

Corium International, Inc.
Form 10-Q
August 12, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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, 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: 001-36375

Corium International, Inc.

(Exact name of registrant as specified in its charter)

Delaware

38-3230774

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(State or other jurisdiction of (I.R.S. Employer
incorporation or organization) 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 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 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

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 August 9, 2016, there were approximately 22,359,011 shares of the Registrant's Common Stock outstanding.

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PART I

ITEM 1. FINANCIAL STATEMENTS

CORIUM INTERNATIONAL, INC.

CONDENSED BALANCE SHEETS

(in thousands, except share amounts)

(Unaudited)

	As of June 30, 2016	As of September 30, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 47,394	\$ 72,218
Accounts receivable	4,091	4,461
Unbilled accounts receivable	517	812
Inventories, net	2,830	2,902
Prepaid expenses and other current assets	1,459	1,367
Total current assets	56,291	81,760
Restricted cash	666	—
Property and equipment, net	11,139	11,593
Debt financing costs, net	599	554
Intangible assets, net	7,072	6,837
TOTAL ASSETS	\$ 75,767	\$ 100,744
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,071	\$ 3,952
Accrued expenses and other current liabilities	3,895	4,091
Long-term debt, current portion	69	57
Capital lease obligations, current portion	285	820
Recall liability, current portion	460	760
Deferred contract revenues, current portion	292	134
Total current liabilities	8,072	9,814
Long-term debt, net of current portion	51,080	49,807
Capital lease obligations, net of current portion	—	72
Recall liability, net of current portion	1,971	2,229

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Deferred contract revenues, net of current portion	3,500	3,500
Total liabilities	64,623	65,422
Commitments and contingencies		
Stockholders' equity:		
Common stock, par value of \$0.001 per share, 150,000,000 shares authorized; 22,359,011 and 22,160,991 shares issued and outstanding as of June 30, 2016 and September 30, 2015	22	22
Additional paid-in capital	169,283	166,085
Accumulated deficit	(158,161)	(130,785)
Total stockholders' equity	11,144	35,322
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 75,767	\$ 100,744

See accompanying notes to condensed financial statements.

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CORIUM INTERNATIONAL, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share data)

(Unaudited)

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2016	2015	2016	2015
Revenues:				
Product revenues	\$ 7,264	\$ 6,296	\$ 18,930	\$ 20,467
Contract research and development revenues	1,983	3,505	4,228	9,798
Other revenues	1,359	797	1,947	1,390
Total revenues	10,606	10,598	25,105	31,655
Costs and operating expenses:				
Cost of product revenues	4,626	4,063	12,924	13,369
Cost of contract research and development revenues	2,742	4,065	8,601	12,292
Research and development expenses	5,516	3,493	15,566	11,670
General and administrative expenses	3,116	2,835	9,106	8,192
Amortization of intangible assets	168	141	489	464
(Gain) / loss on disposal of equipment	—	(5)	2	2
Total costs and operating expenses	16,168	14,592	46,688	45,989
Loss from operations	(5,562)	(3,994)	(21,583)	(14,334)
Interest income	54	5	142	11
Interest expense	(1,984)	(1,925)	(5,932)	(5,490)
Loss before income taxes	(7,492)	(5,914)	(27,373)	(19,813)
Income tax expense	—	—	3	2
Net loss and comprehensive loss	\$ (7,492)	\$ (5,914)	\$ (27,376)	\$ (19,815)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.34)	\$ (0.33)	\$ (1.23)	\$ (1.10)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	22,321,581	18,116,021	22,254,849	18,073,879

See accompanying notes to condensed financial statements

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CORIUM INTERNATIONAL, INC.

Condensed Statement of Stockholders' Equity

(in thousands, except share data)

(Unaudited)

	Common Stock		Additional	Accumulated	Total
	Shares	Amount	Paid-in	Deficit	Stockholders'
			Capital		Equity
Balance - September 30, 2015	22,160,991	\$ 22	\$ 166,085	\$ (130,785)	\$ 35,322
Issuance of common stock under Employee Stock Purchase Plan	126,471	—	488	—	488
Issuance of common stock upon exercise of stock options	71,549	—	170	—	170
Stock-based compensation expense	—	—	2,540	—	2,540
Net loss and comprehensive loss	—	—	—	(27,376)	(27,376)
Balance - June 30, 2016	22,359,011	\$ 22	\$ 169,283	\$ (158,161)	\$ 11,144

See accompanying notes to condensed financial statements.

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CORIUM INTERNATIONAL, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

(Unaudited)

	Nine Months Ended June 30,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss and comprehensive loss	\$ (27,376)	\$ (19,815)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization of property and equipment	1,375	1,546
Loss on disposal of equipment	2	2
Amortization of intangible assets	489	464
Noncash amortized debt issue costs on long-term debt and capital leases	155	127
Noncash amortized discount on long-term debt and capital leases	15	17
Stock-based compensation expense	2,540	2,019
Changes in operating assets and liabilities:		
Accounts receivable	370	(472)
Unbilled accounts receivable	295	513
Inventories, net	72	(701)
Prepaid expenses and other current assets	(92)	(536)
Accounts payable	(748)	1,143
Accrued expenses and other current liabilities	1,130	837
Deferred contract revenues	158	(81)
Recall liability	(558)	(521)
Net cash used by operating activities	(22,173)	(15,458)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(1,056)	(690)
Proceeds from sale of equipment	—	10
Payments for patents and licensing rights	(724)	(548)
Change in restricted cash	(666)	—
Net cash used by investing activities	(2,446)	(1,228)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of long-term debt	—	10,000
Payment of transaction costs associated with issuance of long-term debt	(200)	(150)
Principal payments on long-term debt	(53)	(50)
Principal payments on capital lease obligations	(610)	(571)
Proceeds from exercise of stock options	170	30
Proceeds from exercise of common stock warrants	—	1
Proceeds from issuance of common stock under Employee Stock Purchase Plan	488	570
Net cash provided (used) by financing activities	(205)	9,830

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NET DECREASE IN CASH AND CASH EQUIVALENTS	(24,824)	(6,856)
CASH AND CASH EQUIVALENTS — Beginning of period	72,218	36,395
CASH AND CASH EQUIVALENTS — End of period	\$ 47,394	\$ 29,539
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for interest	\$ 4,434	\$ 4,130
Cash paid for income taxes	\$ 3	\$ 1
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Property and equipment purchases included in accounts payable	\$ 65	\$ 176
Issuance of payment-in-kind notes in lieu of cash interest payments	\$ 1,326	\$ 1,215

See accompanying notes to condensed 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 the Company’s broad experience with advanced 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 and product development expertise. 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 collaboration agreements with partners. The Company is also engaged in the research and development of its own proprietary transdermal drug delivery products using its Corplex and MicroCor technologies.

The Company’s fiscal year ends on September 30. References to “fiscal” refer to the years ended September 30.

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 follow 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. The interim balance sheet as of June 30, 2016 and the statements of operations and comprehensive loss for the three and nine months ended June 30, 2016 and 2015, statement of stockholders’ equity for the nine months ended June 30, 2016 and statements of cash flows for the nine months ended June 30, 2016 and 2015 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary to present fairly the Company’s financial position as of June 30, 2016 and its results of operations for the three and nine months ended June 30, 2016 and 2015 and cash flows for the nine months ended June 30, 2016 and 2015. The financial data and the other financial information contained in these notes to the financial statements related to the three and nine month periods are also unaudited. The results of

operations for the nine months ended June 30, 2016 are not necessarily indicative of the results to be expected for the year ending September 30, 2016 or for any future annual or interim period. The balance sheet as of September 30, 2015 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, 2015 included in the Company's Annual Report on Form 10-K, which was filed with the SEC on December 16, 2015.

There have been no material changes to the significant accounting policies previously disclosed in the Company's audited financial statements for the year ended September 30, 2015.

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

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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, deferred revenues, impairment of long-lived assets, determination of fair value of stock-based awards and other debt- and equity-related instruments, accounting for clinical trials 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

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash and cash equivalents and accounts receivable. The Company maintains its cash and cash equivalents with a single domestic financial institution that is well capitalized. The Company provides credit, in the normal course of business, to its partners and performs credit evaluations of such partners.

For the three and nine months ended June 30, 2016, three partners accounted for 84% and 85% of the Company's revenues and 84% of accounts receivable as of June 30, 2016. For the three and nine months ended June 30, 2015, four partners accounted for 87% and 88% of the Company's revenues. As of September 30, 2015, three partners accounted for 84% of accounts receivable.

Restricted Cash

The Company's restricted cash consists of cash maintained in a separate deposit account to secure a letter of credit issued by a bank to the landlord pursuant to a lease agreement for the Company's new corporate headquarters. The Company has classified the restricted cash as noncurrent on the condensed balance sheet.

Facility Lease

On February 12, 2016, the Company entered into a lease agreement pursuant to which the Company agreed to lease approximately 48,240 square feet of space in Fremont, California, which was intended to replace the Company's current headquarters. Subject to certain conditions, the lease agreement provided for a term of ten years. The lease agreement provided for annual base rent of \$72,360 per month for the first twelve months, \$110,952 per month for the next twelve months with rent increasing by approximately 3% annually thereafter. In addition, the lease provided that the landlord will reimburse the Company for up to \$2.4 million in tenant improvements. On July 29, 2016, the Company exercised its termination right under Section 4.2 of the lease by providing the landlord with written notice to terminate the lease agreement effective immediately. For further details, see Note 14.

Comprehensive Income (Loss)

For the three and nine months ended June 30, 2016 and 2015, the Company did not recognize any other comprehensive income (loss) and, therefore, the net loss and comprehensive loss was the same for all periods presented.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board issued Accounting Standards Update (“ASU”) No. 2014-09, “Revenue from Contracts with Customers, (Topic 606)” (“ASU 2014-09”). This ASU affects any entity that either enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets, unless those contracts are within the scope of other standards. The guidance in this ASU supersedes the revenue recognition requirements in Topic 605, Revenue Recognition and most industry-specific guidance. The core principle of the guidance is that an entity should recognize revenue upon the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The new guidance also includes a set of disclosure requirements that will provide users of financial statements with comprehensive information about the nature, amount, timing, and uncertainty of revenue and cash flows

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arising from a reporting organization's contracts with customers. In August 2015, the Financial Accounting Standards Board issued ASU No. 2015-14, "Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date", which defers the effective date of ASU 2014-09 by one year. This ASU is effective for annual reporting periods, and interim periods within those years, beginning after December 15, 2017 for public companies and permits the use of either the retrospective or cumulative effect transition method, with early adoption permitted as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within those annual periods. In April 2016, the FASB issued ASU 2016-10, "Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing" which further clarifies guidance related to identifying performance obligations and licensing implementation guidance contained in ASU 2014-09. In May 2016, the FASB issued ASU 2016-12, "Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients" which addresses narrow-scope improvements to the guidance on collectibility, noncash consideration, and completed contracts at transition and provides a practical expedient for contract modifications at transition and an accounting policy election related to the presentation of sales taxes and other similar taxes collected from customers. We are currently evaluating the effect, if any, these ASUs may have on our future financial position, results of operations and cash flows.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"), which supersedes existing guidance on accounting for leases in "Leases (Topic 840)" and generally requires all leases to be recognized in the statement of financial position. The provisions of ASU 2016-02 are effective for annual reporting periods beginning after December 15, 2018. Early adoption is permitted. The provisions of this ASU are to be applied using a modified retrospective approach. We are currently evaluating the effect that this ASU will have on our future financial position, results of operations and cash flows.

In March 2016, the FASB issued ASU 2016-09, "Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting" ("ASU 2016-09"). ASU 2016-09 modifies U.S. GAAP by requiring the following, among others: (1) all excess tax benefits and tax deficiencies are to be recognized as income tax expense or benefit on the income statement (excess tax benefits are recognized regardless of whether the benefit reduces taxes payable in the current period); (2) excess tax benefits are to be classified along with other income tax cash flows as an operating activity in the statement of cash flows; (3) in the area of forfeitures, an entity can still follow the current U.S. GAAP practice of making an entity-wide accounting policy election to estimate the number of awards that are expected to vest or may instead account for forfeitures when they occur; and (4) classification as a financing activity in the statement of cash flows of cash paid by an employer to the taxing authorities when directly withholding shares for tax withholding purposes. ASU 2016-09 is effective for annual periods beginning after December 15, 2016. Early adoption is permitted. We are currently evaluating the effect that this ASU will have on our future financial position, results of operations and cash flows.

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 I —Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

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Level II —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 III —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 did not have any transfers between Level I, II and III of the fair value hierarchy during the nine months ended June 30, 2016. The Company’s policy for determining transfers between levels occurs at the end of the reporting period when circumstances in the underlying valuation criteria change and result in transfer between levels.

The Company’s financial assets that are measured at fair value on a recurring basis by level within the fair value hierarchy are as follows (in thousands):

	As of June 30, 2016			
	Level I	Level II	Level III	Total
Financial Assets:				
Money market funds	\$ 47,573	\$ —	\$ —	\$ 47,573

	As of September 30, 2015			
	Level I	Level II	Level III	Total
Financial Assets:				
Money market funds	\$ 71,970	\$ —	\$ —	\$ 71,970

The following financial liabilities have carrying values that differ from their fair value as estimated by the Company based on market quotes for instruments with similar terms and remaining maturities (Level III valuation) (in thousands):

As of June 30,
2016
Carrying