Corium International, Inc.
Form 10-Q
August 10, 2018
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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, 2018

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
(State or other jurisdiction of incorporation or organization)	(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 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, a 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 7, 2018, there were approximately 36,250,261 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 and per share data)

(Unaudited)

	As of June 30, 2018	As of September 30, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 82,523	$ 57,466
Accounts receivable	3,556	4,641
Unbilled accounts receivable	228	169
Inventories	1,686	2,300
Prepaid expenses and other current assets	924	982
Total current assets	88,917	65,558
Property and equipment, net	15,810	12,176
Intangible assets, net	7,404	7,117
TOTAL ASSETS	$ 112,131	$ 84,851
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,519	$ 3,978
Accrued expenses and other current liabilities	6,860	6,411
Long-term debt, current portion	49	13,172
Recall liability, current portion	119	114
Deferred contract revenues, current portion	137	626
Total current liabilities	11,684	24,301
Convertible notes, net	70,021	—
Long-term debt, net of current portion	337	39,027
Recall liability, net of current portion	1,697	1,811
Deferred contract revenues, net of current portion	3,500	3,500
Total liabilities	87,239	68,639
Commitments and contingencies		
Stockholders' equity:		
Common stock, par value of $0.001 per share, 150,000,000 shares authorized; 36,244,074 and 36,004,602 shares issued and outstanding as of June 30, 2018 and September 30, 2017	36	36
Additional paid-in capital	283,826	231,457
Accumulated deficit	(258,970)	(215,281)

Total stockholders’ equity	24,892	16,212
TOTAL LIABILITIES AND STOCKHOLDERS’ EQUITY	$ 112,131	$ 84,851

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,	
	2018	2017	2018	2017
Revenues:				
Product revenues	$ 5,901	$ 5,906	$ 18,512	$ 16,301
Contract research and development revenues	1,529	1,936	7,813	5,320
Other revenues	240	267	720	801
Total revenues	7,670	8,109	27,045	22,422
Costs and operating expenses:				
Cost of product revenues	3,507	3,935	10,806	10,892
Cost of contract research and development revenues	2,339	2,977	9,238	7,891
Research and development expenses	8,305	9,122	30,511	22,650
General and administrative expenses	3,325	3,284	10,728	9,288
Amortization of intangible assets	183	159	541	514
Loss on disposal of equipment	4	6	4	6
Total costs and operating expenses	17,663	19,483	61,828	51,241
Loss from operations	(9,993)	(11,374)	(34,783)	(28,819)
Interest income	332	77	617	149
Interest expense	(3,370)	(2,087)	(7,903)	(6,178)
Loss on extinguishment of long-term debt	—	—	(2,258)	—
Other income	640	—	640	—
Loss before income taxes	(12,391)	(13,384)	(43,687)	(34,848)
Income tax expense	—	—	2	2
Net loss and comprehensive loss	$ (12,391)	$ (13,384)	$ (43,689)	$ (34,850)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.34)	$ (0.43)	$ (1.21)	$ (1.30)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	36,214,740	31,457,702	36,144,746	26,784,678

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 Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders’ Equity
Balance - September 30, 2017	36,004,602	$ 36	$ 231,457	$ (215,281)	$ 16,212
Issuance of common stock under Employee Stock Purchase Plan	126,298	—	427	—	427
Issuance of common stock upon exercise of stock options	108,705	—	377	—	377
Issuance of common stock upon net exercise of common stock warrants	4,469	—	—	—	—
Equity component of convertible notes, net of issuance costs of $2.5 million	—	—	46,154	—	46,154
Warrant issued in connection with the convertible note offering	—	—	1,792	—	1,792
Stock-based compensation expense	—	—	3,619	—	3,619
Net loss and comprehensive loss	—	—	—	(43,689)	(43,689)
Balance - June 30, 2018	36,244,074	$ 36	$ 283,826	$ (258,970)	$ 24,892

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,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss and comprehensive loss	$ (43,689)	$ (34,850)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization of property and equipment	703	801
Loss on disposal of equipment	4	6
Amortization of intangible assets	541	514
Noncash amortized debt discount and issuance costs on convertible notes	2,379	—
Noncash amortized debt discount and issuance costs on long-term debt and capital leases	172	285
Stock-based compensation expense	3,619	2,711
Issuance of payment-in-kind notes in lieu of cash interest payments	—	1,369
Loss on extinguishment of long-term debt	2,258	—
Other income	(640)	—
Changes in operating assets and liabilities:		
Accounts receivable	1,085	(241)
Unbilled accounts receivable	(59)	86
Inventories	614	(97)
Prepaid expenses and other current assets	58	208
Accounts payable	199	2,530
Accrued expenses and other current liabilities	974	110
Deferred contract revenues	(489)	(234)
Recall liability	(109)	(351)
Net cash used by operating activities	(32,380)	(27,153)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(3,999)	(1,974)
Payments for patents and licensing rights	(828)	(813)
Net cash used by investing activities	(4,827)	(2,787)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of convertible notes	120,000	—
Payments for convertible notes issuance costs	(3,772)	—
Proceeds from issuance of common stock, net of issuance costs	—	56,136
Principal payments on long-term debt	(52,537)	(58)
Payments for long-term debt extinguishment costs	(2,231)	—
Principal payments on capital lease obligations	—	(73)
Proceeds from exercise of stock options	377	229
Proceeds from issuance of common stock under Employee Stock Purchase Plan	427	436
Net cash provided by financing activities	62,264	56,670
NET INCREASE IN CASH AND CASH EQUIVALENTS	25,057	26,730

CASH AND CASH EQUIVALENTS — Beginning of period	57,466	39,833
CASH AND CASH EQUIVALENTS — End of period	$ 82,523	$ 66,563
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for interest	$ 3,434	$ 4,524
Cash paid for income taxes	$ 6	$ 4
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Property and equipment purchases included in accounts payable	$ 372	$ 310
Warrant issued in connection with convertible note offering	$ 1,792	$ —
Unpaid transaction costs associated with issuance of long-term debt	$ —	$ 544

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. The Company refers to its Transdermal Delivery Systems as "TDS."

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.

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, 2018, statements of operations and comprehensive loss for the three and nine months ended June 30, 2018 and 2017, statement of stockholders' equity for the nine months ended June 30, 2018, and statements of cash flows for the nine months ended June 30, 2018 and 2017 are all 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, 2018, its results of operations for the three and nine months ended June 30, 2018 and 2017, and its cash flows for the nine months ended June 30, 2018 and 2017. The financial data and the other financial information contained in these notes to the financial statements related to the nine-month periods are also unaudited. The results of operations for the nine months ended June 30, 2018 are not necessarily indicative of the results to be expected for the year ending September 30, 2018 or for any future annual or interim period. The balance sheet as of September 30, 2017 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, 2017 included in the Company's Annual Report on Form 10-K, which was filed with the SEC on December 29, 2017.

There have been no material changes to the significant accounting policies or recent accounting pronouncements previously disclosed in the Company's audited financial statements for the year ended September 30, 2017.

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Liquidity

With the exception of fiscal 2013, the Company has incurred losses from operations since fiscal 2006 and has an accumulated deficit of $259.0 million as of June 30, 2018. The Company has financed its operations primarily through the proceeds from the sale of equity securities, and various debt and capital lease financings.

During the nine months ended June 30, 2018, the Company issued $120.0 million aggregate principal amount of convertible notes (the “Convertible Notes”) due in 2025 (see Note 4). The Company used the proceeds from the issuance of the Convertible Notes to prepay in full all outstanding borrowings, fees and other amounts due under the earlier term loan agreement with CRG, a structured debt and equity investment management firm. With the addition of the $61.5 million net proceeds arising from the issuance of the Convertible Notes and simultaneous retirement of the CRG indebtedness, the Company believes that its existing cash and cash equivalents will be sufficient to fund operations as currently planned beyond the next 12 months. Consequently, the Company believes there is no longer substantial doubt regarding its ability to continue as a going concern because the Company is no longer required to maintain compliance with covenants related to liquidity or revenues. The unaudited condensed financial statements as of June 30, 2018 have been prepared under the assumption that the Company will continue as a going concern for the next 12 months.

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, 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 trial expenses 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 both the three and nine months ended June 30, 2018, three partners accounted for 100% and 99% of the Company’s revenues and three partners accounted for 99% of accounts receivable as of June 30, 2018. For the three and nine months ended June 30, 2017, three partners accounted for 96% and 93% of the Company’s revenues. As of September 30, 2017, three partners accounted for 88% of accounts receivable.

Comprehensive Income (Loss)

For the three and nine months ended June 30, 2018 and 2017, 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.

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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 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. These ASUs are 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 modified retrospective 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. In December 2016, the FASB issued ASU No. 2016-20, “Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers,” which clarifies areas for correction or improvement in the Accounting Standards Codification.

The Company will adopt the new revenue recognition standard effective October 1, 2018, utilizing the modified retrospective method. The Company is in the process of evaluating the impact the adoption of this standard will have on its financial statements and has performed an initial review of its major contracts with partners. Based on the initial reviews, the Company believes the adoption of the new standard will not have a significant quantitative impact on product revenues, as the timing of revenue recognition for product sales, profit sharing and royalties is not expected to significantly change. For the Company’s collaboration and partner arrangements, the consideration the Company is eligible to receive under these arrangements typically consists of nonrefundable upfront payments, reimbursement of research and development costs and milestone payments. The Company believes the adoption of the new standard will not have a significant quantitative impact on the revenue recognition of the reimbursement of research and development costs as the timing of the revenue recognition is not expected to significantly change. The Company continues to review the impact that this new standard will have on the timing of recognition for nonrefundable upfront payments and milestone payments as well as on its financial statement disclosures and has not made a determination on the impact to its financial statements. The Company is also evaluating changes to its accounting processes, internal controls and disclosures required to support the new standard.

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 separating leases into liability and asset components to be presented in the statement of financial position. Certain qualitative disclosures are also required to enable users of financial statements to understand the amount, timing, and uncertainty of cash flows arising from leases. 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. The Company is evaluating the effect that this ASU will have on the Company’s future financial position, results of operations or cash flows.

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In May 2017, the FASB issued ASU No. 2017-09, “Compensation-Stock Compensation (Topic 718) – Scope of Modification Accounting (Topic 718)”. This ASU clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification, and provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. An entity should account for the effects of a modification unless all three of the following conditions are met:

(1) The fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the modified award is the same as the fair value (or calculated value or intrinsic value, if such an alternative measurement is used) of the original award immediately before the original award is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification.

(2) The vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified.

(3) The classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified.

This ASU is effective for annual periods beginning after December 15, 2017 and the Company will adopt the standard effective October 1, 2018. The adoption of this standard is not expected to have a material impact on the Company’s future financial position, results of operations or 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;

Level II —Inputs that 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 Levels I, II and III of the fair value hierarchy during the three and nine months ended June 30, 2018. The Company’s policy is to determine the need for transfers between levels at the end of the reporting period when circumstances in the underlying valuation criteria are evaluated for changes requiring transfer between levels.

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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, 2018			
	Level I	Level II	Level III	Total
Financial Assets:				
Money market funds	$ 83,012	$ —	$ —	$ 83,012

	As of September 30, 2017			
	Level I	Level II	Level III	Total
Financial Assets:				
Money market funds	$ 57,928	$ —	$ —	$ 57,928

The Company did not have any Level III liabilities as of September 30, 2017.

In March 2018, the Company issued $120.0 million aggregate principal amount of Convertible Notes due 2025 with embedded conversion features. The Company estimated the fair value of the liability component at issuance based on a hypothetical non-convertible debt instrument with a seven-year term, but with a fair market value interest rate derived from a Monte Carlo simulation of the coupon and conversion option outcomes of the Convertible Notes. The Company recorded $71.3 million as the gross fair value of the liability at issuance on March 5, 2018, with the balance of $48.7 million recorded to equity as additional paid-in capital, before issuance costs. The fair value of the liability component is based on unobservable inputs and is, therefore, a Level III liability. As of June 30, 2018, the carrying value of the Convertible Notes liability approximates the fair value, net of issuance costs allocated to it.

The carrying value of the Company's long-term debt as of September 30, 2017 reflects the principal amount, adjusted for any unamortized debt issuance costs and discount. The long-term debt liability as of September 30, 2017 includes $51.8 million of adjusted debt principal relating to the then-outstanding term loan with CRG (see Note 4). The fair value of certain debt liabilities have been estimated by the Company based on market quotes for instruments with similar terms and remaining maturities. The following table lists both the carrying and fair values for such liabilities (in thousands):

	As of June 30, 2018		
	Carrying Value	Fair Value	Difference
Long-term debt	$ 386	$ 386	$ —

	As of September 30, 2017		
	Carrying Value	Fair Value	Difference
Long-term debt	$ 52,199	$ 55,888	$ 3,689

3. Inventories

Inventories consist of the following (in thousands):

	As of June 30, 2018	As of September 30, 2017
Raw materials	$ 1,076	$ 1,683
Work in process	386	