March 23, 2015

Flexion Reports Year-End 2014 Financial Results

- *Strong cash position bolstered through IPO and follow-on financing, raising a combined total of over $173 million*
- *Lead drug candidate FX006 advanced into late-stage pivotal trials for patients with osteoarthritis (OA) of the knee*

BURLINGTON, Mass., March 23, 2015 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) today announced financial results for the year-ended December 31, 2014.

In February 2014, the successful completion of an initial public offering of Flexion common stock raised gross proceeds of approximately $75 million; and, in December 2014, a follow-on offering raised additional gross proceeds of approximately $98 million. At December 31, 2014, Flexion had cash, cash equivalents and marketable securities totaling $151.6 million compared to $16.4 million at December 31, 2013.

For 2014, the company reported a net loss of $27.3 million as compared to a net loss of $18.2 million for 2013. Research and development expenses were $17.9 million and $11.1 million for the years ended December 31, 2014 and 2013, respectively. The increase in research and development expenses of $6.8 million in 2014 as compared to 2013 was primarily a result of increased costs related to the company's FX006 clinical development program and expenses associated with headcount additions throughout 2014. General and administrative expenses were $9.1 million and $6.7 million for the years ended December 31, 2014 and 2013, respectively. The increase in general and administrative expenses of $2.4 million in 2014 as compared to 2013 was primarily due to an increase in stock compensation expense, other employee-related costs due to increased headcount and expenses associated with being a publicly traded company.

Michael Clayman, M.D., President and Chief Executive Officer of Flexion, stated, "For Flexion Therapeutics, 2014 was a transformational year. We completed two public stock offerings that place the company in a strong position to execute on its business plan. To that end, the Flexion team has advanced FX006 into two pivotal clinical trials that we expect will form the basis for a regulatory submission for a product that has the potential to make a meaningful and durable difference for the many patients suffering from OA knee pain. In addition, we strengthened our board of directors and management team."

Dr. Clayman continued, "We expect 2015 to be another important year for the company as the readout from our first pivotal trial will happen later this year along with completion of enrollment in our Phase 3 trial. With positive data from both trials we look forward to the prospect of filing a New Drug Application (NDA) thereafter."

2014 and Recent Corporate Highlights

- In February 2014, completed a successful initial public offering of our common stock and raised gross proceeds of approximately $75 million; in December 2014, completed a follow-on financing, raising over $98 million. Total funds raised from both financings were more than $173 million
- Completed and reported positive data from the FX006 Phase 2a synovial fluid pharmacokinetic clinical trial
- Initiated and completed enrollment in a confirmatory, pivotal Phase 2b multi-center, randomized, double-blind, placebo-controlled study in 310 patients with OA of the knee. Results will address the safety, tolerability and efficacy of FX006
- Initiated a Phase 3 clinical trial of FX006 that will be the final step before submitting an NDA to the U.S. Food & Drug Administration
- Entered an exclusive worldwide licensing agreement with the SwRI® to use proprietary microsphere technology to produce Flexion's sustained-release drug candidates, including FX006
- Received from the U.S. Patent and Trademark Office a composition of matter patent (No. 8828440), entitled "Corticosteroids for the Treatment of Joint Pain," which provides coverage for FX006 into 2031
- Strengthened Flexion's board of directors by adding Ann Merrifield, former President of Genzyme Biosurgery, Sandesh (Sandy) Mahatme, LLM, Senior Vice President, Chief Financial Officer at Sarepta Therapeutics, Inc. and Scott Canute, former President of Global Manufacturing and Corporate Operations at Genzyme Corporation
- Added several highly-skilled professionals with deep domain experience in Clinical Research, Regulatory Affairs, Quality Assurance, Commercial Operations and Legal Affairs

Anticipated Events in 2015

- Announce the results of pivotal Phase 2b trial in the fourth quarter
- Complete final, pivotal Phase 3 clinical trial enrollment for FX006

About Flexion Therapeutics

Flexion is a clinical-stage specialty pharmaceutical company focused on the development and commercialization of novel pain therapies. The company is currently advancing a portfolio of local, injectable drug candidates that have the potential to provide better and more persistent analgesia compared with existing therapy. The company's lead program, FX006, is an intra-articular sustained-release steroid in development for patients with moderate to severe OA pain. The company also has two additional product candidates, FX007, a locally administered TrkA receptor antagonist for post-operative pain, and FX005, an intra-articular, sustained-release p38 MAP kinase inhibitor for end-stage OA patients.

Conference Call

Flexion's management will host a conference call today at 4:30 p.m. ET. The conference call will be to discuss financial results and provide an update on the business and will be accessible at that time on Flexion's website at www.flexiontherapeutics.com under "Investor/Events & Presentations" or by telephone at 1 (855) 770-0022 (Domestic) or 1 (908) 982-4677 (International), Conference ID # 98509423. A replay of the webcast will be available on the Flexion Therapeutics website for 30 days after the conference call. For more information please visit www.flexiontherapeutics.com.

Forward-Looking Statements

Statements in this press release regarding matters that are not historical facts, including statements relating to the future of Flexion, its ongoing development of its product candidates, expected design, timing and results of the ongoing Phase 2b and ongoing Phase 3 clinical trials, plans and timing for regulatory submissions, anticipated clinical and other milestones (including the timing of such milestones) expected coverage from existing patents and potential benefits of FX006 are forward-looking statements. These forward-looking statements are based on management's expectations and assumptions as of the date of this press release and are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include, without limitation, risks associated with the process of discovering, developing and obtaining regulatory approval for drugs that are safe and effective for use as human therapeutics, the fact that results of past clinical trials may not be predictive of subsequent trials, the fact that Flexion relies on third parties to manufacture and conduct the clinical trials of its product candidates, which could delay or limit their future development or regulatory approval, the fact that Flexion will require additional capital, including prior to commercializing FX006 or any of its other product candidates, and may be unable to obtain such additional capital in sufficient amounts or on terms acceptable to it, the risk that Flexion's patents may be challenged or invalidated, and other risks and uncertainties described in Flexion's filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in Flexion's Annual Report on Form 10-K for the year ended December 31, 2014 and subsequent filings with the SEC. You are encouraged to read Flexion's filings with the SEC, available at www.sec.gov, for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this press release, and Flexion undertakes no obligation to update or revise any of the statements.

FLEXION THERAPEUTICS

CONSOLIDATED STATEMENT OF OPERATIONS

(in thousands, except for per share information)

	Year Ended December 31,	
	2014	**2013**
Revenue	$ --	$ --
Operating expenses:		
Research and development	17,923	11,061
General and administrative	9,064	6,704
Total expenses	26,987	17,765
Loss from operations	(26,987)	(17,765)
Interest income (expense), net	78	(215)
Other income (expense)	(404)	(207)
Loss from operations before income tax	(27,313)	(18,187)
Net loss	(27,313)	(18,187)

Basic and diluted net loss per share	$ (1.97)	$ (23.02)
Basic and diluted weighted average number of common shares outstanding	13,894[1]	790

[1] Note that the issuance of additional common stock and the conversion of preferred stock in connection with the Company's IPO in February 2014 resulted in a significant increase in the Company's weighted average shares outstanding impacts the year-over-year comparability of the Company's earnings/loss per share in 2014.

FLEXION THERAPEUTICS

SELECTED BALANCE SHEET DATA

(in thousands)

	December 31,	
	2014	**2013**
Cash and cash equivalents	$ 103,098	$ 16,188
Marketable securities	48,527	250
Total current assets	152,127	16,620
Working capital	145,328	11,584
Total assets	153,377	18,776
Total notes payable	3,593	5,047
Convertible preferred stock (Series A and B)	--	74,806
Total stockholders' equity (deficit)	144,942	(64,704)

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