



August 7, 2014

Flexion Therapeutics Reports Second-Quarter 2014 Financial Results

Recent Highlights

- *Announced positive topline results from Phase 2a synovial fluid pharmacokinetic (PK) study of lead clinical candidate FX006*
- *Initiated confirmatory Phase 2b clinical trial evaluating FX006 in patients with osteoarthritis (OA) of the knee*
- *Appointed two new Directors to Flexion Board*
- *Recently announced execution of Southwest Research Institute® (SwRI®) exclusive license to bolster Flexion's intellectual property protection*

BURLINGTON, Mass., Aug. 7, 2014 (GLOBE NEWSWIRE) -- [Flexion Therapeutics, Inc.](#) (Nasdaq:FLXN) today announced key operational highlights and financial results for the second quarter ended June 30, 2014, as well as more recent accomplishments.

"During the second quarter of 2014, Flexion reported on schedule, two important clinical milestones for the company's lead product candidate FX006, including the release of positive topline clinical trial data from our Phase 2a synovial fluid PK study and the initiation of a confirmatory Phase 2b efficacy trial," said Michael Clayman, M.D., Flexion Therapeutics President and Chief Executive Officer.

"As we continue to progress FX006 toward commercialization, we believed it important to further expand the expertise of the Board of Directors. To that end, we've added two new Board members: Ann Merrifield and Sandesh (Sandy) Mahatme - which, with the departure of three of our VC directors, brings the Board's size to eight members. Ms. Merrifield has most recently served as President and CEO of PathoGenetix, Inc. and was formerly President of Genzyme Biosurgery, where she had responsibilities for Synvisc®, an intra-articular treatment for OA. There, Ann led the growth in Synvisc revenues to over \$400 million. Mr. Mahatme currently serves as Senior Vice President and Chief Financial Officer at Sarepta Therapeutics and has formerly held senior financial positions at Celgene and Pfizer," Dr. Clayman noted.

Second-Quarter Financial Results

The company reported a net loss of \$5.9 million for the three months ended June 30, 2014, compared to a net loss of \$4.6 million for the same period in 2013.

Research and development expenses increased to \$3.6 million for the three months ended June 30, 2014, compared to \$3.1 million for the same period in 2013, due to higher salary and other employee related costs of \$0.5 million, as a result of greater headcount levels.

General and administrative expenses increased to \$2.2 million for the three months ended June 30, 2014, as compared to \$1.4 million for the same period in 2013, due primarily to salary and related employee costs associated with higher headcount levels, as well as insurance costs associated with being a publicly-traded company.

For the six months ended June 30, 2014, the company reported a net loss of \$12.5 million, compared to a net loss of \$9.4 million for the same period in 2013.

Research and development expenses increased to \$7.8 million for the six months ended June 30, 2014 compared to \$6.3 million for the same period in 2013 due to FX006 program expenses related to the initiation of the Phase 2b dose confirmatory trial and manufacturing expenses associated with clinical trial supplies. In addition, increases in salary and other employee related costs including stock compensation expense also contributed to the higher spending level.

General and administrative expenses increased to \$4.5 million for the six months ended June 30, 2014 compared to \$2.9 million for the same period in 2013 due to salary and related employee costs including stock compensation expense due to additional headcount. In addition, increases in legal and professional fees and insurance costs contributed to the higher spending level.

As of June 30, 2014, the company had \$72.0 million in cash and cash equivalents and marketable securities compared to \$16.4 million as of December 31, 2013.

Second Quarter and Recent Corporate Highlights:

- In June 2014, we announced positive topline clinical trial results from a Phase 2a synovial fluid PK study of our lead clinical candidate, FX006. In this trial, we demonstrated for the first time that a single intra-articular injection of FX006 can provide therapeutic concentrations of triamcinolone acetonide in joint fluid for at least 12 weeks. In addition, the PK data from the trial support our previously completed Phase 2b dose-ranging efficacy trial that demonstrated superior magnitude and duration of pain relief over 12 weeks compared to the current standard of care immediate-release triamcinolone acetonide.
- In April 2014, we initiated a confirmatory dose-ranging Phase 2b clinical trial to further identify a safe and well-tolerated dose of FX006 that demonstrates superior pain relief compared to placebo. The Phase 2b clinical trial is a multi-center, randomized, double-blind study in approximately 300 patients with OA of the knee. We expect to have topline data from this clinical trial in the first half of 2015.
- We announced two new Board member appointments: Industry veteran Ann Merrifield, who most recently served as President and CEO of PathoGenetix, Inc. and was formerly President of Genzyme Biosurgery, became a member of our Board in June. In July, Sandy Mahatme, Senior Vice President and Chief Financial Officer at Sarepta Therapeutics, joined the Board and was also appointed as Chairman of the Audit Committee of the Board.
- Also in July, we announced the execution of an exclusive worldwide licensing agreement with SwRI to utilize proprietary microsphere manufacturing technologies for production of Flexion's sustained-release drug candidates, including lead candidate FX006. The exclusive license adds another layer of intellectual property protection for FX006 and provides for an expanded field of use in a variety of musculoskeletal disorders where sustained-release technology could be useful for patients.

Conference Call

At 4:30 p.m. ET today, Flexion's management will host a conference call and webcast to review the Company's second quarter financial results and provide a general business update. The dial-in number for the conference call is toll-free (855) 770-0022 for domestic participants and (908) 982-4677 for international participants. A live webcast of the conference call can also be accessed through the "[Investors](#)" tab on the Flexion Therapeutics website at www.flexiontherapeutics.com. A webcast replay will be available online after the call.

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 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.

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, the potential duration and impact of patent protection for FX006, anticipated clinical and other milestones (including the timing of such milestones), the potential role of FX006 in the treatment of patients with OA of the knee and other musculoskeletal disorders and the protectability of FX006 intellectual property rights 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, whether the company's patents will be held valid and enforceable, 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 possibility that future trial results may not be consistent with past results, the fact that Flexion will require additional capital, including prior to completing Phase 3 development of, filing for regulatory approval for, or 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, 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, 2013 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 we undertake no obligation to update or revise any of the statements.

FLEXION THERAPEUTICS
CONDENSED STATEMENT OF OPERATIONS
(in thousands, except for per share information)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2014	2013	2014	2013
Revenue	\$ --	\$ --	\$ --	\$ --
Operating expenses:				
Research and development	3,615	3,068	7,766	6,255
General and administrative	2,234	1,422	4,518	2,943
Total expenses	5,849	4,490	12,284	9,198
Loss from operations	(5,849)	(4,490)	(12,284)	(9,198)
Interest income (expense), net	28	(52)	(52)	(41)
Other income (expense)	(110)	(56)	(137)	(157)
Loss from operations before income tax	(5,931)	(4,598)	(12,473)	(9,396)
Net loss	(5,931)	(4,598)	(12,473)	(9,396)
Basic and diluted net loss per share	\$ (0.38)	\$ (5.83)	\$ (1.07)	\$ (11.91)
Basic and diluted weighted average number of common shares outstanding	15,619 ¹	789	11,670 ¹	789

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 that is expected to impact the year-over-year comparability of the Company's earnings/loss per share in 2014.

FLEXION THERAPEUTICS
SELECTED BALANCE SHEET DATA
(in thousands)

	June 30,	December 31,
	2014	2013
Cash and cash equivalents	\$12,015	\$16,188
Marketable securities	59,977	250
Total current assets	72,676	16,620
Working capital	68,229	11,584
Total assets	73,212	18,776

Total notes payable	4,570	5,047
Convertible preferred stock (Series A and B)	--	74,806
Total stockholders' equity (deficit)	66,127	(64,704)

CONTACT: Media Contact

Jamie Lacey-Moreira

PressComm PR, LLC

T: 410-299-3310

jamielacey@presscommpr.com

Corporate Contact

Lisa Davidson, MBA

Vice President, Finance and Administration

Flexion Therapeutics, Inc.

T: 781-305-7765

ldavidson@flexiontherapeutics.com