



May 11, 2017

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

MENLO PARK, Calif., May 11, 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 second fiscal quarter and the six months ended March 31, 2017, and reported on recent corporate developments. Corium's fiscal year ends on September 30.

### Recent Corporate Developments

- 1 **Pilot bioequivalence study for Corplex™ Donepezil complete; positive preliminary results reported** — Corium has completed a three-way crossover pilot bioequivalence study for Corplex Donepezil, a once-weekly transdermal therapeutic for Alzheimer's disease, comparing steady-state plasma concentrations achieved with the transdermal systems with those of daily oral Aricept® (donepezil hydrochloride) after five weeks of treatment. The combined preliminary results demonstrated that the Corplex Donepezil product candidate meets the primary statistical criteria for bioequivalence to oral Aricept, and provided clear guidance on the parameters for the company's upcoming pivotal study. Corplex Donepezil was well tolerated with favorable adhesion, skin safety and gastrointestinal side effect profiles.
- 1 **Preparation for pivotal Corplex Donepezil study underway** — The company expects to initiate the pivotal bioequivalence study this fall, with preliminary topline results expected in February 2018. Corium is targeting submission of a Section 505(b)(2) New Drug Application (NDA) in the second half of 2018.
- 1 **New five-year Procter & Gamble agreement** — Corium and P&G entered into a new commercial supply agreement that, among other things, extends the term of the supply relationship to March 31, 2022. Corium is the sole supplier to P&G of oral care products incorporating Corium's proprietary Corplex technology, sold under the brand name Crest® Whitestrips.
- 1 **Mayne Pharma partnership expanded** — In March, Mayne Pharma acquired from Par Pharmaceutical the rights to market the fentanyl transdermal delivery system (TDS) manufactured by Corium. Mayne's acquisition of this product strengthens the alliance between Corium and Mayne, which encompasses other products developed and manufactured by Corium, including the commercial Clonidine TDS and a development-stage motion sickness patch.
- 1 **Partner Agile Therapeutics to resubmit NDA for Twirla® once-weekly contraceptive** — Based on recent feedback from the FDA, Agile confirmed that it plans to resubmit the NDA for Twirla by the end of June 2017. Corium has completed the registration batch, and has provided Agile with all of the Chemistry, Manufacturing and Controls information required for Agile's resubmission. Corium is the exclusive manufacturer and supplier of Twirla.

"The second quarter was an especially productive one for Corium, culminating in the recent clinical success of our proprietary Corplex Donepezil product candidate," said Peter D. Staple, President and Chief Executive Officer of Corium. "With that data now in hand, we have increased confidence in our ability to bring this important new therapeutic option to Alzheimer's patients and their caregivers. In addition, we have strengthened a core component of our partner-focused development and manufacturing business by renewing our strategic oral care relationship with Procter & Gamble for a five-year term, and we also expanded the breadth of our partnership with Mayne Pharma to include additional generic transdermal products."

### Financial Results for the Quarter and Six Months Ended March 31, 2017

Corium reported total revenues in the second quarter of fiscal 2017 of \$7.3 million, compared with \$7.0 million in the second quarter of fiscal 2016, and for the six-month period ended March 31, 2017 reported total revenues of \$14.3 million compared with \$14.5 million in the same period of fiscal 2016. Contract research and development revenues increased for both the second quarter and the six-month period ended March 31, 2017 compared to the same periods in fiscal 2016, primarily as the result of increased activities supporting Agile's NDA for Twirla. Product revenues decreased for both the second quarter and the six-month period ended March 31, 2017 compared to same periods in fiscal 2016, primarily as a result of a reduction in demand for both Fentanyl TDS and Clonidine TDS, which were partially offset by an increase in revenues from Crest Whitestrips.

Total research and development (R&D) expenses in the second quarter of fiscal 2017 were \$10.3 million compared with \$8.4 million in the second quarter of fiscal 2016, and for the six-month period ended March 31, 2017 total R&D expenses were \$18.4 million compared with \$15.9 million in the same period of fiscal 2016. The increase in R&D expenses was driven by Corium's investment in its proprietary product programs, primarily the advancement of Corplex Donepezil into a pilot bioequivalence study beginning in late fiscal 2016. This increase in proprietary R&D spending was partially offset by a lower level of resources required for contract research and development programs.

General and administrative (G&A) expenses in the second quarter of fiscal 2017 were \$3.0 million compared with the same amount for the second quarter of fiscal 2016, and for the six-month period ended March 31, 2017, total G&A expenses were \$6.0 million compared with the same amount for the same period of fiscal 2016.

Corium reported a net loss for the second quarter of fiscal 2017 of \$11.0 million, or \$0.42 per share, compared with a net loss of \$10.5 million, or \$0.47 per share, in the second quarter of fiscal 2016. For the six-month period ended March 31, 2017, Corium reported a net loss of \$21.5 million, or \$0.88 per share, compared with a net loss of \$19.9 million, or \$0.89 per share, in the same period of fiscal 2016. As of March 31, 2017, there were 29,232,292 shares of Corium common stock outstanding, reflecting the issuance of 6,666,667 shares in connection with a public offering completed in February 2017.

Cash and cash equivalents as of March 31, 2017 were \$40.6 million.

### **Conference Call and Webcast Details**

Corium will host a conference call today at 8:30 a.m. ET (5:30 a.m. PT) to discuss the financial results for the second fiscal quarter ended March 31, 2017 and the preliminary results of the Corplex Donepezil pilot bioequivalence study. 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 20268962. 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> where an accompanying slide presentation will be available. 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. 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.coriumgroup.com](http://www.coriumgroup.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 December 31, 2016, filed with the Securities and Exchange Commission (SEC) on February 14, 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.

Corplex™ and MicroCor®<sup>®</sup> are trademarks of Corium International Inc.  
Twirla®<sup>®</sup> 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.

**CORIUM INTERNATIONAL, INC.**  
**CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
(In thousands, except share and per share data)  
(Unaudited)

	Three Months Ended March 31,		Six Months Ended March 31,	
	2017	2016	2017	2016
Revenues:				
Product revenues	\$ 4,657	\$ 5,694	\$ 10,395	\$ 11,666
Contract research and development revenues	2,421	975	3,384	2,245
Other revenues	267	293	534	588
Total revenues	<u>7,345</u>	<u>6,962</u>	<u>14,313</u>	<u>14,499</u>
Costs and operating expenses:				
Cost of product revenues	2,876	4,000	6,957	8,298
Cost of contract research and development revenues	2,794	2,803	4,914	5,859
Research and development expenses	7,530	5,593	13,528	10,050
General and administrative expenses	2,999	2,973	6,004	5,990
Amortization of intangible assets	178	162	355	321
Loss on disposal of equipment	—	2	—	2
Total costs and operating expenses	<u>16,377</u>	<u>15,533</u>	<u>31,758</u>	<u>30,520</u>
Loss from operations	(9,032)	(8,571)	(17,445)	(16,021)
Interest income	44	58	72	88
Interest expense	(2,049)	(1,971)	(4,091)	(3,948)
Loss before income taxes	(11,037)	(10,484)	(21,464)	(19,881)
Income tax expense	—	—	2	3
Net loss and comprehensive loss	<u>\$ (11,037)</u>	<u>\$ (10,484)</u>	<u>\$ (21,466)</u>	<u>\$ (19,884)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.42)</u>	<u>\$ (0.47)</u>	<u>\$ (0.88)</u>	<u>\$ (0.89)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	26,487,493	22,255,365	24,448,166	22,221,666

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

	As of March 31, 2017	As of September 30, 2016
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 40,574	\$ 39,833
Accounts receivable	3,440	4,336
Unbilled accounts receivable	183	346
Inventories	2,668	2,424
Prepaid expenses and other current assets	797	1,341
Total current assets	<u>47,662</u>	<u>48,280</u>
Restricted cash	666	666
Property and equipment, net	11,966	11,147
Intangible assets, net	7,221	7,057
<b>TOTAL ASSETS</b>	<u>\$ 67,515</u>	<u>\$ 67,150</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		

Current liabilities:		
Accounts payable	\$ 3,674	\$ 2,737
Accrued expenses and other current liabilities	4,365	4,271
Long-term debt, current portion	62	77
Capital lease obligations, current portion	—	72
Recall liability, current portion	330	460
Deferred contract revenues, current portion	241	355
Total current liabilities	<u>8,672</u>	<u>7,972</u>
Long-term debt, net of current portion	51,485	50,966
Recall liability, net of current portion	1,717	1,859
Deferred contract revenues, net of current portion	3,500	3,500
Total liabilities	<u>65,374</u>	<u>64,297</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock	29	22
Additional paid-in capital	191,066	170,319
Accumulated deficit	(188,954)	(167,488)
Total stockholders' equity	<u>2,141</u>	<u>2,853</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 67,515</u>	<u>\$ 67,150</u>

Source: Corium

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