



Corium Reports Third Quarter Fiscal 2018 Financial Results and Corporate Highlights

August 9, 2018

MENLO PARK, Calif., Aug. 09, 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 third fiscal quarter and the nine months ended June 30, 2018 and reported on recent corporate developments. Corium's fiscal year ends on September 30.

Corporate Highlights

- **Corplex™ Donepezil on track for filing**—Corium has completed treatment in all of the ancillary clinical studies required for its New Drug Application (NDA) for Corplex Donepezil, a once-weekly patch that delivers the most commonly prescribed medication for Alzheimer's patients. These studies included standard skin tolerability, alternative patch application site and heat effect studies. Corium remains on track to submit a Section 505(b)(2) NDA in the first quarter of calendar 2019. In addition, Corium reported clinical pharmacodynamic results at the Alzheimer's Association International Conference® 2018 that provide additional validation of the therapeutic equivalence between Aricept® and Corplex Donepezil.
- **First two key patents issued for Corplex Donepezil**—In June and July, Corium announced the issuance of two U.S. patents, including composition elements, unique design features of the drug product and methods to achieve sustained, controlled and effective delivery of donepezil across the skin for a 7-day wear period. Eligible for listing in the FDA Orange Book, these patents establish the foundation of a strong IP portfolio for the transdermal delivery of donepezil and extend patent coverage of the product to at least July 2037. Corium has several additional pending patent applications relating to various features of Corplex Donepezil, as well as similar products.
- **Pipeline advances in additional indications** —Corium has progressed its development and feasibility evaluation of several pipeline product candidates, leveraging nonclinical and clinical studies that the company has already performed. The pipeline candidates include programs in several important disease areas including multiple sclerosis, Alzheimer's and pain management. Corium anticipates advancing select programs into clinical pharmacokinetic and safety studies during fiscal 2019.
- **Commercial production commenced using expanded capacity for P&G**—Corium's expanded commercial manufacturing capacity for Procter & Gamble's Crest® Whitestrips is now fully operational and in production. Part of an extended supply agreement with P&G, the additional production provides the companies with greater ability to meet significant increases in demand for Crest Whitestrips.

"We remain on track to file our Corplex Donepezil NDA in the first quarter of 2019 and look forward to delivering an important new treatment option for patients with Alzheimer's disease and their caregivers," said Peter D. Staple, President and Chief Executive Officer of Corium. "We are executing on our strategic plan to leverage our Corplex technology to expand our proprietary pipeline with the development of additional "first-in-patch" transdermal therapeutics. We've identified several promising candidates in therapeutic areas with significant unmet needs that, based on our initial formulation and feasibility work, meet our technical and commercial criteria for further development."

Financial Results for the Quarter and Nine Months Ended June 30, 2018

Corium reported total revenues of \$7.7 million for the third quarter of fiscal 2018, compared with \$8.1 million for the same period of fiscal 2017, and reported total revenues of \$27.0 million for the nine-month period ended June 30, 2018, compared with \$22.4 million for the same period in fiscal 2017. Product revenues were essentially unchanged for the third quarter of fiscal 2018, compared to the same period in fiscal 2017, primarily as a result of a decrease in Clonidine TDS revenues, offset by an increase in revenues from Crest Whitestrips and Fentanyl TDS. Product revenues increased for the nine-month period ended June 30, 2018, compared to the same period in fiscal 2017, as revenues from Procter & Gamble increased, reflecting strong demand for the Crest Whitestrips products. Contract research and development (R&D) revenues decreased for the third quarter of fiscal 2018, compared to the same period in fiscal 2017, as a result of reduced development work for Agile's Twirla® product and several other partner programs, partially offset by higher revenues from activities associated with implementing the new production capacity for P&G. Contract R&D revenues increased for the nine-month period ended June 30, 2018, compared to the same period in fiscal 2017, due to increased support for Agile's regulatory activities, increased product development for Mayne, and the implementation of the new production capacity for P&G.

Total R&D expenses were \$10.6 million in the third quarter of fiscal 2018, compared with \$12.1 million in the same period of fiscal 2017, and were

\$39.7 million for the nine-month period ended June 30, 2018, compared with \$30.5 million in the same period in fiscal 2017. The decrease in total R&D expenses for the third quarter reflects the lower level of clinical activity for Corplex Donepezil during this period. The increase in total R&D expenses for the nine-month period was driven by Corium's investment in bioequivalence trials for Corplex Donepezil, as well as the ancillary clinical trials required to support the NDA filing for the product, in addition to increased expenses associated with feasibility programs for new products.

General and administrative (G&A) expenses were \$3.3 million for both the third quarter of fiscal 2018 and for the same period of fiscal 2017, and were \$10.7 million for the nine-month period ended June 30, 2018, compared with \$9.3 million in the same period in fiscal 2017. The increase in G&A expenses for the nine months was primarily driven by higher one-time legal and outside services costs in the second quarter, as well as higher stock-based compensation costs.

Corium reported a net loss of \$12.4 million for the third quarter of fiscal 2018, or \$0.34 per share, compared with a net loss of \$13.4 million, or \$0.43 per share, in the same period of fiscal 2017. For the nine-month period ended June 30, 2018, the net loss was \$43.7 million, or \$1.21 per share, compared with a net loss of \$34.9 million, or \$1.30 per share, for the same period in fiscal 2017. As of June 30, 2018, there were 36,244,074 shares of Corium common stock outstanding.

Cash and cash equivalents as of June 30, 2018 were \$82.5 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 third fiscal quarter and the nine months ended June 30, 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 4192359. 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. 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 and demand for our commercial products, financial and operating performance, 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 March 31, 2018, filed with the Securities and Exchange Commission (SEC) on May 15, 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.
 Aricept® is a registered trademark of Eisai R&D Management Co, Ltd.
 Crest® Whitestrips is a registered trademark of The Procter & Gamble Company.
 Twirla® is a registered trademark of Agile Therapeutics, Inc.

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

	Three Months Ended		Nine Months Ended June 30,	
	June 30,		2018	2017
	2018	2017	2018	2017
Revenues:				
Product revenues	\$ 5,901	\$ 5,906	\$ 18,512	\$ 16,301
Contract research and development revenues	1,529	1,936	7,813	5,320
Other revenues	240	267	720	801
Total revenues	7,670	8,109	27,045	22,422

Costs and operating expenses:				
Cost of product revenues	3,507	3,935	10,806	10,892
Cost of contract research and development revenues	2,339	2,977	9,238	7,891
Research and development expenses	8,305	9,122	30,511	22,650
General and administrative expenses	3,325	3,284	10,728	9,288
Amortization of intangible assets	183	159	541	514
Loss on disposal of equipment	4	6	4	6
Total costs and operating expenses	17,663	19,483	61,828	51,241
Loss from operations	(9,993)	(11,374)	(34,783)	(28,819)
Interest income	332	77	617	149
Interest expense	(3,370)	(2,087)	(7,903)	(6,178)
Loss on extinguishment of long-term debt	—	—	(2,258)	—
Other income	640	—	640	—
Loss before income taxes	(12,391)	(13,384)	(43,687)	(34,848)
Income tax expense	—	—	2	2
Net loss and comprehensive loss	\$ (12,391)	\$ (13,384)	\$ (43,689)	\$ (34,850)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.34)	\$ (0.43)	\$ (1.21)	\$ (1.30)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	36,214,740	31,457,702	36,144,746	26,784,678

CORIUM INTERNATIONAL, INC.
CONDENSED BALANCE SHEETS
(In thousands, except share and per share data)
(Unaudited)

	As of June 30, 2018	As of September 30, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 82,523	\$ 57,466
Accounts receivable	3,556	4,641
Unbilled accounts receivable	228	169
Inventories	1,686	2,300
Prepaid expenses and other current assets	924	982
Total current assets	88,917	65,558
Property and equipment, net	15,810	12,176
Intangible assets, net	7,404	7,117
TOTAL ASSETS	\$ 112,131	\$ 84,851
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,519	\$ 3,978
Accrued expenses and other current liabilities	6,860	6,411
Long-term debt, current portion	49	13,172
Recall liability, current portion	119	114
Deferred contract revenues, current portion	137	626
Total current liabilities	11,684	24,301
Convertible notes, net	70,021	—
Long-term debt, net of current portion	337	39,027
Recall liability, net of current portion	1,697	1,811
Deferred contract revenues, net of current portion	3,500	3,500
Total liabilities	87,239	68,639
Commitments and contingencies		
Stockholders' equity:		
Common stock	36	36
Additional paid-in capital	283,826	231,457
Accumulated deficit	(258,970)	(215,281)
Total stockholders' equity	24,892	16,212
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 112,131	\$ 84,851

Source: Corium



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