



Corium Reports First Quarter Fiscal 2018 Financial Results and Corporate Highlights

February 8, 2018

MENLO PARK, Calif., Feb. 08, 2018 (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 first fiscal quarter ended December 31, 2017, and reported on recent corporate developments. Corium's fiscal year ends on September 30.

Corporate Highlights

- **Dosing commenced in final treatment period of Corplex™ Donepezil pivotal trial**—In January, Corium commenced the second and final treatment period of its Corplex Donepezil pivotal bioequivalence (BE) study, which compares the company's once-weekly transdermal patch to daily oral Aricept® (donepezil hydrochloride). The pivotal BE study design is a streamlined version of the successful pilot BE trial, and is a single center, randomized, multiple dose, two-way crossover study in healthy volunteers, conducted at the same clinical site as the pilot BE trial. The dosing in the second treatment period is scheduled to be completed in February; top-line results are expected in the second quarter of calendar 2018.
- **Ancillary studies underway in preparation for NDA** — Corium is conducting ancillary studies that are required in the New Drug Application (NDA) data package for Corplex Donepezil, including standard skin tolerability and alternative patch application site studies, which are underway, and a heat effects study planned to commence in February. Corium is targeting submission of a Section 505(b)(2) NDA in the fourth quarter of calendar 2018.
- **Corium joined NASDAQ Biotechnology Index** — In December, Corium was added to the NASDAQ Biotechnology Index (NBI) as part of the NBI's annual re-ranking. Companies in the NBI must meet certain requirements, including minimum market capitalization and average daily trading volume, among other criteria. The NASDAQ Biotechnology Index forms the basis for a number of Exchange Traded Funds (ETFs), including the iShares NASDAQ Biotechnology ETF.

"During the quarter, we continued to build on the momentum created in fiscal 2017," said Peter D. Staple, President and Chief Executive Officer of Corium. "Our proprietary Corplex Donepezil program has moved forward at a rapid pace; we generated our first human data in 2016 and are actively working towards filing an NDA by the end of this year. In parallel, we have been conducting formulation and feasibility work on preclinical candidates that represent substantial market opportunities, most of which could also benefit from a similar bioequivalence development path. In our partner-based business, we are working with Agile Therapeutics to address questions from the FDA relating to Twirla®, Agile's once-weekly contraceptive patch, which we believe represents a significant upside opportunity. We are also in the process of expanding manufacturing capacity for Procter & Gamble's Crest® Whitestrips, as global demand for these products increases."

Financial Results for the Quarter Ended December 31, 2017

Corium reported total revenues in the first quarter of fiscal 2018 of \$9.3 million, compared with \$7.0 million in the same period of fiscal 2017. Product revenues increased for the first quarter of fiscal 2018 compared to same period of fiscal 2017, primarily as a result of an increase in revenues from Procter & Gamble for Crest® Whitestrips and an increase in revenues from Mayne Pharma for our Fentanyl transdermal delivery system (TDS), partially offset by a reduction in demand from Mayne Pharma for Clonidine TDS. Contract research and development revenues increased for the first quarter of fiscal 2018 compared to the same period of fiscal 2017, primarily resulting from increased activities supporting Agile's development program for Twirla.

Total research and development (R&D) expenses in the first quarter of fiscal 2018 were \$13.8 million compared with \$8.1 million in the same period of fiscal 2017. The increase in total R&D expenses was driven by Corium's investment in its proprietary product programs, primarily the advancement of Corplex Donepezil into its pivotal BE trial.

General and administrative (G&A) expenses in the first quarter of fiscal 2018 were \$3.3 million compared with \$3.0 million for the same period of fiscal 2017. The increase was primarily driven by higher stock-based compensation costs.

Corium reported a net loss for the first quarter of fiscal 2018 of \$13.3 million, or \$0.37 per share, compared with a net loss of \$10.4 million, or \$0.46 per share, in the same period of fiscal 2017. As of December 31, 2017, there were 36,117,913 shares of Corium common stock outstanding, and as of December 31, 2016, there were 22,557,450 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 December 31, 2017 were \$45.2 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 first fiscal quarter ended December 31, 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 7046249. 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®, 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.

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, market and growth opportunities, financial and operating performance, product pipeline, clinical trial and regulatory timing and plans, 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 Annual Report on Form 10-K for the year ended September 30, 2017, filed with the Securities and Exchange Commission (SEC) on December 29, 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 speak 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.
 Crest® Whitestrips is a registered trademark of The Procter & Gamble Company.

Source: Corium

Investor and Media Contact:
 SMP Communications
 Susan M. Pietropaolo
susan@smpcommunications.com
 (201) 923-2049

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

	Three Months Ended December 31,	
	2017	2016
Revenues:		
Product revenues	\$ 5,921	\$ 5,738
Contract research and development revenues	3,154	963
Other revenues	240	267
Total revenues	9,315	6,968
Costs and operating expenses:		
Cost of product revenues	3,284	4,081
Cost of contract research and development revenues	3,605	2,120
Research and development expenses	10,238	5,998
General and administrative expenses	3,300	3,005
Amortization of intangible assets	177	177
Total costs and operating expenses	20,604	15,381
Loss from operations	(11,289)	(8,413)
Interest income	122	28
Interest expense	(2,123)	(2,042)
Loss before income taxes	(13,290)	(10,427)
Income tax expense	2	2

Net loss and comprehensive loss	\$ (13,292)	\$ (10,429)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.37)	\$ (0.46)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	36,073,008	22,453,172

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

	As of December 31, 2017	As of September 30, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 45,230	\$ 57,466
Accounts receivable	4,856	4,641
Unbilled accounts receivable	407	169
Inventories	2,526	2,300
Prepaid expenses and other current assets	1,263	982
Total current assets	54,282	65,558
Property and equipment, net	12,922	12,176
Intangible assets, net	7,149	7,117
TOTAL ASSETS	\$ 74,353	\$ 84,851
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 7,712	\$ 3,978
Accrued expenses and other current liabilities	4,132	6,411
Long-term debt, current portion	26,298	13,172
Recall liability, current portion	221	114
Deferred contract revenues, current portion	390	626
Total current liabilities	38,753	24,301
Long-term debt, net of current portion	25,994	39,027
Recall liability, net of current portion	1,698	1,811
Deferred contract revenues, net of current portion	3,500	3,500
Total liabilities	69,945	68,639
Commitments and contingencies		
Stockholders' equity:		
Common stock	36	36
Additional paid-in capital	232,945	231,457
Accumulated deficit	(228,573)	(215,281)
Total stockholders' equity	4,408	16,212
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 74,353	\$ 84,851

 [Primary Logo](#)

Source: Corium International, Inc.