

**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): December 11, 2018

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

DELAWARE
(State or Other Jurisdiction of Incorporation or
Organization)

001-31564
(Commission File No.)

87-0458888
(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-4(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 December 11, 2018, Fibrocell Science Inc. (the "Company") issued a press release announcing that EB Research Partnership, Inc. and Epidermolysis Bullosa Medical Research Foundation have invested \$900,000 to help further the progress of FCX-007, the Company's gene therapy candidate for the treatment of recessive dystrophic epidermolysis bullosa, a rare, devastating, blistering skin disease with high mortality. 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 December 11, 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.

By: **Fibrocell Science, Inc.**
/s/ John M. Maslowski

John M. Maslowski
President and Chief Executive Officer

Date: December 11, 2018



**Fibrocell Receives \$900,000 Investment from EB Research Partnership and
Epidermolysis Bullosa Medical Research Foundation**

**– Funding to Help Further Clinical Development of FCX-007 Gene Therapy
for Treatment of Recessive Dystrophic Epidermolysis Bullosa –**

EXTON, PA – December 11, 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 that EB Research Partnership, Inc. (EBRP) and Epidermolysis Bullosa Medical Research Foundation (EBMRF) have invested \$900,000 to help further the progress of FCX-007, the Company's gene therapy candidate for the treatment of recessive dystrophic epidermolysis bullosa (RDEB), a rare, devastating, blistering skin disease with high mortality.

Fibrocell received this funding following a competitive application and evaluation process managed by EBRP's Scientific Advisory Board (SAB), a prominent panel of physicians and scientists specializing in genetics, hematology, protein therapy and dermatology. The SAB awards research grants to products and therapies that offer notable commercial promise for treating and/or curing epidermolysis bullosa.

"We are grateful for this investment from EBRP and EBMRF that will be used to support the continued clinical development of FCX-007," said John Maslowski, President and Chief Executive Officer of Fibrocell. "We believe this funding further recognizes the significant potential of FCX-007 to make a difference for RDEB patients by treating the underlying cause of the chronic, debilitating and painful wounds and blisters of the disease."

Under the terms of the investment, EBRP and EBMRF received an aggregate of 443,350 shares of Fibrocell's common stock. The offer, sale, and issuance of the shares were made in a private placement transaction exempt from registration pursuant to Rule 506 of Regulation D and Section 4(a)(2) of the Securities Act of 1933, as amended. The shares are subject to certain restrictions on re-sale under Rule 144.

"Through our venture philanthropy model, EB Research Partnership is proud to support the trailblazers of industry, research and academia who are tirelessly working to develop potentially transformative therapies for EB patients," said Michael Hund, Executive Director of EBRP. "We are delighted to have Fibrocell as a partner who shares our team's dedication and vision to one day deliver a cure for EB."

"The EB Medical Research Foundation is pleased to support Fibrocell's clinical development of FCX-007, a potentially life-changing, gene therapy that addresses the underlying cause of RDEB," said Paul Joseph, Chief Financial Officer of EBMRF. "Our organization is dedicated to finding a

cure for EB and, we believe, Fibrocell's innovative approach aligns with our goal and distinguishes FCX-007 as a promising therapeutic solution for patients suffering from this devastating disease."

FCX-007 is currently being evaluated in the Phase 2 portion of a Phase 1/2 clinical trial for the treatment of RDEB. Fibrocell recently announced the 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, and plans to submit the protocol in the fourth quarter of 2018 and initiate the trial in the first half of 2019.

The FDA has granted FCX-007 Orphan Drug, Rare Pediatric Disease and Fast Track Designation. 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 cell manufacturing facility located in Exton, Pennsylvania.

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 the Phase 1/2 Clinical Trial

The primary objective of this open-label clinical trial is to evaluate the safety of FCX-007 in RDEB patients. Additionally, the trial is assessing wound healing and pharmacology at 4, 12, 25 and 52 weeks post-administration. Six patients ages seven and older are targeted to be treated with FCX-007 in the Phase 2 portion of the trial. To learn more about the clinical trial, please visit www.clinicaltrials.gov and search the identifier [NCT02810951](https://clinicaltrials.gov/ct2/show/study/NCT02810951).

About EB Research Partnership

Founded in 2010, EB Research Partnership (EBRP) is the largest 501(c)(3) nonprofit dedicated to funding research aimed at treating and ultimately curing Epidermolysis Bullosa (EB), a group of devastating and life-threatening skin disorders that affect children from birth. EB Research Partnership works to treat and cure EB as quickly and efficiently as possible and fulfills their mission by partnering with non-profit and for-profit organizations, foundations, individual donors, and the EB and research communities. EB Research Partnership utilizes an innovative business model of venture philanthropy, when making a grant to a research project they retain the added upside of generating a recurring revenue stream if the therapy or product is commercially

successful, then use the return on investment to fund additional EB research until a cure is found. To learn more about EB Research Partnership visit www.ebresearch.org.

About EB Medical Research Foundation

The EBMRF is an all-volunteer, non-profit 501(c) Foundation dedicated to funding research for EB, a rare, debilitating and often fatal skin disease. Our mission is to determine its causes, develop successful treatments, and ultimately find a cure. The grants awarded with your donations fund an aggressive research agenda aimed at developing breakthrough therapies in collaboration with Universities and leading private and public biotechnology companies. EBMRF's scientific collaborations incorporate a venture philanthropy model, in which we participate in the economics of any potential scientific commercialization. Royalties and revenue generated from our venture agreements are then reinvested to further advance critical research. The foundation's goal is to cure EB by raising awareness through special events, the media and fundraising programs. For more information, please visit www.ebmrf.org.

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](https://twitter.com/Fibrocell).

Trademarks

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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 expected use of the proceeds from the investment; Fibrocell's expectations regarding the timing and clinical development of FCX-007; the potential advantages of FCX-007 and Fibrocell's other product candidates; the potential benefits of the investment from EBRP and EBMRF; 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 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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