



November 16, 2017

## Corium Reports Fourth Quarter and Fiscal Year 2017 Financial Results and Corporate Highlights

MENLO PARK, Calif., Nov. 16, 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 fourth fiscal quarter and the year ended September 30, 2017, and reported on recent corporate developments. Corium's fiscal year ends on September 30.

### Corporate Highlights

- 1 **Successful pilot bioequivalence study in Alzheimer's program** — In May, Corium reported results for its successful three-way crossover pilot bioequivalence (BE) trial for Corplex™ Donepezil, a once-weekly transdermal therapeutic for Alzheimer's disease, comparing steady-state pharmacokinetics (PK) to daily oral Aricept® (donepezil hydrochloride) after five weeks of treatment. Donepezil is the most commonly prescribed medication for Alzheimer's patients. The study results demonstrated that Corplex Donepezil met the primary statistical criteria for bioequivalence to oral Aricept. Corplex Donepezil was well tolerated with favorable adhesion, skin safety and gastrointestinal side effect profiles.
- 1 **Positive FDA feedback on Corplex Donepezil** — In August, Corium held an end of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) in which the company reviewed the results from the pilot BE trial of Corplex Donepezil. The FDA confirmed the choice of PK parameters and statistical testing approaches used in Corium's BE study. The agency also confirmed Corium's design of planned supportive studies and other requirements for product registration.
- 1 **Corplex Donepezil pivotal trial underway** — Corium has initiated dosing of Corplex Donepezil in its pivotal bioequivalence study. The design of the pivotal BE study is similar to the pilot study, and is a single center, randomized, multiple dose, two-way crossover study in healthy volunteers, conducted at the same clinical site as the successful pilot BE study. The first treatment period will be complete in December. Top-line results are expected in the first half of calendar 2018 and Corium is targeting submission of a Section 505(b)(2) New Drug Application (NDA) in the fourth quarter of calendar 2018.
- 1 **Strengthened balance sheet; addition to Russell Indexes** — During the year, Corium completed two financings, raising gross proceeds in excess of \$60 million. In June 2017, the Company was added to the Russell 3000® and Russell 2000® as part of Russell Investments' annual reconstitution of its U.S. indexes, based on total market capitalization as of the end of May 2017.
- 1 **PDUFA date for partner Agile Therapeutics Twirla® once-weekly contraceptive** — In July 2017, the FDA accepted resubmission of Agile's New Drug Application (NDA) for Twirla, an investigational, once-weekly low-dose hormonal contraceptive patch, and assigned December 26, 2017 as the Prescription Drug User Fee Act (PDUFA) goal date. Corium is the exclusive manufacturer and supplier of Twirla and is working closely with Agile to prepare for approval and launch of the product.

"The fiscal year was marked by outstanding achievement, as we executed on both clinical and financial objectives and created significant shareholder value," said Peter D. Staple, President and Chief Executive Officer of Corium. "A key highlight was the positive bioequivalence result in our Corplex Donepezil pilot study, in which we demonstrated bioequivalence to oral Aricept with an improved gastrointestinal tolerability profile. This study clearly showed that our Corplex technology can overcome difficult challenges and address unmet needs in transdermal drug formulations. We have initiated dosing in our pivotal clinical trial and look forward to reporting results in the first half of 2018. The anticipated success of Corplex Donepezil will be transformative for Corium, and based on our experience in that program, we are developing a pipeline of CNS product candidates that could benefit from a similar development path."

### Financial Results for the Quarter and Fiscal Year Ended September 30, 2017

Corium reported total revenues in the fourth quarter of fiscal 2017 of \$9.4 million, compared with \$7.9 million in the fourth quarter of fiscal 2016, and for the fiscal year ended September 30, 2017, reported total revenues of \$31.9 million compared with \$33.0 million in the same period of fiscal 2016. Product revenues decreased for both the fourth quarter and the fiscal

year ended September 30, 2017 compared to the same periods of fiscal 2016, primarily as a result of a reduction in demand from Mayne Pharma for both Fentanyl transdermal delivery systems (TDS) and Clonidine TDS, partially offset by an increase in revenues from Procter & Gamble for Crest<sup>®</sup> Whitestrips. Contract research and development revenues increased for both the fourth quarter and the fiscal year ended September 30, 2017 compared to the same periods of fiscal 2016; these increases were primarily the result of increased activities supporting Agile's NDA resubmission for Twirla, along with initial preparations in support of the commercial launch of Twirla in 2018.

Total research and development (R&D) expenses in the fourth quarter of fiscal 2017 were \$12.2 million compared with \$8.2 million in the fourth quarter of fiscal 2016, and for the fiscal year ended September 30, 2017, total R&D expenses were \$42.8 million compared with \$32.4 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 and preparation for the subsequent pivotal BE trial.

General and administrative (G&A) expenses in the fourth quarter of fiscal 2017 were \$3.9 million compared with \$2.5 million for the fourth quarter of fiscal 2016, and for the fiscal year ended September 30, 2017, total G&A expenses were \$13.2 million compared with \$11.6 million for the same period of fiscal 2016. These increases were primarily driven by higher incentive compensation costs and the costs associated with settlement of litigation relating to the Company's termination of a facility lease in 2016. Both of these increases were primarily the result of expenses recognized in the fourth quarter of fiscal 2017, compared to the same period in fiscal 2016.

Corium reported a net loss for the fourth quarter of fiscal 2017 of \$12.9 million, or \$0.36 per share, compared with a net loss of \$9.3 million, or \$0.42 per share, in the fourth quarter of fiscal 2016. For the fiscal year ended September 30, 2017, Corium reported a net loss of \$47.8 million, or \$1.64 per share, compared with a net loss of \$36.7 million, or \$1.65 per share, in the same period of fiscal 2016. As of September 30, 2017, there were 36,004,602 shares of Corium common stock outstanding, and as of September 30, 2016 there were 22,391,631 shares of Corium common stock outstanding, so comparisons of per share losses between periods may not be useful to investors.

Cash and cash equivalents as of September 30, 2017 were \$57.5 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 fourth fiscal quarter and the year ended September 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 4879369. 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<sup>™</sup> 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 June 30, 2017, filed with the Securities and Exchange Commission (SEC) on August 11, 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.

Crest® Whitestrips is a registered trademark of The Procter & Gamble Company.

Source: Corium

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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		Year Ended September 30,	
	September 30,	September 30,	2017	2016
	2017	2016	2017	2016
Revenues:				
Product revenues	\$ 6,055	\$ 6,432	\$ 22,356	\$ 25,362
Contract research and development revenues	3,120	1,192	8,440	5,420
Other revenues	267	294	1,068	2,241
Total revenues	<u>9,442</u>	<u>7,918</u>	<u>31,864</u>	<u>33,023</u>
Costs and operating expenses:				
Cost of product revenues	4,123	4,422	15,015	17,346
Cost of contract research and development revenues	2,976	2,073	10,867	10,674
Research and development expenses	9,234	6,121	31,884	21,687
General and administrative expenses	3,875	2,460	13,163	11,566
Amortization of intangible assets	176	170	690	659
Loss on disposal of equipment	—	13	6	15
Total costs and operating expenses	<u>20,384</u>	<u>15,259</u>	<u>71,625</u>	<u>61,947</u>
Loss from operations	(10,942)	(7,341)	(39,761)	(28,924)
Interest income	129	29	278	171
Interest expense	(2,125)	(2,015)	(8,303)	(7,947)
Loss before income taxes	(12,938)	(9,327)	(47,786)	(36,700)
Income tax expense	5	—	7	3
Net loss and comprehensive loss	<u>\$ (12,943)</u>	<u>\$ (9,327)</u>	<u>\$ (47,793)</u>	<u>\$ (36,703)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.36)</u>	<u>\$ (0.42)</u>	<u>\$ (1.64)</u>	<u>\$ (1.65)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>35,854,815</u>	<u>22,365,247</u>	<u>29,070,849</u>	<u>22,282,599</u>

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

As of September 30,	
2017	2016

**ASSETS**

## Current assets:

Cash and cash equivalents	\$	57,466	\$	39,833
Accounts receivable		4,641		4,336
Unbilled accounts receivable		169		346
Inventories		2,300		2,424
Prepaid expenses and other current assets		982		1,341
Total current assets		<u>65,558</u>		<u>48,280</u>
Restricted cash		—		666
Property and equipment, net		12,176		11,147
Intangible assets, net		7,117		7,057
TOTAL ASSETS	\$	<u>84,851</u>	\$	<u>67,150</u>

**LIABILITIES AND STOCKHOLDERS' EQUITY**

## Current liabilities:

Accounts payable	\$	3,978	\$	2,737
Accrued expenses and other current liabilities		6,411		4,271
Long-term debt, current portion		13,172		77
Capital lease obligations, current portion		—		72
Recall liability, current portion		114		460
Deferred contract revenues, current portion		626		355
Total current liabilities		<u>24,301</u>		<u>7,972</u>
Long-term debt, net of current portion		39,027		50,966
Recall liability, net of current portion		1,811		1,859
Deferred contract revenues, net of current portion		3,500		3,500
Total liabilities		<u>68,639</u>		<u>64,297</u>

## Commitments and contingencies

## Stockholders' equity:

Common stock		36		22
Additional paid-in capital		231,457		170,319
Accumulated deficit		(215,281)		(167,488)
Total stockholders' equity		<u>16,212</u>		<u>2,853</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	<u>84,851</u>	\$	<u>67,150</u>

Source: Corium International, Inc.

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