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## Corium Reports Second Quarter Fiscal 2016 Financial Results and Recent Corporate Highlights

MENLO PARK, Calif., May 10, 2016 (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, 2016 and reported on recent corporate developments. Corium's fiscal year ends on September 30.

"In the second quarter we announced positive clinical results in three transdermal CNS therapeutic programs, including our proprietary Corplex Donepezil and Corplex Memantine candidates, which deliver the two leading treatments for Alzheimer's disease. We are also very pleased to have received clear feedback from the FDA supporting our plans for a bioequivalence development pathway for Corplex Donepezil, and to report positive data on newly optimized formulations of this product candidate," said Peter D. Staple, President and Chief Executive Officer of Corium. "With these results, we expect our Alzheimer's programs to be a major focus for internal development efforts and resources. Corplex Donepezil, in particular, provides Corium with an exciting opportunity to introduce a high-value product into a large and growing market within an accelerated timeframe."

### Recent Corporate Developments

- 1 **Favorable feedback from FDA on proposed bioequivalence development plan for Corplex™ Donepezil** — On May 2, the company announced that it had received a written response from the U.S. Food and Drug Administration (FDA) that concurred with the company's development plan and confirmed that if the company can adequately demonstrate bioequivalence between Corplex Donepezil and oral Aricept® (donepezil hydrochloride) in its planned pharmacokinetic (PK) studies, additional clinical efficacy studies will not be required. The company plans to advance Corplex Donepezil into a pilot bioequivalence study later this year, followed by a pivotal bioequivalence study starting in mid-2017, enabling it to submit a 505(b)(2) New Drug Application (NDA) as early as mid-2018.
- 1 **Topline results in Phase 1 PK study of Corplex™ Donepezil provide basis for FDA pre-IND submission** — This initial PK study demonstrated sustained and controlled delivery of donepezil in a once-weekly patch. The PK data generated by Corplex Donepezil was comparable to daily oral administration of Aricept and demonstrated the potential for bioequivalence.
- 1 **Topline results in subsequent dose-optimization PK study of Corplex™ Donepezil achieved target dosing** — Corium announced positive clinical results from a follow-on PK study of optimized formulations of once-weekly Corplex Donepezil. In this study, two new formulations achieved the targeted rates of donepezil delivery across the skin, comparable PK profiles to oral Aricept and acceptable skin tolerability.
- 1 **Positive topline results in Phase 1 PK study of Corplex™ Memantine** — In this trial, Corium's proprietary transdermal candidate delivered memantine (the active ingredient in Namenda XR®) on a sustained and controlled basis with pharmacokinetics comparable to orally administered memantine. Based on the results from this trial, a follow-on wear study is underway to confirm the skin tolerability profile of the product candidate.
- 1 **Results from initial bioavailability study support feasibility of once-weekly transdermal aripiprazole patch** — Aripiprazole is an atypical antipsychotic and the active ingredient in ABILIFY®, a leading medication for the treatment of a number of psychiatric disorders, including bipolar I disorder, schizophrenia, major depressive disorder and irritability associated with autistic disorder. Corium's collaboration partner Aequus Pharmaceuticals conducted the study and has announced plans to initiate a multiple dose, 28-day bioavailability study during the first half of 2016.
- 1 **Rapid pharmacokinetics demonstrated in animal study of MicroCor® Zolmitriptan product candidate** — Corium generated promising *in vivo* PK data in a pig model, demonstrating that the company's proprietary MicroCor® transdermal technology is able to rapidly deliver zolmitriptan (the active ingredient in ZOMIG®), a leading migraine treatment. This product candidate is designed to provide rapid onset of pain relief in a needle-free system for the treatment of acute migraine.

### Financial Results for the Quarter and Six Months Ended March 31, 2016

Corium reported total revenues in the second quarter of fiscal 2016 of \$7.0 million, compared with \$11.3 million in the second quarter of fiscal 2015, and for the six-month period ended March 31, 2016 reported total revenues of \$14.5 million, compared with \$21.1 million in the same period of fiscal 2015. The decrease in total revenues resulted from a decline in contract research and development revenues, as well as a decline in product revenues. The decrease in contract research and development revenues is primarily the result of several programs advancing into later stages of clinical development, when there are fewer revenue-generating development activities until preparations begin for approval and commercial launch, along with the discontinuation of one development project in fiscal 2015. The decline in product revenues is primarily the result of the lower level of units ordered and shipments made for the quarter for Clonidine TDS and Fentanyl TDS, partially offset by a slight increase in revenues from Crest<sup>®</sup> Whitestrips.

Total research and development (R&D) expenses in the second quarter of fiscal 2016 were \$8.4 million, compared with \$8.5 million in the second quarter of fiscal 2015, and for the six-month period ended March 31, 2016 total R&D expenses were \$15.9 million, compared with \$16.4 million in the same period of fiscal 2015. The decrease in total R&D expenses primarily reflects the lower level of resources required for contract research and development programs and corresponds to the lower level of revenue from contract research and development. This decrease was partially offset by Corium's increased investment in its proprietary product programs, including the advancement of Corium's two programs for Alzheimer's disease, Corplex Donepezil and Corplex Memantine, through Phase 1 clinical trials.

General and administrative (G&A) expenses in the second quarter of fiscal 2016 were \$3.0 million, compared with \$2.7 million in the second quarter of fiscal 2015, and for the six-month period ended March 31, 2016 G&A expenses were \$6.0 million, compared with \$5.4 million in the same period of fiscal 2015. The increase in G&A was primarily attributable to higher personnel costs along with an increase in stock-based compensation expense.

Corium reported a net loss for the second quarter of fiscal 2016 of \$10.5 million, or \$0.47 per share, compared with a net loss of \$7.1 million, or \$0.40 per share, in the second quarter of fiscal 2015. For the six-month period ended March 31, 2016 Corium reported a net loss of \$19.9 million, or \$0.89 per share, compared with a net loss of \$13.9 million, or \$0.77 per share, in the same period of fiscal 2015. As of March 31, 2016, there were 22,287,830 shares of Corium common stock outstanding.

Cash and cash equivalents as of March 31, 2016 were \$54.4 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 second fiscal quarter and six months ended March 31, 2016. 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 5526997. The conference call will also be available via a live audio webcast on the Investors section of Corium's website at <http://ir.coriumgroup.com/events.cfm>. Please access the website 10 minutes prior to the start of the call to ensure adequate time for any software downloads that may be necessary. A replay of the conference call will be available for two weeks and may be accessed by dialing toll-free (855) 859-2056 (United States) or +1 (404) 537-3406 (international) and entering the conference ID# 5526997 or by visiting Corium's website.

## **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 Teva Pharmaceuticals, Par Pharmaceutical 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. The company's late-stage pipeline includes a contraceptive patch co-developed with Agile Therapeutics that is currently in Phase 3 trials, 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, product pipeline, clinical trial 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 and 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, 2015, filed with the Securities and Exchange Commission on February 12, 2016, and other reports as filed from time to time with the Securities and Exchange Commission. 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® are registered trademarks of Corium International, Inc.

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

Namenda XR® is a registered trademark of Merz Pharma GmbH & Co. KGaA.

ABILIFY® is a registered trademark of Otsuka Pharmaceutical Co., Ltd.

ZOMIG® is a registered trademark of the AstraZeneca group of companies.

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		Six Months Ended March 31,	
	2016	2015	2016	2015
Revenues:				
Product revenues	\$ 5,694	\$ 7,632	\$ 11,666	\$ 14,171
Contract research and development revenues	975	3,363	2,245	6,293
Other revenues	293	296	588	593
Total revenues	<u>6,962</u>	<u>11,291</u>	<u>14,499</u>	<u>21,057</u>
Costs and operating expenses:				
Cost of product revenues	4,000	5,219	8,298	9,306
Cost of contract research and development revenues	2,803	4,510	5,859	8,227
Research and development expenses	5,593	3,980	10,050	8,177
General and administrative expenses	2,973	2,670	5,990	5,357
Amortization of intangible assets	162	162	321	323
Loss on disposal of equipment	2	—	2	7
Total costs and operating expenses	<u>15,533</u>	<u>16,541</u>	<u>30,520</u>	<u>31,397</u>
Loss from operations	(8,571)	(5,250)	(16,021)	(10,340)
Interest income	58	4	88	6
Interest expense	(1,971)	(1,896)	(3,948)	(3,565)
Loss before income taxes	(10,484)	(7,142)	(19,881)	(13,899)
Income tax expense	—	—	3	2
Net loss and comprehensive loss	<u>\$ (10,484)</u>	<u>\$ (7,142)</u>	<u>\$ (19,884)</u>	<u>\$ (13,901)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.47)</u>	<u>\$ (0.40)</u>	<u>\$ (0.89)</u>	<u>\$ (0.77)</u>
Weighted average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>22,255,365</u>	<u>18,071,320</u>	<u>22,221,666</u>	<u>18,052,809</u>

**CORIUM INTERNATIONAL, INC.**  
**CONDENSED BALANCE SHEETS**  
(in thousands, except share amounts)  
(Unaudited)

As of March 31, 2016   As of September 30, 2015

**ASSETS**

Current assets:

Cash and cash equivalents	\$ 54,445	\$ 72,218
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Accounts receivable	3,532	4,461
Unbilled accounts receivable	763	812
Inventories, net	3,213	2,902
Prepaid expenses and other current assets	955	1,367
Total current assets	62,908	81,760
Restricted cash	666	—
Property and equipment, net	11,298	11,593
Debt financing costs, net	652	554
Intangible assets, net	6,951	6,837
<b>TOTAL ASSETS</b>	<b>\$ 82,475</b>	<b>\$ 100,744</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,412	\$ 3,952
Accrued expenses and other current liabilities	3,888	4,091
Long-term debt, current portion	59	57
Capital lease obligations, current portion	492	820
Recall liability, current portion	720	760
Deferred contract revenues, current portion	341	134
Total current liabilities	8,912	9,814
Long-term debt, net of current portion	50,660	49,807
Capital lease obligations, net of current portion	—	72
Recall liability, net of current portion	1,883	2,229
Deferred contract revenues, net of current portion	3,500	3,500
Total liabilities	64,955	65,422
Stockholders' equity:		
Common stock	22	22
Additional paid-in capital	168,167	166,085
Accumulated deficit	(150,669)	(130,785)
Total stockholders' equity	17,520	35,322
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 82,475</b>	<b>\$ 100,744</b>

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