Fibrocell Reports Second Quarter 2019 Financial Results and Recent Operational Highlights

August 14, 2019

- Company to Host Conference Call and Webcast on Thursday, August 15 at 8:30 a.m. EDT -

EXTON, Pa., Aug. 14, 2019 (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 second quarter ended June 30, 2019 and recent operational highlights. Fibrocell will also host a conference call and webcast on Thursday, August 15 at 8:30 am EDT to discuss its financial results and operational highlights. A question-and-answer session will follow Fibrocell's remarks.

"Our dedicated team has continued to make progress during the second quarter of 2019 by achieving key milestones that, we believe, will serve as catalysts for advancing our gene therapy clinical programs for rare genetic conditions of the skin and connective tissue," said John Maslowski, President and Chief Executive Officer of Fibrocell.

Recent program highlights are as follows:

FCX-007

- Fibrocell announced in May 2019 that the U.S. Food and Drug Administration (FDA) granted the Regenerative Medicine Advanced Therapy (RMAT) designation to FCX-007 for the treatment of recessive dystrophic epidermolysis bullosa (RDEB). The RMAT designation augments the Orphan Drug, Rare Pediatric Disease and Fast Track designations previously granted to FCX-007 by the FDA.

- Based on guidance from a Type C meeting and a Type B end-of-Phase 2 meeting with the FDA on the design of a proposed Phase 3 clinical trial of FCX-007, Fibrocell updated the Chemistry, Manufacturing and Controls (CMC) information filed to the Investigational New Drug (IND) application for FCX-007 in early July 2019. Fibrocell's Phase 3 clinical trial, named DEFI-RDEB (***de****rmal* ***fi****broblasts-****RDEB***), is designed as an open label, multi-centered, intra-patient controlled trial expected to enroll 15-20 patients.

- In late July 2019, Fibrocell initiated the Phase 3 clinical trial of FCX-007. Fibrocell projects enrollment and dosing of Phase 3 patients will be completed in the third quarter of 2020, and data collection for the primary endpoint will be completed in the fourth quarter of 2020. The Phase 3 trial's primary outcome measure is the comparison of the proportion of FCX-007 treated and untreated matched wounds with complete wound closure at week 12. If the Phase 3 clinical trial is successful and completed within the projected timeframe, Fibrocell expects to file a Biologics License Agreement (BLA) for FCX-007 in 2021.

FCX-013

- Fibrocell is currently enrolling the Phase 1 portion of a Phase 1/2 clinical trial for FCX-013 for the treatment of moderate to severe localized scleroderma and expects to complete enrollment of Phase 1 adult patients in the third quarter of 2019. The Company projects that safety and efficacy data for the adult patients will be available in mid-2020.

Financial Results for the Six Months Ended June 30, 2019

For the six months ended June 30, 2019, Fibrocell reported diluted net income of $0.78 per share, compared to a diluted net loss of $1.03 per share for the same period in 2018. This change in the 2019 period was due to our April 2019 collaboration with Castle Creek Pharmaceuticals.

Revenue for the six months ended June 30, 2019, was approximately $21.8 million. Related to the sale of an exclusive license to commercialize FCX-007 in the United States, we recognized approximately $21.0 million in revenue consisting of the $7.5 million upfront payment received and approximately $13.5M to be collected over the development period. In addition, we recognized approximately $0.8 million in revenue related to the reimbursement of expenses for FCX-007 under the Castle Creek Pharmaceuticals Agreement. We had no revenues for the 2018 period.

Cost of revenue for the six months ended June 30, 2019, was approximately $5.2 million. These expenses were the result of an approximately $3.8 million license fee due to our clinical partner, Intrexon Corporation (Intrexon) related to the $7.5 million upfront payment we received under the Castle Creek Pharmaceuticals Agreement, and approximately $1.4 million in research and development expenses paid for by Castle Creek Pharmaceuticals under the Castle Creek Pharmaceuticals Agreement as reimbursement.

Research and development expenses decreased approximately $0.3 million, or 11.4%, to approximately $2.5 million for the six months ended June 30, 2019. Exclusive of the reclassification of $1.4 million of research and development expenses to costs of revenue, research and development expenses would have increased by approximately $1.1 million to approximately $4.0 million, or 39.9%. This increase was due primarily to increased costs related to the FCX-007 program of approximately $1.3 million, primarily for the purchase of vector and plasmid material in the 2019 period, while the 2018 period included an approximately $0.5 million credit for the settlement of a dispute with a vendor. Research and development expenses related to our FCX-013 program were reduced by approximately $0.3 million due to lower costs from Intrexon and decreased costs for lab supplies and consulting expenses.

Selling, general and administrative costs increased approximately $1.1 million to approximately $4.3 million for the six months ended June 30, 2019, due primarily to increased investment banking and legal fees related to the Castle Creek Pharmaceuticals Agreement.

Fibrocell used approximately $0.6 million in cash for operations during the six months ended June 30, 2019 and used approximately $7.5 million in cash for operations during the six months ended June 30, 2018. This decrease is due primarily to the $7.5 million upfront payment the Company received as part of the Castle Creek Pharmaceuticals Agreement.

As of June 30, 2019, the Company had cash and cash equivalents of approximately $13.7 million and working capital of approximately $17.8 million. The Company believes that its cash and cash equivalents at June 30, 2019, along with the anticipated milestone payment due upon enrollment of the first patient in the Phase 3 clinical trial of FCX-007 ($2.5 million less $1.25 million payable to Intrexon) and the reimbursement of development costs for FCX-007 under the Castle Creek Pharmaceuticals Agreement, will be sufficient to fund operations into the third quarter of 2020.

Conference Call and Webcast

To participate on the live call, please dial 888-254-3590 (domestic) or +1-929-477-0448 (international) and provide the conference code 3755211 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 FCX-007

FCX-007 is Fibrocell's clinical stage, gene therapy product candidate for the treatment of RDEB, a congenital and progressive orphan skin disease caused by the deficiency of the protein COL7. FCX-007 is a genetically-modified autologous fibroblast that encodes the gene for COL7. By genetically modifying autologous fibroblasts *ex vivo* to produce COL7, culturing them and then treating wounds locally via injection, FCX-007 offers the potential to address the underlying cause of the disease by providing high levels of COL7 directly to the affected areas while avoiding systemic distribution.

FCX-007 has been granted Orphan Drug designation, Rare Pediatric Disease designation, Fast Track designation and RMAT designation by the FDA.

Fibrocell is developing FCX-007 in collaboration with Intrexon (Nasdaq: XON), a leader in synthetic biology. In addition, Fibrocell is working in collaboration with Castle Creek Pharmaceuticals to develop and commercialize FCX-007 for the treatment of RDEB. Castle Creek Pharmaceuticals is recognized for its innovation in drug development for rare skin diseases and its commitment to bringing novel therapies to those living with epidermolysis bullosa.

About FCX-013

FCX-013 is Fibrocell's clinical stage, gene therapy candidate for the treatment of moderate to severe localized scleroderma. FCX-013 is an autologous fibroblast genetically modified using lentivirus and encoded for matrix metalloproteinase 1 (MMP-1), a protein responsible for breaking down collagen. FCX-013 incorporates Intrexon's proprietary RheoSwitch Therapeutic System ®, a biologic switch activated by veledimex—an orally administered compound—to control protein expression at the site of the localized scleroderma lesions. FCX013 is designed to be injected under the skin at the location of the fibrotic lesions where the genetically-modified fibroblast cells will produce MMP-1 to break down excess collagen accumulation.

The FDA has granted Orphan Drug designation, Rare Pediatric Disease designation and Fast Track designation to FCX-013.

About Fibrocell

Fibrocell is a cell and gene therapy company focused on improving the lives of people with rare diseases of the skin and connective tissue. The Company is utilizing its proprietary autologous fibroblast technology to develop personalized biologics that target the underlying cause of disease. Fibrocell's pipeline of localized gene therapy candidates include FCX-007 for the treatment of RDEB, a life-threatening genetic disorder diagnosed in infancy with no cure or treatment approved by the FDA. A pivotal Phase 3 clinical trial for FCX-007 was initiated in late July 2019. Fibrocell is also developing FCX-013 for the treatment of moderate to severe localized scleroderma and is currently enrolling the Phase 1 portion of a Phase 1/2 clinical trial. For more information, visit www.fibrocell.com or follow us 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; Fibrocell's potential to earn future milestone and profit share payments under the Castle Creek Pharmaceuticals Agreement; the expected trial design of DEFI-RDEB, and expectation to enroll 15-20 patients therein; the timing of Fibrocell's Phase 1/2 clinical trial of FCX-013, including its expectation to complete enrollment of Phase 1 adult patients in the third quarter of 2019; Fibrocell's projection to complete enrollment and dosing of FCX-007 Phase 3 patients in the third quarter of 2020 and complete data collection for the primary endpoint in the fourth quarter of 2020; Fibrocell's expectation to file a BLA for FCX-007 in 2021; Fibrocell's projection that safety and efficacy data for the adult patients in the Phase 1 portion of a Phase 1/2 clinical trial for FCX-013 will be available in mid-2020; the potential advantages of FCX-007, FCX-013 and Fibrocell's other product candidates; the potential benefits of the Fast Track designation, Orphan Drug designation, Rare Pediatric Disease designation and RMAT designation; the Company's belief that its cash and cash equivalents, along with the anticipated milestone payment due upon enrollment of the first patient in the Phase 3 clinical trial of FCX-007 and the reimbursement of development costs for FCX-007 under the Castle Creek Pharmaceuticals Agreement, will be sufficient to fund operations into the third quarter of 2020 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: the

ability of Fibrocell and Castle Creek Pharmaceuticals to meet objectives tied to milestones and profit share payments; 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; Fibrocell's ability to maintain its collaborations with Intrexon and Castle Creek Pharmaceuticals; Castle Creek Pharmaceuticals' ability to successfully commercialize FCX-007, if approved; 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)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
License revenue	$ 20,979	$ —	$ 20,979	$ —
Collaboration revenue	813	—	813	—
Total revenues	21,792	—	21,792	—
Cost of license - related party	3,750	—	3,750	—
Cost of collaboration revenue	1,355	—	1,355	—
Cost of collaboration revenue - related party	67	—	67	—
Total cost of revenue	5,172	—	5,172	—
Gross profit	16,620	—	16,620	—
Research and development expense	600	1,415	2,543	3,060
Research and development expense - related party (see Note 10)	(4)	106	40	(197)
Selling, general and administrative expense	2,456	1,556	4,326	3,195
Operating income (loss)	13,568	(3,077)	9,711	(6,058)
Other income (expense):				
Warrant revaluation income	37	91	8	326
Derivative revaluation income (expense)	(1,138)	242	(1,083)	179
Interest expense	(200)	(191)	(397)	(381)
Other income, net	110	41	472	139
Income (loss) before income taxes	12,377	(2,894)	8,711	(5,795)
Income tax (expense)	(634)	—	(634)	—
Net income (loss)	11,743	(2,894)	8,077	(5,795)
Dividend paid in-kind to preferred stockholders	(86)	(83)	(171)	(165)
Deemed dividend on preferred stock (see Note 12)	(145)	(126)	(285)	(247)
Net income (loss) attributable to common stockholders	$ 11,512	$ (3,103)	$ 7,621	$ (6,207)
Per Share Information:				
Net income (loss):				
Basic	$ 1.18	$ (0.49)	$ 0.78	$ (1.03)
Diluted	$ 1.12	$ (0.49)	$ 0.77	$ (1.03)
Weighted average number of common shares outstanding:				
Basic	9,758,332	6,376,048	9,758,332	6,026,454
Diluted	11,697,391	6,376,048	10,509,881	6,026,454

Condensed Consolidated Balance Sheets Data:	June 30, 2019	December 31, 2018
Cash and cash equivalents	$ 13,675	$ 14,430
Working capital	17,765	12,363
Total assets	34,856	15,758
Warrant liability, long term	144	152
Total liabilities	16,993	6,201
Total stockholders' equity	17,863	9,557

Source: Fibrocell Science Inc.