



November 12, 2015

Corium Reports Fourth Quarter and Fiscal Year 2015 Financial Results and Year-End Highlights

MENLO PARK, Calif., Nov. 12, 2015 (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 quarter and fiscal year ended September 30, 2015 and reported on recent corporate developments.

Fourth Quarter and Fiscal Year 2015 Highlights

- | **Completion of a successful follow-on offering** in August with gross proceeds to the company, before expenses, of \$52 million.
- | **Completion of a Phase 2a trial of the needle-free MicroCor[®] PTH system** for the treatment of osteoporosis, and the announcement of positive topline results, including pharmacokinetic (PK) and pharmacodynamic (PD) profiles that met each of the study objectives, as well as excellent safety and skin tolerability outcomes. This trial was the first Phase 2 study undertaken with a dissolving microstructure system technology.
- | **Initiation of Phase 1 clinical trial of Corium's Corplex[™] Donepezil Transdermal System** for the weekly treatment of Alzheimer's disease and the commencement of clinical development for the Corplex Memantine Transdermal System.
- | **Receipt of "Drug-in-Tip" U.S. Patent for MicroCor Transdermal System** covering novel, dissolving microstructure arrays as an alternative to injections for a range of therapeutics and vaccines. The patent extends at least until September 2031, and expands upon the existing Corium patents and patent filings relating to the MicroCor technology, including the microstructure design, microstructure formulation compositions, MicroCor applicators, manufacturing methods and packaging methodologies.
- | **Completion of Phase 3 patient enrollment by Corium's partner Agile Therapeutics in the Twirla[®] SECURE clinical trial**, a confirmatory study evaluating the only low-dose combined hormonal contraceptive transdermal patch for once-weekly application.
- | **Additions to leadership** including the appointment of [Joseph J. Sarret, M.D., J.D. as Chief Business Officer](#), and Ivan Gergel, M.D. and Eric H. Bjerkholt to the Company's Board of Directors.
- | **Collaboration agreement with Aequus for a once-weekly transdermal aripiprazole patch** targeting the treatment of bipolar I disorder, schizophrenia, irritability associated with autistic disorder, and major depressive disorder, as well as the potential development of other therapeutics.
- | **Publication of promising needle-free transdermal influenza vaccine preclinical data** in *Vaccine* using the MicroCor transdermal system.
- | **Recognition of [Corium Co-Founder Gary W. Cleary, Ph.D. with the 2015 Controlled Release Society Founders Award](#).**
- | **Close of an expanded term loan facility** in December 2014 with CRG and certain of its affiliate funds that provided an additional \$10 million to the company and extended the maturity date of all debt to CRG from June 2017 to June 2019. This loan facility is primarily intended to support the advancement of Corium's product development programs and proprietary technologies.

"We have had a year of tremendous achievement, executing on our key clinical, corporate and financing objectives. In our proprietary pipeline, we made significant strides in advancing three programs into the clinic. With our MicroCor PTH product, we initiated and completed a Phase 2a study, reported positive results, and in doing so, provided strong clinical validation of Corium's MicroCor transdermal platform. We also initiated clinical development of our two Alzheimer's disease product candidates, and are currently conducting Phase 1 trials of Corplex patches incorporating the two most widely used therapeutic agents," said Peter D. Staple, Corium's President and Chief Executive Officer. "Strategically, we are committed to expanding our own product pipeline with a focus on CNS and to exploring first-in-patch applications that leverage our novel transdermal technologies. As we enter 2016, we are well-positioned to advance our clinical-stage programs and to move new high-value transdermal therapeutics from concept through the clinic."

Financial Results for the Quarter Ended September 30, 2015

Corium reported total revenues in the fourth quarter of fiscal 2015 of \$9.3 million, compared with \$11.1 million in the fourth quarter of fiscal 2014. The decrease in total revenues primarily resulted from declining product revenues from Fentanyl TDS (marketed by Par Pharmaceutical) and Clonidine TDS (marketed by Teva Pharmaceuticals), partially offset by growth in contract research and development revenues.

Total research and development (R&D) expenses, including both proprietary and partnered programs, in the fourth quarter of fiscal 2015 were \$8.6 million, compared with \$7.8 million in the fourth quarter of fiscal 2014. The increase in total R&D expenses primarily reflects Corium's increased investment in its proprietary product programs, including its development programs for Alzheimer's and Parkinson's diseases, as it advanced multiple formulation candidates through preclinical evaluation and two programs into Phase 1 clinical trials.

General and administrative (G&A) expenses in the fourth quarter of fiscal 2015 were \$3.0 million, compared with \$2.6 million in the fourth quarter of fiscal 2014. The increase in G&A was primarily attributable to higher personnel and professional expenses.

Corium reported a net loss for the fourth quarter of fiscal 2015 of \$8.6 million, or a loss of \$0.42 per share on a fully-diluted basis, compared with a net loss of \$6.4 million, or a loss of \$0.35 per share, in the fourth quarter of fiscal 2014. As of September 30, 2014 and September 30, 2015, there were 18,003,883 and 22,160,991 shares of Corium common stock outstanding, respectively.

Cash and cash equivalents as of September 30, 2015 were \$72.2 million, reflecting the addition of capital from the Company's follow-on equity financing in August.

Financial Results for the Year Ended September 30, 2015

Corium reported total revenues for the year ended September 30, 2015 of \$40.9 million. This amount reflected a decline from revenues of \$42.4 million for the year ended September 30, 2014, primarily due to expected declines in product revenues from both Clonidine TDS (marketed by Teva Pharmaceuticals) and Fentanyl TDS (marketed by Par Pharmaceutical), partially offset by an increase in contract research and development revenues from co-development programs and new partner-funded programs. In addition, revenues for the fiscal year ended September 30, 2014, included recognition of \$1.8 million in non-cash product revenue that had been previously deferred since 2007. The recognition of this revenue related to the expiration of a contractual liability, and does not have an impact on revenues after fiscal 2014.

Total research and development (R&D) expenses for 2015, including both proprietary and partnered programs, were \$32.5 million, compared with \$22.8 million for 2014. The increase primarily reflects the additional investment in 2015 for MicroCor technology and product programs, including the MicroCor PTH Phase 2a clinical trial, the first full year of investment in our Corplex CNS programs, along with new partner-funded development programs, and our co-development programs in which development costs are shared with the partner.

General and administrative (G&A) expenses for 2015 were \$11.2 million, compared with \$9.1 million for 2014. The increase was primarily attributable to increased professional expenses, personnel costs and stock-based compensation expense associated with our first full year of operating as a public company.

Corium reported a net loss for 2015 of \$28.5 million, or a loss of \$1.52 per share on a fully-diluted basis, compared with a net loss of \$9.9 million, or a loss of \$0.99 per share, for 2014. The 2014 net loss included a \$7.4 million gain related to the valuation of a derivative liability that was recognized at the closing of the initial public offering. Without the effect of the \$7.4 million non-cash gain in 2014, Corium would have recognized a non-GAAP net loss for 2014 of \$17.3 million, or \$1.72 per share.

Conference Call and Webcast Details

Corium will host a conference call today at 5 p.m. ET/2 p.m. PT to discuss the financial results for the fourth quarter and fiscal year ended September 30, 2015. 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 74326175. 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# 74326175 or by visiting Corium's website.

Statement regarding use of non-GAAP financial measures

The company reported non-GAAP net loss and net loss per share in this release in addition to, and not as a substitute for, or superior to, net loss and net loss per share calculated in accordance with GAAP.

Management believes the presentation of net loss and net loss per share that excludes the non-cash, non-recurring charge or gain from the change in fair value of an embedded derivative provides useful supplemental information to investors and facilitates the analysis of the company's core operating results and comparison of net loss and net loss per share across reporting periods, especially as the number of shares outstanding were materially different across the same periods.

Management also believes that this supplemental non-GAAP information is therefore useful to investors in analyzing and assessing the company's past and future operating performance.

The company encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP information and the reconciliation between these presentations, to more fully understand its business.

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 in advanced transdermal and transmucosal delivery systems. 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™ 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 is currently in Phase 3 trials, and additional transdermal products that are being developed with Teva. Corium has multiple proprietary programs in preclinical and clinical development for the treatment of osteoporosis and neurological disorders. For further information, please visit 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, clinical and 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 financial results are detailed in Corium's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed with the Securities and Exchange Commission on July 30, 2015, 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 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.
Crest® *Whitestrips* is a registered trademark of The Procter & Gamble Company.

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

	Three Months		Years Ended September 30,	
	Ended September 30,		2015	2014
	2015	2014	2015	2014
Revenues:				
Product revenues	\$ 6,047	\$ 9,006	\$ 26,514	\$ 32,202
Contract research and development revenues	2,923	1,767	12,721	9,026
Other revenues	296	299	1,686	1,212
Total revenues	<u>9,266</u>	<u>11,072</u>	<u>40,921</u>	<u>42,440</u>
Costs and operating expenses:				
Cost of product revenues	4,239	5,412	17,608	20,204
Cost of contract research and development revenues	3,772	4,155	16,064	15,391
Research and development expenses	4,784	3,623	16,454	7,365
General and administrative expenses	2,993	2,552	11,185	9,095
Amortization of intangible assets	158	148	622	547
(Gain)/ loss on disposal and sale and leaseback of equipment	10	(21)	12	(112)
Total costs and operating expenses	<u>15,956</u>	<u>15,869</u>	<u>61,945</u>	<u>52,490</u>
Loss from operations	(6,690)	(4,797)	(21,024)	(10,050)
Interest income	12	3	23	7
Interest expense	(1,956)	(1,572)	(7,446)	(6,961)
Change in fair value of preferred stock warrant liability	—	—	—	(274)
Change in fair value of subordinated note embedded derivative liability	—	—	—	7,367
Loss before income taxes	(8,634)	(6,366)	(28,447)	(9,911)
Income tax expense	1	1	3	1
Net loss and comprehensive loss	<u>\$ (8,635)</u>	<u>\$ (6,367)</u>	<u>\$ (28,450)</u>	<u>\$ (9,912)</u>
Net loss attributable to common stockholders, basic and diluted	<u>\$ (8,635)</u>	<u>\$ (6,367)</u>	<u>\$ (28,450)</u>	<u>\$ (9,912)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.42)</u>	<u>\$ (0.35)</u>	<u>\$ (1.52)</u>	<u>\$ (0.99)</u>
Weighted average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>20,594,810</u>	<u>18,000,693</u>	<u>18,709,292</u>	<u>10,043,640</u>

CORIAM INTERNATIONAL, INC.
Condensed Balance Sheets
(unaudited, in thousands)

	As of September 30,	
	2015	2014
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 72,218	\$ 36,395
Accounts receivable	4,461	4,168
Unbilled accounts receivable	812	1,385
Inventories, net	2,902	2,592
Prepaid expenses and other current assets	1,367	1,292
Total current assets	<u>81,760</u>	<u>45,832</u>
Property and equipment, net	11,593	12,658
Debt financing costs, net	554	571
Intangible assets, net	<u>6,837</u>	<u>6,683</u>

TOTAL ASSETS	<u>\$ 100,744</u>	<u>\$ 65,744</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,952	\$ 2,512
Accrued expenses and other current liabilities	4,091	4,008
Long-term debt, current portion	57	107
Capital lease obligations, current portion	820	760
Recall liability, current portion	760	774
Deferred contract revenues, current portion	134	301
Total current liabilities	<u>9,814</u>	<u>8,462</u>
Long-term debt, net of current portion	49,807	38,155
Capital lease obligations, net of current portion	72	891
Recall liability, net of current portion	2,229	2,936
Deferred contract revenues, net of current portion	3,500	3,500
Total liabilities	<u>65,422</u>	<u>53,944</u>
Stockholders' equity:		
Common stock	22	18
Additional paid-in capital	166,085	114,117
Accumulated deficit	<u>(130,785)</u>	<u>(102,335)</u>
Total stockholders' equity	<u>35,322</u>	<u>11,800</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 100,744</u>	<u>\$ 65,744</u>

Investor and Media Contact:
Karen L. Bergman
BCC Partners
kbergman@bccpartners.com
(650) 575-1509