



November 21, 2016

Corium Reports Fourth Quarter and Fiscal Year 2016 Financial Results and Recent Corporate Highlights

MENLO PARK, Calif., Nov. 21, 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 fourth fiscal quarter and the year ended September 30, 2016, and reported on recent corporate developments. Corium's fiscal year ends on September 30.

"During the 2016 fiscal year we made outstanding progress in moving our two lead Alzheimer's programs forward," said Peter D. Staple, President and Chief Executive Officer of Corium. "Corplex™ Donepezil and Corplex™ Memantine are novel once-weekly transdermal product candidates that deliver the two most widely used treatments for patients with Alzheimer's disease, and would be the first transdermal dosage forms of these drugs. Our two Alzheimer's programs provide a powerful foundation for a CNS-focused proprietary pipeline. At the beginning of the fiscal year, we had just initiated our first-in-human clinical trials of both of these product candidates, and since then we have generated positive human clinical data. With those results, we have gained clear regulatory guidance from the FDA on a streamlined bioequivalence-based development path that applies to both products. The first of those bioequivalence studies has just begun, and we look forward to submitting Corium's first NDA in 2018."

Fourth Quarter and Fiscal Year 2016 Highlights

- 1 **Initiated pilot bioequivalence study for Corplex Donepezil** — Following the submission of an Investigational New Drug application in September, the company has completed enrollment and commenced dosing in a pilot bioequivalence study for Corplex Donepezil, a once-weekly transdermal therapeutic, compared to daily oral Aricept® (donepezil hydrochloride) for Alzheimer's disease. The pilot study is a crossover study in healthy subjects, and will compare the steady-state plasma concentrations of the transdermal and oral products after several weeks of treatment. Based on the pilot study results, the Company will set the parameters of the pivotal study based on statistical bioequivalence (BE) criteria. The pivotal study is expected to start in the second half of 2017 and will have a duration of approximately 16 weeks, which would enable Corium to submit a 505(b)(2) New Drug Application (NDA) as early as mid-2018.
- 1 **Streamlined bioequivalence development paths for both of Corium's Alzheimer's programs** — In April 2016, the FDA advised the company that, following demonstration of bioequivalence between Corplex Donepezil and daily oral Aricept in the company's pivotal BE study, additional clinical efficacy studies will not be required. The company also reported in August that it received similar written guidance from the FDA regarding its proposal for a pivotal study based on the demonstration of bioequivalence between Corplex Memantine and oral Namenda XR® (memantine HCl) extended release capsules.
- 1 **Positive Corplex Donepezil data presented at Alzheimer's Association International Conference® 2016** — The company presented full clinical trial results demonstrating sustained and controlled delivery of donepezil in the plasma concentrations of all subjects treated with Corium's once-weekly Corplex Donepezil patch, comparable to daily oral Aricept, which were indicative of bioequivalence.
- 1 **Positive Phase 1 clinical results drove advances in Alzheimer's programs** — The company separately announced top-line results from Phase 1 studies of Corplex Donepezil and Corplex Memantine. These studies demonstrated positive pharmacokinetic data with sustained and controlled drug delivery, and provided a strong foundation for advancing clinical development of both product candidates.
- 1 **Partner Agile Therapeutics announces completion of subject visits for Phase 3 trial of Twirla® once-weekly contraceptive patch** — Agile has indicated that it expects to report top-line data in early January 2017. Corium provided all required clinical trial supplies and CMC support for the trial in which over 2,000 women participated. Preparations are currently underway for the manufacture of commercial quantities of Twirla in Corium's state-of-the-art facility.
- 1 **Partner Aequus Pharmaceuticals reported successful outcome of aripiprazole clinical study** — Aequus completed a Phase 1 PK study of its once-weekly transdermal product candidate incorporating the active ingredient of Abilify® in December 2015 and, pending approval by Health Canada, is preparing to initiate a multiple-dose follow-

on study prior to the end of calendar 2016. Under its development agreement with Aequus, Corium has contributed to the formulation of the aripiprazole candidate, will have an undisclosed share in Aequus' revenues from the resulting product, and will be the exclusive manufacturer of the product.

- 1 **Completion of divestiture of Clonidine TDS from Teva to Mayne Pharma** — Corium enabled the successful transfer of the Clonidine TDS product from Teva Pharmaceuticals to Mayne Pharma, in connection with Teva's divestiture of the product as a result of its acquisition of the Allergan generics business. Mayne Pharma acquired the rights to more products divested from Teva than any other company.

Financial Results for the Quarter and Fiscal Year Ended September 30, 2016

Corium reported total revenues in the fourth quarter of fiscal 2016 of \$7.9 million, compared with \$9.3 million in the fourth quarter of fiscal 2015, and for the fiscal year ended September 30, 2016, reported total revenues of \$33.0 million, compared with \$40.9 million in fiscal 2015. For fiscal 2016, the decrease in total revenues resulted primarily from a decline in contract research and development revenues, as well as a decline in product revenues versus fiscal 2015. 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 two development projects in fiscal 2015. The \$1.2 million decline in product revenues for fiscal 2016 compared to fiscal 2015 is primarily the result of fewer Fentanyl TDS units ordered and shipped, which was partially offset by an increase in revenues from Crest[®] Whitestrips.

Total research and development (R&D) expenses in the fourth quarter of fiscal 2016 were \$8.2 million, compared with \$8.6 million in the fourth quarter of fiscal 2015, and for the fiscal year ended September 30, 2016, total R&D expenses were \$32.4 million, compared with \$32.5 million in fiscal 2015. For fiscal 2016, R&D expenses associated with Corium's investment in its proprietary product programs increased, including the advancement of Corium's two programs for Alzheimer's disease through Phase 1 clinical trials. This increase in R&D spending was offset by a lower level of resources required for contract research and development programs, corresponding to the lower level of revenues from contract research and development.

General and administrative (G&A) expenses in the fourth quarter of fiscal 2016 were \$2.5 million, compared with \$3.0 million in the fourth quarter of fiscal 2015, and for the fiscal year ended September 30, 2016, G&A expenses were \$11.6 million, compared with \$11.2 million in fiscal 2015. The increase in G&A for the year was primarily attributable to an increase in stock-based compensation expense and higher personnel costs.

Corium reported a net loss for the fourth quarter of fiscal 2016 of \$9.3 million, or \$0.42 per share, compared with a net loss of \$8.6 million, or \$0.42 per share, in the fourth quarter of fiscal 2015. For the fiscal year ended September 30, 2016, Corium reported a net loss of \$36.7 million, or \$1.65 per share, compared with a net loss of \$28.5 million, or \$1.52 per share, in fiscal 2015. As of September 30, 2016, there were 22,391,631 shares of Corium common stock outstanding.

Cash and cash equivalents as of September 30, 2016 were \$39.8 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 year ended September 30, 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 17537774. 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, Endo Pharmaceuticals and Procter & Gamble. The company has two proprietary transdermal platforms: Corplex[™] for small molecules and MicroCor[®], 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 has recently completed all subject visits for its Phase 3 trial, and additional transdermal products that are being developed with other partners. For further information, please visit

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 August 12, 2016, filed with the Securities and Exchange Commission on June 30, 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 trademarks of Corium International, Inc.

Twirla® is a registered trademark of Agile Therapeutics, 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.

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

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

CORIUM INTERNATIONAL, INC.
Condensed Statements of Operations and Comprehensive Loss
(unaudited, in thousands, except share and per share data)

	Three Months Ended		Years	
	September 30,		Ended September 30,	
	2016	2015	2016	2015
Revenues:				
Product revenues	\$ 6,432	\$ 6,047	\$ 25,362	\$ 26,514
Contract research and development revenues	1,192	2,923	5,420	12,721
Other revenues	294	296	2,241	1,686
Total revenues	7,918	9,266	33,023	40,921
Costs and operating expenses:				
Cost of product revenues	4,422	4,239	17,346	17,608
Cost of contract research and development revenues	2,073	3,772	10,674	16,064
Research and development expenses	6,121	4,784	21,687	16,454
General and administrative expenses	2,460	2,993	11,566	11,185
Amortization of intangible assets	170	158	659	622
Loss on disposal and sale and leaseback of equipment	13	10	15	12
Total costs and operating expenses	15,259	15,956	61,947	61,945
Loss from operations	(7,341)	(6,690)	(28,924)	(21,024)
Interest income	29	12	171	23
Interest expense	(2,015)	(1,956)	(7,947)	(7,446)
Loss before income taxes	(9,327)	(8,634)	(36,700)	(28,447)
Income tax expense	—	1	3	3
Net loss and comprehensive loss	\$ (9,327)	\$ (8,635)	\$ (36,703)	\$ (28,450)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.42)	\$ (0.42)	\$ (1.65)	\$ (1.52)
Weighted average shares used in computing net loss per share attributable to common stockholders, basic and diluted	22,365,247	20,594,810	22,282,599	18,709,292

CORIUM INTERNATIONAL, INC.
Condensed Balance Sheets
(In thousands)
(Unaudited)

As of September 30,
2016 2015

ASSETS

Current assets:		
Cash and cash equivalents	\$ 39,833	\$ 72,218
Accounts receivable	4,336	4,461
Unbilled accounts receivable	346	812
Inventories, net	2,424	2,902
Prepaid expenses and other current assets	1,341	1,367
Total current assets	<u>48,280</u>	<u>81,760</u>
Restricted cash	666	—
Property and equipment, net	11,147	11,593
Intangible assets, net	7,057	6,854
TOTAL ASSETS	<u><u>\$ 67,150</u></u>	<u><u>\$ 100,207</u></u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	\$ 2,737	\$ 3,952
Accrued expenses and other current liabilities	4,271	4,091
Long-term debt, current portion	77	57
Capital lease obligations, current portion	72	820
Recall liability, current portion	460	760
Deferred contract revenues, current portion	355	134
Total current liabilities	<u>7,972</u>	<u>9,814</u>
Long-term debt, net of current portion	50,966	49,270
Capital lease obligations, net of current portion	—	72
Recall liability, net of current portion	1,859	2,229
Deferred contract revenues, net of current portion	3,500	3,500
Total liabilities	<u>64,297</u>	<u>64,885</u>
Stockholders' equity:		
Common stock	22	22
Additional paid-in capital	170,319	166,085
Accumulated deficit	(167,488)	(130,785)
Total stockholders' equity	<u>2,853</u>	<u>35,322</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u><u>\$ 67,150</u></u>	<u><u>\$ 100,207</u></u>

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