



Corium Reports Second Quarter Fiscal 2018 Financial Results and Corporate Highlights

May 14, 2018

MENLO PARK, Calif., May 14, 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 second fiscal quarter and the six months ended March 31, 2018 and reported on recent corporate developments. Corium's fiscal year ends on September 30.

Corporate Highlights

- **Corplex™ Donepezil NDA to be submitted using pilot bioequivalence data** — Based on positive feedback from the U.S. Food and Drug Administration (FDA), Corium announced that it will submit the data from its successful pilot bioequivalence (BE) study for the planned New Drug Application (NDA) for Corplex Donepezil. Corium is now in the process of conducting the ancillary clinical studies required for the NDA. These ancillary studies, which include standard skin tolerability, alternative patch application site and heat effect studies, are well underway and progressing as planned. As previously announced, Corium is targeting submission of a Section 505(b)(2) NDA in the first quarter of calendar 2019.
- **Notice of allowance for key U.S. Corplex Donepezil patent** — The United States Patent and Trademark Office issued a notice of allowance for a foundational patent related to Corplex Donepezil. This patent provides coverage of the drug product and its unique design features, including composition elements that achieve a sustained, controlled and effective delivery of donepezil across the skin for the 7-day wear period. This patent will be eligible for listing in the FDA Orange Book and should provide patent protection to at least July 2037. It is the first to be allowed in a series of pending Corium patent applications related to Corplex Donepezil.
- **Completed \$120 million convertible debt offering**— In March, Corium completed the sale of \$120 million in aggregate principal amount of 5.00% Convertible Senior Notes due 2025 in a private offering to qualified institutional buyers. Corium used approximately \$56 million of the proceeds to repay in full its outstanding borrowings under its term loan agreement with CRG, and will use the remainder for working capital and other general corporate purposes.

"The quarter was highlighted by our decision to use our successful pilot bioequivalence data comparing Corplex Donepezil and Aricept® as the basis for our NDA submission. This decision was driven by favorable feedback from the FDA following the agency's review of the full pharmacokinetic report for that study and our consultations with external experts," said Peter D. Staple, President and Chief Executive Officer of Corium. "The notice of allowance for our new composition of matter patent on this product validates the innovative approach that we have taken in developing Corplex Donepezil and further strengthens the long-term commercial value of the product."

Financial Results for the Quarter Ended March 31, 2018

Corium reported total revenues of \$10.1 million in the second quarter of fiscal 2018, compared with \$7.3 million in the same period of fiscal 2017, and reported total revenues of \$19.4 million for the six-month period ended March 31, 2018, compared with \$14.3 million in the same period in fiscal 2017. Product revenues increased for both the second quarter of fiscal 2018 and for the six-month period ended March 31, 2018, compared to the same periods in fiscal 2017, primarily as a result of an increase in revenues from Mayne Pharma for Clonidine TDS and an increase in revenues from Procter & Gamble for Crest® Whitestrips. Contract research and development revenues increased for both the second quarter and the six-month period ended March 31, 2018, compared to the same periods in fiscal 2017, primarily as a result of increased activities supporting Agile's development program for Twirla®, increased development activity for Mayne on multiple product candidates, and increased development for Procter & Gamble related to the ongoing acquisition of a third production line.

Total research and development (R&D) expenses were \$15.3 million in the second quarter of fiscal 2018, compared with \$10.3 million in the same period of fiscal 2017, and were \$29.1 million for the six-month period ended March 31, 2018, compared with \$18.4 million in the same period in 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 a second BE trial, along with the ancillary clinical trials required to support the NDA filing for this product.

General and administrative (G&A) expenses were \$4.1 million in the second quarter of fiscal 2018, compared with \$3.0 million for the same period of fiscal 2017, and were \$7.4 million for the six-month period ended March 31, 2018, compared with \$6.0 million in the same period in fiscal 2017. The increase was primarily driven by higher one-time legal and outside services costs, as well as higher stock-based compensation costs.

Corium reported a net loss of \$18.0 million for the second quarter in fiscal 2018, or \$0.50 per share, compared with a net loss of \$11.0 million, or \$0.42 per share, in the same period of fiscal 2017. For the six-month period ended March 31, 2018, the net loss was \$31.3 million, or \$0.87 per share, compared with a net loss of \$21.5 million, or \$0.88 per share, for the same period in fiscal 2017. As of March 31, 2018, there were 36,139,058 shares of Corium common stock outstanding.

Cash and cash equivalents as of March 31, 2018 were \$94.2 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 second fiscal quarter and the six months ended March 31, 2018. 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 7690614. 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, use of proceeds from the recent convertible debt offering, product pipeline, intellectual property rights and portfolio, 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-Q for the quarter ended December 31, 2017, filed with the Securities and Exchange Commission (SEC) on February 12, 2018, 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.

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

Source: Corium

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,	
	2018	2017	2018	2017
Revenues:				
Product revenues	\$ 6,690	\$ 4,657	\$ 12,611	\$ 10,395
Contract research and development revenues	3,130	2,421	6,284	3,384
Other revenues	240	267	480	534
Total revenues	10,060	7,345	19,375	14,313
Costs and operating expenses:				
Cost of product revenues	4,015	2,876	7,299	6,957
Cost of contract research and development revenues	3,294	2,794	6,899	4,914
Research and development expenses	11,968	7,530	22,206	13,528
General and administrative expenses	4,103	2,999	7,403	6,004
Amortization of intangible assets	181	178	358	355
Total costs and operating expenses	23,561	16,377	44,165	31,758
Loss from operations	(13,501)	(9,032)	(24,790)	(17,445)
Interest income	163	44	285	72
Interest expense	(2,410)	(2,049)	(4,533)	(4,091)
Loss on extinguishment of long-term debt	(2,258)	—	(2,258)	—
Loss before income taxes	(18,006)	(11,037)	(31,296)	(21,464)
Income tax expense	—	—	2	2
Net loss and comprehensive loss	\$ (18,006)	\$ (11,037)	\$ (31,298)	\$ (21,466)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.50)	\$ (0.42)	\$ (0.87)	\$ (0.88)

Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	36,147,306	26,487,493	36,109,749	24,448,166
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CORIUM INTERNATIONAL, INC.
CONDENSED BALANCE SHEETS
(In thousands, except share and per share data)
(Unaudited)

	As of March 31, 2018	As of September 30, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 94,221	\$ 57,466
Accounts receivable	4,165	4,641
Unbilled accounts receivable	274	169
Inventories	1,975	2,300
Prepaid expenses and other current assets	415	982
Total current assets	101,050	65,558
Property and equipment, net	14,190	12,176
Intangible assets, net	7,235	7,117
TOTAL ASSETS	\$ 122,475	\$ 84,851
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 6,308	\$ 3,978
Accrued expenses and other current liabilities	5,764	6,411
Long-term debt, current portion	48	13,172
Recall liability, current portion	187	114
Deferred contract revenues, current portion	157	626
Total current liabilities	12,464	24,301
Convertible notes, net	68,159	—
Long-term debt, net of current portion	350	39,027
Recall liability, net of current portion	1,684	1,811
Deferred contract revenues, net of current portion	3,500	3,500
Total liabilities	86,157	68,639
Commitments and contingencies		
Stockholders' equity:		
Common stock	36	36
Additional paid-in capital	282,861	231,457
Accumulated deficit	(246,579)	(215,281)
Total stockholders' equity	36,318	16,212
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 122,475	\$ 84,851

[Primary Logo](#)

Source: Corium International, Inc.