreement of $1.1 million and $2.1 million, respectively, in connection with the $25.0 million upfront payment. In addition, as of June 30, 2017, we have a deferred revenue balance related to the Maruho G.T. Agreement of $21.7 million, of which $4.3 million is recorded in deferred revenue, current on the condensed consolidated balance sheets.

UCB (a Related Party) Agreement

In March 2014, we entered into a development and commercialization agreement with UCB, a related party ("UCB Agreement"), which provides that we will develop Cimzia for the treatment of psoriasis in order for UCB to seek regulatory approval from the U.S. Food and Drug Administration ("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 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 $1.0 million and $1.5 million for the three months ended June 30, 2017 and 2016, respectively, and $2.0 million and $4.4 million for the six months ended June 30, 2017 and 2016, respectively. As of June 30, 2017, we recorded $2.6 million in prepaid expense and other current assets and $1.5 million in accounts payable related to the UCB Agreement. As of December 31, 2016, we recorded $2.8 million in prepaid expense and other current assets and $1.2 million in accounts payable related to UCB.

UCB is obligated to pay us up to an aggregate of $13.5 million upon the grant of regulatory approval, including pricing and reimbursement approval, in certain European countries, and, as of the date of execution of the UCB Agreement, was obligated to pay us up to an aggregate of $36.0 million if certain development milestones were met. 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 revenue from a related party 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 revenue from a related party in the consolidated statements of operations for the year ended December 31, 2015. In December 2016, we earned the third and fourth development milestones of $10.7 million each for the completion of a clinical study report for a Phase 3 clinical trial for Cimzia and recorded the amount as collaboration revenue from a related party in the consolidated statements of operations for the year ended December 31, 2016 and as collaboration receivables from a related party in the consolidated balance sheets as of December 31, 2016. As a result of achieving and receiving payment for these milestones, there are no remaining development milestone payments that we are eligible to earn and receive.

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 June 30, 2017, UCB beneficially owned 1,841,234 shares, representing approximately 4% of our outstanding common stock. Pursuant to the UCB Agreement, UCB is entitled to designate one member to our board of directors.

8. Stock-Based Compensation

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

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

	Shares Subject to Outstanding Stock Options	Weighted-Average Exercise Price Per Share
Stock options outstanding at December 31, 2016	4,526,079	$ 13.92
Stock options granted	1,317,520	$ 32.80
Stock options exercised	(141,378)	$ 8.08
Stock options forfeited	(19,253)	$ 27.22
Stock options outstanding at June 30, 2017	5,682,968	$ 18.40

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

	Shares Subject to Outstanding RSUs	Weighted-Average Grant Date Fair Value Per Share
RSUs outstanding at December 31, 2016	147,634	$ 27.21
RSUs granted	221,390	$ 32.70
RSUs forfeited	(1,900)	$ 30.30
RSUs outstanding at June 30, 2017	367,124	$ 30.50

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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Research and development	$2,018	$990	$3,814	$1,944
General and administrative	3,086	1,471	5,905	3,111
Total stock-based compensation expense	$5,104	$2,461	$9,719	$5,055

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

The interim financial statements included in this Quarterly Report on Form 10-Q and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the consolidated financial statements and notes thereto for the year ended December 31, 2016, included as part of our Annual Report on Form 10-K for the year ended December 31, 2016, and our unaudited Condensed Consolidated Financial Statements for the three- and six-month periods ended June 30, 2017 and other disclosures (including the disclosures under "Part II — Other Information, Item 1A. Risk Factors") included in this Quarterly Report on Form 10-Q. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended ("Exchange Act"). These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "potential," "project," "estimate," or "continue," and similar expressions or variations. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the

forward-looking statements. Factors that could cause or contribute to these differences include those set forth elsewhere in this Quarterly Report on Form 10-Q, particularly in Part II — Other Information, Item 1A. Risk Factors below, that could cause actual results to differ materially from historical results or anticipated results. Except as may be required by law, we disclaim any obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

We are a biopharmaceutical company dedicated to bringing biotech ingenuity to medical dermatology by delivering differentiated, new therapies to the millions of patients living with chronic skin conditions. We are committed to understanding the needs of both patients and physicians and using our insight to identify and develop leading-edge medical dermatology clinical programs. Our management team has extensive experience in product development and commercialization, having served in leadership roles at several leading dermatology companies. Our pipeline includes three late-stage product candidates that could have a profound impact on the lives of patients: Cimzia (certolizumab pegol), for which marketing applications have been submitted for potential approval for the treatment of moderate-to-severe chronic plaque psoriasis, in collaboration with UCB Pharma S.A., a related party (“UCB”); glycopyrronium tosylate (formerly DRM04), which has completed a Phase 3 program for the treatment of primary axillary hyperhidrosis, or excessive underarm sweating; and olumacostat glasaretil (formerly DRM01), in Phase 3 development for the treatment of acne vulgaris, or acne.

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 an agreement with UCB 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 ("UCB Agreement"). In December 2014, we commenced a Phase 3 clinical program for Cimzia in moderate-to-severe chronic plaque psoriasis that comprises three trials – CIMPASI-1, CIMPASI-2 and CIMPACT. In December 2015, we completed enrollment in this Phase 3 program, enrolling a total of 1,020 patients. In October 2016, December 2016 and January 2017, we announced positive topline results for the CIMPASI-2, CIMPASI-1 and CIMPACT trials, respectively. In all three trials, Cimzia demonstrated statistically significant improvements for all primary or co-primary endpoints compared to placebo at both treatment doses. The adverse event profile across all three trials is consistent with the safety profile of Cimzia in currently approved indications. Based on these results, UCB submitted a supplemental Biologics License Application ("sBLA") to the U.S. Food and Drug Administration ("FDA") and a Type II Variation to the European Medicines Agency ("EMA") in July 2017 to support potential approvals for Cimzia as a treatment option for patients with moderate-to-severe chronic plaque psoriasis. An additional submission to expand the use of CIMZIA in this patient population is also planned with the Canadian federal department for health ("Health Canada").
- Glycopyrronium tosylate, a small-molecule anticholinergic product for topical application we are developing for the treatment of primary axillary hyperhidrosis. In July 2015, we commenced a Phase 3 clinical program for glycopyrronium tosylate in patients with primary axillary hyperhidrosis that comprised three clinical trials – the ATMOS-1 and ATMOS-2 pivotal trials and the ARIDO open-label safety trial. In February 2016, we completed patient enrollment in ATMOS-1 and ATMOS-2 and in June 2016, we announced positive topline results from these trials. The ATMOS-1 and ATMOS-2 trials enrolled a total of 697 adult and adolescent (ages nine and older) patients with primary axillary hyperhidrosis. In the ATMOS-2 trial, glycopyrronium tosylate demonstrated statistically significant improvements for both co-primary endpoints and both secondary endpoints compared to vehicle. In the ATMOS-1 trial, glycopyrronium tosylate demonstrated statistically significant improvements for one of the co-primary endpoints and both secondary endpoints. Results from both Phase 3 trials were based on the overall dataset from the intent-to-treat population. For the second co-primary endpoint in the ATMOS-1 trial, when extreme outlier data from one analysis center were excluded in accordance with the pre-specified statistical analysis plan submitted to the FDA, glycopyrronium tosylate demonstrated statistically significant results compared to vehicle. Consistent with the results of an earlier Phase 2b trial, glycopyrronium tosylate was well-tolerated with side effects that were primarily mild to moderate in severity. In December 2016, the treatment period for ARIDO, the open-label Phase 3 trial assessing the long-term safety of glycopyrronium tosylate, was completed. The safety and tolerability profile for glycopyrronium tosylate in the ARIDO trial is consistent with what was observed in the ATMOS-1 and ATMOS-2 trials. Based on the results of the glycopyrronium tosylate Phase 3 program and a pre-NDA meeting with the FDA in February 2017, we plan to submit a New Drug Application ("NDA") to the FDA for potential approval of glycopyrronium tosylate for the treatment of primary axillary hyperhidrosis. The NDA submission is targeted for the second half of 2017.
- Olumacostat glasaretil, a novel, small molecule that targets 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 olumacostat glasaretil in adult patients with moderate-to-severe facial acne vulgaris. In January 2016, we completed patient enrollment in this study and in May 2016 we announced positive topline results. In the Phase 2b dose-ranging trial, which enrolled a total of 420 patients, olumacostat glasaretil demonstrated statistically significant improvements in all primary endpoints compared to vehicle at the highest dose and in most primary endpoints at the other doses. Olumacostat glasaretil was well-tolerated with adverse events primarily mild or moderate in severity. Based on these results, in December 2016, we initiated a Phase 3 program to evaluate the safety and efficacy of olumacostat glasaretil as a potential treatment for acne to support a potential NDA submission to the FDA. The Phase 3 program comprises three clinical trials – the CLAREOS-1 and CLAREOS-2

pivotal trials and the CLARITUDE open-label safety trial. The CLAREOS-1 and CLAREOS-2 trials are expected to enroll a total of approximately 1,400 adult and adolescent (ages nine and older) patients with moderate-to-severe acne. We expect to announce topline results from the CLAREOS-1 and CLAREOS-2 trials in the first quarter of 2018.

Key Developments

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

Cimzia

- UCB submitted a sBLA to the FDA and a Type II Variation to the EMA in July 2017 pursuant to the UCB Agreement to support potential approvals for Cimzia as a treatment option for patients with moderate-to-severe chronic plaque psoriasis.
- Announced positive results from CIMPACT, the third of three trials in the Cimzia Phase 3 program, in January 2017. In all three trials comprising the Phase 3 program, including CIMPASI-1 and CIMPASI-2 for which results were announced in December 2016 and October 2016, respectively, Cimzia demonstrated statistically significant improvements for all primary or co-primary endpoints compared to placebo at both treatment doses. The adverse event profile across all three trials was consistent with the safety profile of Cimzia in currently approved indications.

Glycopyrronium Tosylate

- Completed a meeting with the FDA in February 2017 to discuss our planned submission of an NDA for glycopyrronium tosylate.

Olumacostat Glasaretil

- Announced in January 2017 the initiation of a Phase 3 program to evaluate the safety and efficacy of olumacostat glasaretil as a potential treatment for acne to support a potential NDA submission to the FDA. The Phase 3 program comprises three clinical trials – the CLAREOS-1 and CLAREOS-2 pivotal trials and the CLARITUDE open-label safety trial.

Non-Program Developments

- Closed a private placement of 3.00% Convertible Senior Notes due 2022 (“Notes”) in May 2017, which generated net proceeds to us of approximately $278.2 million.
- Closed an underwritten public offering in March 2017 (“2017 Public Offering”), which generated net proceeds to us of $181.5 million.

Financial Overview

For the three months ended June 30, 2017, net loss increased 39% to $38.6 million from $27.8 million for the same period in 2016. We recognized collaboration and license revenue of $1.1 million for the three months ended June 30, 2017 related to a portion of the upfront payment recognized pursuant to our exclusive license agreement with Maruho Co., Ltd., which grants Maruho an exclusive license to develop and commercialize glycopyrronium tosylate for the treatment of hyperhidrosis in Japan (“Maruho G.T. Agreement”). Research and development expenses increased 20% to $26.0 million for the three months ended June 30, 2017 compared to the same period in 2016, driven primarily by growth in clinical trial activities for our olumacostat glasaretil product candidate, partially offset by a reduction in clinical trial activities for our Cimzia and glycopyrronium tosylate product candidates. General and administrative expenses increased 113% to $13.6 million for the three months ended June 30, 2017 compared to the same period in 2016, driven primarily by headcount growth and associated expenses, as well as expenses related to commercial readiness activities.

For the six months ended June 30, 2017, net loss increased 21% to $68.1 million from $56.2 million for the same period in 2016. We recognized collaboration and license revenue of $2.1 million for the six months ended June 30, 2017 related to a portion of the upfront payment recognized pursuant to our exclusive license agreement with Maruho. Research and development expenses increased 3% to $45.8 million for the six months ended June 30, 2017 compared

to the same period in 2016, driven primarily by growth in clinical trial activities for our olumacostat glasaretil product candidate and in internal costs, partially offset by a reduction in clinical trial activities for our Cimzia and glycopyrronium tosylate product candidates. General and administrative expenses increased 103% to $24.9 million for the six months ended June 30, 2017 compared to the same period in 2016, driven primarily by headcount growth and associated expenses, as well as expenses related to commercial readiness activities.

As of June 30, 2017, we had cash and cash equivalents and investments of $695.9 million.

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

We have never been profitable and may never be profitable. As of June 30, 2017, we had an accumulated deficit of $318.2 million. We expect to continue to incur net losses for the foreseeable future as we advance our current and potential additional product candidates through clinical development, seek regulatory approval for them and prepare for and proceed to commercialization. We expect to incur significant commercialization costs in advance of any of our product candidates receiving regulatory approval. As a result, we will need substantial additional funding to support our operating activities. Adequate funding may not be available to us on acceptable terms, or at all. We currently anticipate that we will seek to fund our operations through public or private equity or debt financings or other sources, such as potential collaboration or license agreements. Our failure to obtain sufficient funds on acceptable terms as and when needed could have a material adverse effect on our business, results of operations and financial condition.

Critical Accounting Policies and Significant Estimates

Our management's discussion and analysis of financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions. There were no material changes in our critical accounting policies and significant estimates as disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC") on February 28, 2017.

Results of Operations

	Three Months Ended	Six Months Ended