Fibrocell Reports Third Quarter 2018 Financial Results and Recent Highlights

November 13, 2018

- Company to Host Conference Call and Webcast Today at 8:30 a.m. EST –

- Announces patient enrollment completed in Phase 2 of Phase 1/2 clinical trial for FCX-007 for recessive dystrophic epidermolysis bullosa -

EXTON, Pa., Nov. 13, 2018 (GLOBE NEWSWIRE) -- Fibrocell Science, Inc. (NASDAQ: FCSC), a gene therapy company focused on transformational autologous cell-based therapies for skin and connective tissue diseases, today reported financial results for the third quarter ended September 30, 2018 and recent operational highlights. Fibrocell will host a conference call and webcast today at 8:30 a.m. EST.

“During the third quarter, Fibrocell made important progress with the clinical development of our gene therapy programs focused on rare diseases of the skin and connective tissue,” said John Maslowski, President and Chief Executive Officer of Fibrocell. “Most recently, we completed enrollment in the Phase 2 portion of our Phase 1/2 clinical trial for FCX-007 for the treatment of recessive dystrophic epidermolysis bullosa (RDEB).”

“In addition, we completed a Type C meeting with the U.S. Food and Drug Administration (FDA) to discuss the design of a Phase 3 clinical trial protocol for FCX-007. We received valuable guidance from the FDA on the trial’s design and Chemistry, Manufacturing and Control (CMC) requirements. As a result of the feedback from this meeting, we plan to submit the Phase 3 clinical trial protocol in the fourth quarter of 2018 and expect to initiate the trial in the first half of 2019.”

“Our FCX-013 gene therapy program also continued to advance this quarter. We initiated the first investigator site for clinical enrollment in a Phase 1/2 clinical trial for FCX-013 for the treatment of moderate to severe localized scleroderma. Additionally, the FDA granted Fast Track Designation to FCX-013, which augments its Orphan Drug and Rare Pediatric Disease Designations,” said Mr. Maslowski.

Recent program highlights and new updates are as follows:

FCX-007

- Fibrocell completed a Type C meeting with the FDA to discuss the design of a Phase 3 clinical trial protocol for FCX-007 for the treatment of RDEB. The FDA provided guidance on various clinical trial design aspects and Chemistry, Manufacturing and Control requirements of the proposed Phase 3 clinical trial. Based on the feedback from the meeting, Fibrocell plans to submit the Phase 3 clinical trial protocol in the fourth quarter of 2018 and will provide details on the clinical trial design once it is finalized. The Company expects to initiate the Phase 3 clinical trial in the first half of 2019.

- Fibrocell completed the targeted enrollment of six patients in the Phase 2 portion of the Phase 1/2 clinical trial for FCX-007, and has over-enrolled by one patient for a total of seven patients. The Phase 2 population consists of one adult and six pediatric patients. The Company expects to report an interim data analysis for FCX-007’s Phase 1/2 clinical trial and provide a clinical trial update from Phase 1 patients, including available data from Phase 2 patients, in the first quarter of 2019. Fibrocell plans to continue the Phase 2 portion of its ongoing Phase 1/2 clinical trial to collect additional data while submitting the Phase 3 clinical trial protocol to the FDA in parallel.

- The FDA’s Office of Orphan Products Development (OOPD) awarded a $1.4 million clinical trial research grant for Fibrocell’s continued clinical development of FCX-007. This grant, which will be distributed over the next four years, was presented through the FDA OOPD’s Orphan Products Clinical Trials Grants Program.

FCX-013

- Fibrocell initiated the first investigator site for clinical enrollment in an open label, single arm Phase 1/2 clinical trial for FCX-013.

- FCX-013 was granted Fast Track Designation by the FDA for the treatment of moderate to severe localized scleroderma. Previously, the FDA granted Orphan Drug and Rare Pediatric Designation to FCX-013.

Corporate

- Fibrocell closed a registered direct public offering of its common stock in July, which was priced at-the-market, for gross proceeds of approximately $3.9 million. In a concurrent private placement, the Company also issued unregistered warrants, representing 65% of the shares of common stock purchased in the registered direct public offering, to purchase shares of Fibrocell common stock for gross proceeds of approximately $0.1 million. The net proceeds of these offerings were approximately $3.5 million.

Financial Results for the Nine Months Ended September 30, 2018

For the nine months ended September 30, 2018, Fibrocell reported a diluted net loss of $1.31 per share, compared to a diluted net loss of $7.92 per share for the same period in 2017.

The 2018 period included approximately $0.6 million of non-cash warrant revaluation income, as compared to approximately $4.7 million of non-cash warrant revaluation expense for the same period in 2017.

Research and development expenses decreased 50.2% to approximately $4.5 million for the nine months ended September 30, 2018, as compared to approximately $9.0 million for the same nine-month period in 2017. This decrease was due primarily to decreased costs for our FCX-007 program of approximately $3.0 million, or 83.0%, to approximately $0.6 million for the nine months ended September 30, 2018, as compared to approximately $3.6 million for the same period in 2017. These decreased costs were the result primarily of transitioning from dosing of adult patients and analysis of data in the Phase 1 portion of the Phase 1/2 clinical trial for FCX-007 to recruitment for the Phase 2 portion of the trial, and moving our manufacturing operations for the drug product used in the Phase 1/2 clinical trial for FCX-007 in-house from a third party manufacturer.

Costs for the FCX-013 program decreased approximately $1.5 million, or 79.5%, to approximately $0.4 million for the nine months ended September 30, 2018, as compared to approximately $1.8 million for the same period in 2017. This decrease was related primarily to decreased costs from Precigen of approximately $1.3 million, as substantially all of the costs of the pre-clinical phase of the FCX-013 program were incurred at the end of 2017, while the first nine months of 2018 has been used for clinical trial start-up activities.

Selling, general and administrative expenses decreased 8.1% to approximately $4.7 million for the nine months ended September 30, 2018, as compared to approximately $5.1 million for the same nine-month period in 2017. This decrease was related primarily to lower costs for professional fees.

Fibrocell used approximately $10.2 million in cash for operations during the nine months ended September 30, 2018, and used approximately $12.9 million in cash for operations during the nine months ended September 30, 2017.

As of September 30, 2018, the Company had cash and cash equivalents of approximately $16.1 million and working capital of approximately $14.6 million. The Company believes that its cash and cash equivalents will be sufficient to fund operations into the fourth quarter of 2019.

Conference Call and Webcast

To participate on the live call, please dial 877-260-1479 (domestic) or +1-334-323-0522 (international), and provide the conference code 7133925 five to ten minutes before the start of the call. The conference call will also be webcast live under the investor relations section of Fibrocell's website at www.fibrocell.com/investors/events and will be archived there for 30 days following the call.

About Fibrocell

Fibrocell is an autologous cell and gene therapy company translating personalized biologics into medical breakthroughs for diseases affecting the skin and connective tissue. Fibrocell's most advanced product candidate, FCX-007, is the subject of a Phase 1/2 clinical trial for the treatment of RDEB. Fibrocell is also developing FCX-013, the Company's clinical stage candidate for the treatment of moderate to severe localized scleroderma. Fibrocell's gene therapy portfolio is being developed in collaboration with Precigen, Inc., a wholly owned subsidiary of Intrexon Corporation (NASDAQ: XON), a leader in synthetic biology. For more information, visit www.fibrocell.com or follow Fibrocell on Twitter at @Fibrocell.

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Forward-Looking Statements

This press release contains, and our officers and representatives may from time to time make, statements that are "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. All statements that are not historical facts are hereby identified as forward-looking statements for this purpose and include, among others, statements relating to: Fibrocell's expectations regarding the timing and clinical development of FCX-007, including the Company's plans to submit a Phase 3 clinical trial protocol to the FDA in the fourth quarter of 2018 and commence a Phase 3 clinical trial for FCX-007 in the first half of 2019; Fibrocell's plans to continue the Phase 2 portion of its ongoing Phase 1/2 clinical trial for FCX-007 to collect additional data while submitting the Phase 3 protocol to the FDA in parallel; the timing of reporting of interim data and trial updates for its Phase 1/2 clinical trial of FCX-013; the potential advantages of Fibrocell's product candidates; the sufficiency of the Company's cash and cash equivalents to fund operations into the fourth quarter of 2019 and other statements regarding Fibrocell's future operations, financial performance and financial position, prospects, strategies, objectives and other future events.

Forward-looking statements are based upon management's current expectations and assumptions and are subject to a number of risks, uncertainties and other factors that could cause actual results and events to differ materially and adversely from those indicated herein including, among others: that the FDA's official meeting minutes may differ materially from the Company's understanding of the results of the Type C meeting with the FDA; uncertainties and delays in the FDA review and approval of the Phase 3 clinical trial protocol for FCX-007; uncertainties and delays relating to the initiation, enrollment and completion of clinical trials; whether clinical trial results will validate and support the safety and efficacy of Fibrocell's product candidates; unanticipated or excess costs relating to the development of Fibrocell's gene therapy product candidates; Fibrocell's ability to obtain additional capital to continue to fund operations; uncertainties associated with being able to identify, evaluate and complete any strategic transaction or alternative; the impact of the announcement any strategic transaction or alternative that may be pursued, on the Company's business, including its financial and operating results and its employees; Fibrocell's ability to maintain its collaboration with Precigen, Inc.; and the risks, uncertainties and other factors discussed under the caption "Item 1A. Risk Factors" in Fibrocell's most recent Form 10-K filing and Form 10-Q filings. As a result, you are cautioned not to place undue reliance on any forward-looking statements. While Fibrocell may update certain forward-looking statements from time to time, Fibrocell specifically disclaims any obligation to do so, whether as a result of new information, future developments or otherwise.

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Fibrocell Science, Inc.
Condensed Consolidated Statements of Operations
(unaudited)
($ in thousands, except share and per share data)

	Nine Months Ended September 30,	
	2018	**2017**
Total revenues	$ —	$ —
Total cost of revenue	—	—
Gross profit (loss)	—	—
Research and development expense	4,601	4,800
Research and development expense - related party (see Note 8)	(134)	4,168
Selling, general and administrative expense	4,696	5,109
Operating loss	(9,163)	(14,077)
Other income (expense):		
Warrant revaluation income (expense)	591	(4,742)
Derivative revaluation income (expense)	266	287
Interest expense	(575)	(641)
Other income, net	227	33
Loss before income taxes	(8,654)	(19,140)
Income taxes	—	—
Net loss	(8,654)	(19,140)
Dividend paid in-kind to preferred stockholders	(250)	(182)
Deemed dividend on preferred stock (see Note 10)	(377)	(3,981)
Net loss attributable to common stockholders	$ (9,281)	$ (23,303)
Per Share Information:		
Net loss:		
Basic	$ (1.31)	$ (7.92)
Diluted	$ (1.31)	$ (7.92)
Weighted average number of common shares outstanding:		
Basic	7,107,678	2,942,202
Diluted	7,107,678	2,942,202

Condensed Consolidated Balance Sheets Data:	**September 30, 2018**	**December 31, 2017**
Cash and cash equivalents	$ 16,111	$ 17,417
Working capital	14,594	13,477
Total assets	17,701	19,411
Warrant liability, long term	482	1,073
Total liabilities	7,517	10,404
Total stockholders' equity	10,184	9,007