



August 3, 2017

## Corium Reports Recent Corporate Highlights and Financial Results for Third Quarter Fiscal 2017

MENLO PARK, Calif., Aug. 03, 2017 (GLOBE NEWSWIRE) -- Corium International, Inc. (Nasdaq:CORI), a commercial-stage biopharmaceutical company focused on the development, manufacture and commercialization of specialty transdermal products, today announced unaudited financial results for the third fiscal quarter and the nine months ended June 30, 2017, and reported on recent corporate developments. Corium's fiscal year ends on September 30.

### Recent Corporate Developments

- 1 **Initiating pivotal trial of Corplex™ Donepezil for Alzheimer's** — Recruitment and screening of subjects for Corium's pivotal bioequivalence (BE) study of Corplex Donepezil is underway, with dosing expected to begin before the end of September 2017. The pivotal BE trial is a two-way crossover study, and will be conducted in healthy volunteers at the same clinical site as the recently-completed pilot BE study. Topline results are expected in the first calendar quarter of 2018, and Corium is targeting submission of a Section 505(b)(2) New Drug Application (NDA) in the second half of calendar 2018.
- 1 **Positive pilot bioequivalence results presented at Alzheimer's Association International Conference® 2017** — Corium recently presented the results from the company's pilot BE study of Corplex Donepezil in a poster presentation at the Alzheimer's Association International Conference 2017 (AAIC®) in London. Data from the pilot BE study demonstrated that Corium's Corplex Donepezil transdermal product candidate successfully met the primary pharmacokinetic criteria for bioequivalence to oral Aricept® (donepezil hydrochloride), with a favorable tolerability and safety profile.
- 1 **Successful follow-on financing strengthens balance sheet** — In May 2017, Corium completed an underwritten public offering of common stock, with gross proceeds of \$40.3 million, including proceeds from the full exercise of the underwriters' option to purchase additional shares.
- 1 **Partner Agile Therapeutics resubmits NDA for Twirla® once-weekly contraceptive** — In June 2017, Agile Therapeutics resubmitted its NDA for Twirla, its investigational low-dose combined hormonal contraceptive patch, and the FDA has notified Agile of its acceptance of the resubmitted NDA for review. Agile reported that the Prescription Drug User Fee Act (PDUFA) goal date for this NDA is December 26, 2017. Corium is the exclusive manufacturer and supplier of Twirla.

"Our third quarter was highlighted by the positive bioequivalence results we reported in May for our Corplex Donepezil transdermal product candidate," said Peter D. Staple, President and Chief Executive Officer of Corium. "These data have enabled us to finalize the parameters of the pivotal BE study that we are initiating this quarter. Our once-weekly patch formulation of donepezil has the potential to provide meaningful benefits to Alzheimer's disease patients and their caregivers, including both improved compliance and the ability to alleviate the most common gastrointestinal side effects associated with the oral drug."

### Financial Results for the Quarter and Nine Months Ended June 30, 2017

Corium reported total revenues in the third quarter of fiscal 2017 of \$8.1 million, compared with \$10.6 million in the third quarter of fiscal 2016, and for the nine-month period ended June 30, 2017, reported total revenues of \$22.4 million compared with \$25.1 million in the same period of fiscal 2016. Product revenues decreased for both the third quarter and the nine-month period ended June 30, 2017 compared to same periods of fiscal 2016, primarily as a result of a reduction in demand for both Fentanyl transdermal delivery system (TDS) and Clonidine TDS, which was partially offset by an increase in revenues from manufacture of Crest® Whitestrips for Procter & Gamble. Contract research and development revenues were unchanged for the third quarter and increased for the nine-month period ended June 30, 2017 compared to the same periods of fiscal 2016. The increase for the nine-month period was primarily the result of increased activities supporting Agile's NDA resubmission for Twirla.

Total research and development (R&D) expenses in the third quarter of fiscal 2017 were \$12.1 million compared with \$8.3 million in the third quarter of fiscal 2016, and for the nine-month period ended June 30, 2017, total R&D expenses were \$30.5 million compared with \$24.2 million in the same period of fiscal 2016. These increases in total R&D expenses were

driven by Corium's investment in its proprietary product programs, primarily the advancement of Corplex Donepezil into a pilot BE study beginning in late fiscal 2016 and expenses associated with the preparation for the upcoming pivotal BE trial.

General and administrative (G&A) expenses in the third quarter of fiscal 2017 were \$3.3 million compared with \$3.1 million for the third quarter of fiscal 2016, and for the nine-month period ended June 30, 2017, total G&A expenses were \$9.3 million compared with \$9.1 million for the same period of fiscal 2016.

Corium reported a net loss for the third quarter of fiscal 2017 of \$13.4 million, or \$0.43 per share, compared with a net loss of \$7.5 million, or \$0.34 per share, in the third quarter of fiscal 2016. For the nine-month period ended June 30, 2017, Corium reported a net loss of \$34.9 million, or \$1.30 per share, compared with a net loss of \$27.4 million, or \$1.23 per share, in the same period of fiscal 2016. As of June 30, 2017, there were 35,739,278 shares of Corium common stock outstanding, reflecting the issuance of 6,440,000 shares in connection with a public offering completed in May 2017.

Cash and cash equivalents as of June 30, 2017 were \$66.6 million.

## Conference Call and Webcast Details

Corium will host a conference call today at 5:00 p.m. ET (2:00 p.m. PT) to discuss the financial results for the third fiscal quarter and the nine months ended June 30, 2017. Investors and analysts can access the call toll-free by dialing (844) 831-3024 (United States) or +1 (315) 625-6887 (international). The conference ID# is 58879021. The conference call will also be available via a live audio webcast which may be accessed [here](#), or by visiting the Investors section of Corium's website at <http://ir.coriumgroup.com/events.cfm>. The webcast will be archived on the Corium website for two weeks following the presentation.

## About Corium

Corium International, Inc. 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. Corium has multiple proprietary programs in preclinical and clinical development, focusing primarily on the treatment of neurological disorders, with lead programs in Alzheimer's disease. Corium has developed and is the sole commercial manufacturer of seven prescription drug and consumer products with partners Mayne Pharma and Procter & Gamble. The company has two proprietary transdermal platforms: Corplex™ for small molecules and MicroCor®<sup>®</sup>, a biodegradable microstructure technology for small molecules and biologics, including vaccines, peptides and proteins. In addition to its proprietary Alzheimer's program, the company's late-stage pipeline includes a contraceptive patch co-developed with Agile Therapeutics and additional transdermal products that are being developed with other partners. For further information, please visit [www.coriumintl.com](http://www.coriumintl.com).

## Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, including statements regarding our business strategy, financial and operating performance, operating costs and expenses, product pipeline, clinical trial and regulatory timing and plans and associated resource requirements, regulatory pathways for our development programs, the achievement of clinical and commercial milestones, and the advancement of our technologies as well as our proprietary, co-developed and partnered products and product candidates. Forward-looking statements are based on management's current expectations and projections and are subject to risks and uncertainties, which may cause Corium's actual results to differ materially from the statements contained herein. Further information on potential risk factors that could affect Corium's business and its results are detailed in Corium's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, filed with the Securities and Exchange Commission (SEC) on May 12, 2017, and other reports as filed from time to time with the SEC. Undue reliance should not be placed on forward-looking statements, especially guidance on future financial or operating performance, which speaks only as of the date they are made. Corium undertakes no obligation to update publicly any forward-looking statements to reflect new information, events or circumstances after the date they were made or to reflect the occurrence of unanticipated events.

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Twirla® is a registered trademark of Agile Therapeutics, Inc.

Aricept® is a registered trademark of Eisai R&D Management Co, Ltd.

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Source: Corium

**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,	
	2017	2016	2017	2016
Revenues:				
Product revenues	\$ 5,906	\$ 7,264	\$ 16,301	\$ 18,930
Contract research and development revenues	1,936	1,983	5,320	4,228
Other revenues	267	1,359	801	1,947
Total revenues	<u>8,109</u>	<u>10,606</u>	<u>22,422</u>	<u>25,105</u>
Costs and operating expenses:				
Cost of product revenues	3,935	4,626	10,892	12,924
Cost of contract research and development revenues	2,977	2,742	7,891	8,601
Research and development expenses	9,122	5,516	22,650	15,566
General and administrative expenses	3,284	3,116	9,288	9,106
Amortization of intangible assets	159	168	514	489
Loss on disposal of equipment	6	—	6	2
Total costs and operating expenses	<u>19,483</u>	<u>16,168</u>	<u>51,241</u>	<u>46,688</u>
Loss from operations	(11,374)	(5,562)	(28,819)	(21,583)
Interest income	77	54	149	142
Interest expense	(2,087)	(1,984)	(6,178)	(5,932)
Loss before income taxes	(13,384)	(7,492)	(34,848)	(27,373)
Income tax expense	—	—	2	3
Net loss and comprehensive loss	<u>\$ (13,384)</u>	<u>\$ (7,492)</u>	<u>\$ (34,850)</u>	<u>\$ (27,376)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.43)</u>	<u>\$ (0.34)</u>	<u>\$ (1.30)</u>	<u>\$ (1.23)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>31,457,702</u>	<u>22,321,581</u>	<u>26,784,678</u>	<u>22,254,849</u>

**CORIUM INTERNATIONAL, INC.**  
**CONDENSED BALANCE SHEETS**  
(In thousands)  
(Unaudited)

	As of June 30, 2017	As of September 30, 2016
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 66,563	\$ 39,833
Accounts receivable	4,577	4,336
Unbilled accounts receivable	260	346
Inventories	2,521	2,424
Prepaid expenses and other current assets	1,133	1,341
Total current assets	<u>75,054</u>	<u>48,280</u>
Restricted cash	666	666
Property and equipment, net	12,451	11,147
Intangible assets, net	7,356	7,057
TOTAL ASSETS	<u>\$ 95,527</u>	<u>\$ 67,150</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		

Current liabilities:		
Accounts payable	\$ 5,404	\$ 2,737
Accrued expenses and other current liabilities	4,925	4,271
Long-term debt, current portion	54	77
Capital lease obligations, current portion	—	72
Recall liability, current portion	160	460
Deferred contract revenues, current portion	121	355
Total current liabilities	10,664	7,972
Long-term debt, net of current portion	52,040	50,966
Recall liability, net of current portion	1,808	1,859
Deferred contract revenues, net of current portion	3,500	3,500
Total liabilities	68,012	64,297
Commitments and contingencies		
Stockholders' equity:		
Common stock	36	22
Additional paid-in capital	229,817	170,319
Accumulated deficit	(202,338)	(167,488)
Total stockholders' equity	27,515	2,853
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 95,527	\$ 67,150

Investor and Media Contact:

SMP Communications

Susan M. Pietropaolo

[susan@smpcommunications.com](mailto:susan@smpcommunications.com)

(201) 923-2049

 Primary Logo

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