UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 25, 2018

FIBROCELL SCIENCE, INC.
(Exact Name of Registrant as Specified in its Charter)

DELAWARE	**001-31564**	**87-0458888**
(State or Other Jurisdiction of Incorporation or Organization)	(Commission File No.)	(I.R.S. Employer Identification No.)

405 EAGLEVIEW BLVD., EXTON, PA 19341
(Address of principal executive offices and zip code)

(484) 713-6000
(Registrant's telephone number, including area code)

(Former name or former address, if changed from last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

❑ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

❑ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

❑ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

❑ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-14(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On October 25, 2018, Fibrocell Science Inc. (the "Company") issued a press release announcing that it recently held a Type C meeting with the U.S. Food and Drug Administration to discuss the design of a Phase 3 clinical trial protocol of FCX-007, the Company's gene therapy candidate for the treatment of recessive dystrophic epidermolysis bullosa. A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated October 25, 2018.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

Fibrocell Science, Inc.

By: /s/ John M. Maslowski

John M. Maslowski

President and Chief Executive Officer

Date: October 25, 2018

FIBROCELL

Fibrocell Receives Guidance from FDA on Phase 3 Clinical Trial Design for FCX-007

- Company Plans to Submit Phase 3 Protocol to FDA in Fourth Quarter of 2018 and Commence Trial in First Half of 2019 -

EXTON, PA – October 25, 2018 – Fibrocell Science, Inc. (NASDAQ: FCSC), a gene therapy company focused on transformational autologous cell-based therapies for skin and connective tissue diseases, today announced completion of a Type C meeting with the U.S. Food and Drug Administration (FDA) to discuss the design of a Phase 3 clinical trial protocol of FCX-007, the Company's gene therapy candidate for the treatment of recessive dystrophic epidermolysis bullosa (RDEB). The meeting was facilitated by the current data in Fibrocell's ongoing Phase 1/2 clinical trial of FCX-007 and the recent publication of draft guidance from the FDA in the areas of gene therapy and epidermolysis bullosa.

The FDA provided guidance on various design aspects of Fibrocell's proposed Phase 3 clinical trial. In addition, Fibrocell received guidance on Chemistry, Manufacturing and Control (CMC) requirements for the proposed Phase 3 clinical trial and a potential future Biologics License Application (BLA) for FCX-007. Based on the feedback from the meeting, Fibrocell plans to submit the protocol in the fourth quarter of 2018 and will provide details on the clinical trial design once it is finalized.

"We appreciate the valuable and detailed guidance furnished by the FDA on the design of the proposed Phase 3 clinical trial and advice on CMC requirements," said John Maslowski, President and CEO of Fibrocell. "We look forward to finalizing the Phase 3 protocol design, and plan to initiate the Phase 3 clinical trial in the first half of 2019."

To date, FCX-007 has been evaluated in five RDEB patients as part of an ongoing Phase 1/2 clinical trial. 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 protocol to the FDA in parallel.

The FDA has granted Orphan Drug Designation, Rare Pediatric Disease Designation and Fast Track Designation to FCX-007.

Fibrocell is developing FCX-007 in collaboration with Precigen, Inc., a wholly owned subsidiary of Intrexon Corporation (NASDAQ: XON), a leader in synthetic biology. Fibrocell manufactures clinical supply of FCX-007 and, if approved, commercial supply of FCX-007 at its cGMP manufacturing facility located in Exton, Pennsylvania. This multi-product, gene therapy manufacturing facility has existing capacity to serve the U.S. RDEB market.

Fibrocell has not yet received the official FDA meeting minutes from the Type C meeting and the information in this release may be altered or supplemented by the information contained in the official meeting minutes. The Company will provide further regulatory updates on FCX-007 after receipt of the official FDA minutes or other correspondence if there are material developments in such minutes or correspondence.

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 type VII collagen (COL7). FCX-007 is a genetically-modified autologous fibroblast that encodes the gene for COL7 and is being developed in collaboration with Precigen, Inc. 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.

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.

Trademarks

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 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; the potential advantages of FCX-007 and Fibrocell’s other product candidates; the potential benefits of Fast Track Designation, Orphan Drug Designation and Rare Pediatric Disease

Designation; 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 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 of the Board of Directors' review of strategic alternatives, as well as 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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