Corium International, Inc. Form 10-Q August 12, 2014 Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

X	Quarterly Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
	For the quarterly period ended June 30, 2014
	OR
0	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: 001-36375

Corium International, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

38-3230774 (I.R.S. Employer Identification Number)

Corium International, Inc. 235 Constitution Drive Menlo Park, California 94025

(Address of principal executive offices and zip code)

(650) 298-8255

(Registrant s telephone number, including area code)

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

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes x No o

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

Large accelerated filer o Accelerated filer o

Non-accelerated filer x (Do not check if a smaller reporting company)

Smaller reporting company o

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

As of August 1, 2014, there were approximately 18,000,419 shares of the Registrant s Common Stock outstanding.

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PART I

ITEM 1. FINANCIAL STATEMENTS

CORIUM INTERNATIONAL, INC.

CONDENSED BALANCE SHEETS

(unaudited, in thousands)

	As of June 30, 2014	As of September 30, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 44,245	\$ 13,581
Accounts receivable	4,503	3,129
Unbilled accounts receivable	1,800	1,495
Inventories, net	3,115	4,508
Prepaid expenses and other current assets	1,329	1,038
Total current assets	54,992	23,751
Property and equipment, net	12,512	12,622
Debt financing costs, net	645	902
Intangible assets, net	6,757	6,647
Notes receivable related parties		100
TOTAL ASSETS	\$ 74,906	\$ 44,022
LIABILITIES, CONVERTIBLE PREFERRED STOCK, REDEEMABLE COMMON		
STOCK AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 2,573	\$ 2,748
Accrued expenses and other current liabilities	3,859	3,374
Bank line of credit	1,500	3,873
Long-term debt, current portion	113	457
Capital lease obligations, current portion	813	1,029
Preferred stock warrant liability		560
Recall liability, current portion	732	1,004
Deferred contract revenues, current portion	2,251	2,112
Total current liabilities	11,841	15,157
Long-term interest payable		11,590
Long-term debt, net of current portion	37,824	36,956
Convertible notes		9,399
Subordinated note		13,000
Subordinated note embedded derivative liability		7,367
Capital lease obligations, net of current portion	1,084	1,652
Recall liability, net of current portion	3,185	3,828
Deferred contract revenues, net of current portion	3,500	3,688
Total liabilities	57,434	102,637
Convertible preferred stock		57,261

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Redeemable common stock		3,224
Stockholders equity (deficit):		
Common stock	18	2
Additional paid-in capital	113,422	(26,679)
Accumulated deficit	(95,968)	(92,423)
Total stockholders equity (deficit)	17,472	(119,100)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK, REDEEMABLE		
COMMON STOCK AND STOCKHOLDERS EQUITY (DEFICIT)	\$ 74,906 \$	44,022

See accompanying notes to condensed financial statements

CORIUM INTERNATIONAL, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

(in thousands, except share and per share data)

	Three M Ended J		Nine M Ended J		
	2014	2013	2014		2013
Revenues:					
Product revenues	\$ 7,856	\$ 9,732 \$	23,196	\$	29,922
Contract research and development revenues	2,023	2,530	7,260		7,292
Other revenues	304	304	912		512
Total revenues	10,183	12,566	31,368		37,726
Costs and operating expenses:					
Cost of product revenues	4,566	6,080	14,793		18,896
Cost of contract research and development					
revenues	3,789	2,767	11,237		8,709
Research and development expenses	1,614	1,393	3,742		3,965
General and administrative expenses	3,497	1,463	6,543		4,861
Amortization of intangible assets	138	138	399		402
Gain on disposal and sale and leaseback of					
equipment	(24)	(46)	(93)		(137)
Total costs and operating expenses	13,580	11,795	36,621		36,696
Income (loss) from operations	(3,397)	771	(5,253)		1,030
Interest income	2	2	5		7
Interest expense	(1,586)	(1,982)	(5,390)		(5,678)
Change in fair value of preferred stock warrant					
liability			(274)		
Change in fair value of subordinated note					
embedded derivative liability		(7,954)	7,367		(7,954)
Loss before income taxes	(4,981)	(9,163)	(3,545)		(12,595)
Income tax benefit					
Net loss and comprehensive loss	\$ (4,981)	\$ (9,163) \$	(3,545)	\$	(12,595)
Net loss per share attributable to common	, , ,				
stockholders, basic and diluted	\$ (0.28)	\$ (4.12) \$	(0.48)	\$	(5.69)
Weighted-average shares used in computing net	()	() , ,	(4.10)		(5.02)
loss per share attributable to common					
stockholders, basic and diluted	17,624,327	2,226,451	7,362,142		2,213,513
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See accompanying notes to condensed financial statements

CORIUM INTERNATIONAL, INC. CONDENSED STATEMENTS OF CONVERTIBLE PREFERRED STOCK, REDEEMABLE COMMON STOCK AND STOCKHOLDERS EQUITY (DEFICIT)

(Unaudited)
(in thousands, except share and per share data)

	Convertibl Sto Shares	ock	ferred Amount	Redec Commo Shares	on Sto		Commo Shares			Additional Paid-in Capital	Accumulated Deficit	Total Stockholders Equity (Deficit)
Balance September 30, 2013	36,034,900	\$	57,261	347,945	\$	3,224	1,881,177	\$	2 \$	(26,679)	\$ (92,423)\$	(119,100)
Decrease in equity associated with modification of subordinated debt	, ,		ʻ	·		ŕ	, ,		\$		\$	
Issuance of common stock in connection with initial public offering, net of issuance costs of												
\$2.70 million Conversion of							6,874,997	\$	7 \$	48,452	\$	48,459
convertible preferred stock to common stock in connection with												
initial public offering	(36,034,900)	\$	(57,261)				3,567,807	\$	4 \$	57,257	\$	57,261
Issuance of common stock in connection with conversion of convertible debt							2,036,555	\$	2 \$	5 19,367	\$	19,369
Issuance of common stock upon conversion of subordinated debt in connection with the recapitalization							2,030,333	Ψ	2 4	15,507	Ψ	17,307
transaction							3,387,146	\$	3 \$	19,234	\$	19,237
Issuance of common stock upon net exercise of preferred stock warrants and related extinguishment of preferred stock warrant liability							1,191		\$	309	\$	309
Issuance of common stock upon net exercise of common stock warrants							970,249	\$	1 \$	5 (1)		
Repurchase of redeemable common stock and common stock from founders in connection with initial							,—		- 4	(=)		
public offering				(347,945)	\$	(3,224)	(729,864)	\$	(1) \$	(2,000)	\$	(2,001)
Issuance of common stock upon exercise of stock options							3,380		\$	8	\$	8
Stock-based compensation expense									\$	960	\$	960

Aggregate fractional shares cancelled in connection with reverse stock split

stock split		(26)				
Net loss and						
comprehensive loss				\$	(3,545) \$	(3,545)
Balance June 30, 2014	\$ \$	17,992,612	\$ 18 \$	113,422 \$	(95,968) \$	17,472

See accompanying notes to condensed financial statements

CORIUM INTERNATIONAL, INC.

CONDENSED STATEMENTS CASH FLOWS

(unaudited)

(in thousands)

	Nine Months E	Ended June 30, 2013
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss and comprehensive loss \$	(3,545)	\$ (12,595)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	1,642	1,444
Gain on disposal and sale and leaseback of equipment	(93)	(137)
Amortization of premium on modification of subordinated note	(292)	
Change in fair value of preferred stock warrant liability	274	
Change in fair value of subordinated debt embedded derivative liability	(7,367)	7,954
Amortization of intangible assets	399	402
Noncash amortized debt issue costs on long-term debt	257	246
Noncash amortized debt discount	116	143
Write off of patent costs		3
Stock compensation expense	960	272
Changes in operating assets and liabilities:		
Accounts receivable	(1,374)	(2,801)
Unbilled accounts receivable	(305)	(21)
Inventories, net	1,393	(786)
Prepaid expenses and other current assets	(291)	(141)
Accounts payable	599	(656)
Accrued expenses and other liabilities	1,549	818
Deferred contract revenues	(49)	443
Recall liability	(916)	
Long-term interest payable	823	1,234
Net cash used by operating activities	(6,220)	(4,178)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(2,325)	(6,267)
Proceeds from sale of equipment	18	
Issuance of notes receivable related parties		(100)
Proceeds from repayment of notes receivable related parties	100	
Payments for patents and licensing rights	(509)	(548)
Net cash used by investing activities	(2,716)	(6,915)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of issuance costs	48,459	
Repurchase of redeemable common stock from founders, in connection with initial public	(5,225)	
Proceeds from issuance of long-term debt		7,300
Payment of transaction costs associated with issuance of long-term debt		(65)
Principal payments on long-term debt	(468)	(659)
Principal payments on capital lease obligations	(802)	(463)
Borrowings on bank line of credit	1,298	3,157
Payments on bank line of credit	(3,670)	(2,285)
Proceeds from exercise of stock options	8	8
Net cash provided by financing activities	39,600	6,993
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	30,664	(4,100)

CASH AND CASH EQUIVALENTS Beginning of period CASH AND CASH EQUIVALENTS End of period	\$ 13,581 44,245	\$ 12,245 8,145
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for interest	\$ 3,503	\$ 3,600
Property and equipment purchases included in accounts payable and accrued liabilities	\$ 360	\$ 393

See accompanying notes to condensed consolidated financial statements

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CORIUM INTERNATIONAL, INC.
Notes to the Condensed Financial Statements
1. Organization, Description of Business, and Summary of Significant Accounting Policies
Organization
Corium International, Inc., a Delaware corporation (the Company), is a commercial stage biopharmaceutical company focused on the development, manufacture and commercialization of specialty pharmaceutical products that leverage its broad experience in transdermal and transmucosal delivery systems.
In the normal course of business, the Company enters into collaborative agreements with partners to develop and manufacture products based on the Company s drug delivery technologies. Revenues consist of net sales of products manufactured, royalties and profit-sharing payments based on sales of such products by partners, and product development fees for research and development activities under collaborative agreements with strategic partners. The Company is also engaged in the research and development of its own proprietary transdermal drug delivery products using its proprietary technologies.
Basis of Presentation
The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) and following the requirements of the Securities and Exchange Commission (the SEC) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. These financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments that are necessary for a fair statement of the Company's financial information. The results of operations for the three and nine months ended June 30, 2014 are not necessarily indicative of the results to be expected for the year ending September 30, 2014 or for any future period. The balance sheet as of September 30, 2013 has been derived from the audited 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 financial statements and related financial information should be read in conjunction with the audited financial statements and the related notes thereto for the year ended September 30, 2013 included in the Company s Prospectus filed pursuant to Rule 424(b)(4) on April 3, 2014 with the SEC (the Prospectus).

There have been no material changes to the significant accounting policies previously disclosed in the Prospectus.

Reverse Stock Split

On March 20, 2014, the Company effected a 1-for-10.1 reverse stock split of the Company s outstanding common stock resulting in a reduction of the Company s total common stock issued and outstanding from 19,032,056 shares to 1,884,362 shares. The reverse stock split affected all stockholders of the Company s common stock uniformly, and did not materially affect any stockholder s percentage of ownership interest. The par value of the Company s common stock remained unchanged at \$0.001 per share and the number of authorized shares of common stock remained the same after the reverse stock split.

In connection with this reverse stock split, the number of shares of common stock reserved for issuance under the Company s equity incentive, stock option and employee stock purchase plans as well as the shares of common stock underlying outstanding stock options, restricted stock units and warrants were also proportionately reduced while the exercise prices of such stock options and warrants were proportionately increased. All references to shares of common stock and per share data for all periods presented in the accompanying financial statements and notes thereto have been adjusted to reflect the reverse stock split on a retroactive basis.

Initial Public Offering

On April 2, 2014, the Company s registration statements on Form S-1 (File No. 333-195002 and File No. 333-195002) relating to the Initial Public Offering (the IPO) of its common stock were declared effective by the SEC. The IPO closed on April 8, 2014 at which time the Company sold 6,500,000 shares of its common stock at a price of \$8.00 per share. Corium also granted the underwriters a 30-day option to purchase up to 975,000 additional shares of common stock at the IPO price. The underwriters exercised this option to purchase 374,997 shares on May 2, 2014. The Company received cash proceeds of \$48.5 million from the IPO, including proceeds from the partial exercise of the underwriters option, net of underwriting discounts, commissions and issuance costs paid by the Company.

On April 8, 2014, immediately prior to the closing of the IPO, all outstanding shares of convertible preferred stock converted into 3,567,807 shares of common stock, and the related carrying value of \$57.3 million was reclassified to common stock and additional

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paid-in capital. In addition, certain warrants to purchase convertible preferred stock and common stock were also converted and net exercised into 971,440 shares of common stock. Upon the consummation of the IPO, Corium also repurchased 1,077,809 shares of common stock for an aggregate purchase price of \$5.2 million from its founders.

Following the filing of the Restated Certificate of Incorporation of the Company on April 8, 2014, the number of shares of capital stock the Company is authorized to issue is 155,000,000 shares, of which 150,000,000 shares may be common stock and 5,000,000 shares may be preferred stock. Both the common stock and preferred stock have a par value of \$0.001 per share.

Use of Estimates

Estimates and assumptions are required to be used by management in the preparation of financial statements in conformity with U.S. GAAP that affect the reported amounts of assets, liabilities, and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of operating revenues and operating expenses during the reporting period. Those estimates and assumptions affect revenue recognition and deferred revenues, impairment of long-lived assets, determination of fair value of stock-based awards and other debt and equity related instruments, and accounting for income taxes. As future events and their effects cannot be determined with precision, actual results could differ from those estimates.

Concentration of Credit Risk

Four partners accounted for 94% and 95% of the Company s revenues for the three and nine months ended June 30, 2014 respectively, compared to 99% and 99% for the corresponding periods in 2013. These same partners accounted for 100% of accounts receivable as of June 30, 2014 and September 30, 2013, respectively.

Revenue Recognition

The Company generates revenues from agreements for the development and commercialization of its products. The terms of the agreements may include nonrefundable upfront payments, partial or complete reimbursement of research and development costs, milestone payments, product sales and royalties and profit sharing on product sales derived from partner agreements. The Company recognizes revenues when the following criteria are met: persuasive evidence of a sales arrangement exists; delivery has occurred; the price is fixed or determinable; and collectability is reasonably assured.

Revenue related to multiple element arrangements are analyzed to determine whether the deliverables can be separated or whether they must be accounted for as a single unit of accounting. This determination is generally based on whether any deliverable has stand-alone value to the partner. This analysis also establishes a selling price hierarchy for determining how to allocate arrangement consideration to identified units of accounting. The selling price used for each unit of accounting is based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific nor third-party evidence is available. Typically, the Company has not granted licenses to partners at the beginning of its arrangements and thus there are no delivered items separate

from the research and development services provided. As such, upfront payments are recorded as deferred revenues in the balance sheet and are recognized as contract research and development revenues over the estimated period of performance that is consistent with the terms of the research and development obligations contained in the agreement. The Company periodically reviews the estimated period of performance based on the progress made under each arrangement.

Amounts related to research and development funding are generally recognized as the related services or activities are performed, in accordance with the contract terms. To the extent that agreements specify services are to be performed on a cost-plus basis, revenues are recognized as services are rendered. Such work is generally billed on a monthly basis for time incurred at specified rates in the agreements. To the extent that agreements specify services to be performed on a fixed-price basis, revenues are recognized consistent with the pattern of the work performed. Generally, all of the agreements provide for reimbursement of third-party expenses, and such reimbursable expenses are billed as revenues as incurred.

The arrangements may include contractual milestones, which relate to the achievement of pre-specified research, development, regulatory and commercialization events. The milestone events contained in the Company's arrangements coincide with the progression of the Company's product candidates from research and development, to regulatory approval and through to commercialization. The process of successfully developing a new product, having it approved from a regulatory perspective and ultimately sold for a profit is highly uncertain. As such, the milestone payments that the Company may earn from its partners involve a significant degree of risk to achieve. Research and development milestones in the Company's collaboration agreements may include the following types of events: completion of pre-clinical research and development work, completion of certain development events and initiation or completion of clinical trials. Regulatory milestones may include the following types of events: filing of regulatory applications with the Food and Drug Administration and approval of the regulatory applications by the Food and Drug Administration. Commercialization milestones may include product launch. The Company recognizes each milestone payment in its entirety in the period in which the milestone is achieved.

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Upon commercialization, revenues are generated from product sales, royalties and profit sharing. Product sales are generally recognized as products are shipped and title and risk of loss pass to the partner. Royalties and profit sharing are generally recognized when the Company s partners sell the product to their customers and are based on a percentage of the Company s partners gross sales or net profits for products subject to the Company s agreements with its partners. Royalties and profit sharing totaled \$1.0 million and \$4.0 million for the three and nine months ended June 30, 2014, compared to \$1.9 million and \$6.2 million for the corresponding periods in 2013.

Other revenues consist primarily of income derived from the Company s arrangements with its partners, whereby a portion of the revenues received under these agreements relates to rental income from embedded leases associated with these relationships, as well as revenues associated with licenses granted to a third party for intellectual property related to thin film dressings.

2. Fair Value Measurements

Financial assets and liabilities are recorded at fair value. Except as noted below, the carrying values of the Company s financial instruments, including cash equivalents, accounts receivable, and accounts payable, approximated their fair values due to the short period of time to maturity or repayment.

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The authoritative guidance on fair value measurements establishes a three-tier fair value 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 are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities 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 related assets or liabilities; and

Level 3 Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

The Company s financial instruments that are measured at fair value on a recurring basis as of June 30, 2014 and September 30, 2013, by level within the fair value hierarchy, are as follows (in thousands):

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	Level I	Level II	Level III	Total
Financial Assets:				
Money market funds	\$ 44,371	\$	\$	\$ 44,371
Total financial assets	\$ 44,371	\$	\$	\$ 44,371

As of September 30, 2013