

**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): May 21, 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 May 21, 2018, the Company issued a press release announcing interim results and progress of its Phase 1/2 clinical trial of FCX-007. A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
<u>99.1</u>	<u>Press Release dated May 21, 2018.</u>

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: May 21, 2018



Fibrocell Reports on Interim Results and Progress of Phase 1/2 Clinical Trial of FCX-007 Gene Therapy for Recessive Dystrophic Epidermolysis Bullosa

- FCX-007 well-tolerated up to 52 weeks post-administration –
- Continued positive trends noted in wound healing and pharmacology signals, including type VII collagen expression and evidence of anchoring fibrils –
- Company to Host Conference Call & Webcast Today at 8:30 am EDT–

EXTON, PA – May 21, 2018 – Fibrocell Science, Inc. (NASDAQ: FCSC), a gene therapy company focused on transformational autologous cell-based therapies for skin and connective tissue diseases, today provided an update on the interim results and progress of its Phase 1/2 clinical trial of FCX-007 for the treatment of recessive dystrophic epidermolysis bullosa (RDEB). The results were presented by M. Peter Marinkovich, MD, the trial's Study Director at the Stanford University site and Associate Professor of Dermatology at the Stanford University School of Medicine, at the 7th International Investigative Dermatology meeting on May 19, 2018.

Four adult patients (n=7 wounds) aged 20 to 37 have been dosed with FCX-007 in the margins of and across targeted wounds, as well as in separate intact skin sites. Three patients received a single intradermal injection session at baseline. One patient received a second injection session in the remaining unhealed areas of wounds at 25 weeks post-administration, as allowed by the clinical trial protocol.

Safety data from these patients show FCX-007 was well-tolerated up to 52 weeks post-administration. There were no serious adverse events and no product related adverse events reported. No type VII collagen (COL7) autoantibody response was noted.

Various COL7 expression signals were detected throughout the data set using either immunofluorescence (IF) or immunoelectron microscopy (IEM) up to 52 weeks post-administration. Anchoring fibril structures have also been observed using IEM.

Wounds were evaluated during a monitoring period prior to dosing and they were observed to be open for up to eight months. Compared to the baseline measurement collected at Day 0 before the administration of FCX-007, the percentage of dosed wounds healing $\geq 50\%$ when compared to baseline were observed as follows:

- 100% (7/7) at 4 weeks post-administration
- 86% (6/7) at 12 weeks
- 67% (2/3) at 25/32 weeks
- 100% (1/1) at 52 weeks

A similar trend was also observed for treated wounds healing $\geq 75\%$ when compared to baseline. Untreated wounds of similar size to the treated wounds were selected and monitored as controls on each patient. The percentage of untreated control wounds healing $\geq 50\%$ when compared to baseline were observed as follows:

- 14% (1/7) at 4 weeks post-administration
- 17% (1/6) at 12 weeks
- 0% (0/2) at 25/32 weeks
- 0% (0/1) at 52 weeks

"The Phase 1 portion of the trial of FCX-007 continues to be encouraging and reinforces the potential for treating RDEB patients," said Alfred Lane, MD, Chief Medical Advisor of Fibrocell and Professor of Dermatology and Pediatrics (Emeritus) at the Stanford University School of Medicine. "As we move into Phase 2 of the trial, I am looking forward to incorporating these learnings into the trial and determining the impact on patient outcomes."

There is one patient enrolled in the Phase 2 portion of the trial, with three additional screening visits scheduled prior to the end of June 2018. Enrollment of six patients is expected to be completed in the third quarter of 2018.

"We are pleased with the continued progress of our FCX-007 program that offers promise to be transformative for RDEB patients," said John Maslowski, President and Chief Executive Officer of Fibrocell. "Based on safety, pharmacology and wound healing data, we plan to continue exploring dose range and administration for future patients. We are looking forward to moving ahead with this protocol that advances the clinical trial of FCX-007 and positions us to achieve future milestones for the program."

Fibrocell is developing FCX-007 in collaboration with Precigen, Inc., a wholly owned subsidiary of Intrexon Corporation (NYSE: XON), a leader in synthetic biology.

Fibrocell Conference Call & Webcast

On Monday, May 21, 2018 at 8:30 a.m. EDT, Fibrocell will host a conference call and webcast to discuss the interim results and progress of the Phase 1/2 clinical trial of FCX-007. A slide presentation summarizing the data will be referenced during the call and is posted in the Investors section of the Company's website www.fibrocell.com/investors/events under the event, "Fibrocell FCX-007 Conference Call & Webcast." Following the presentation, there will be a question-and-answer session with John Maslowski, President and CEO of Fibrocell, and Alfred Lane, MD, Chief Medical Advisor of Fibrocell and Professor of Dermatology and Pediatrics (Emeritus) at the Stanford University School of Medicine.

To participate on the live call, please dial 866-548-4713 (domestic) or +1-323-794-2093 (international) and provide the conference code 5629866. The conference call will also be webcast live from the Investors section of Fibrocell's website at www.fibrocell.com/investors/events under the event, "Fibrocell FCX-007 Conference Call & Webcast," and will be archived there for 30 days.

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., a wholly owned subsidiary

of Intrexon Corporation. 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, Rare Pediatric Disease and Fast Track Designations by the U.S. Food and Drug Administration.

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 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 product 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 (NYSE: 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

Fibrocell, the Fibrocell logo, and Fibrocell Science are trademarks of Fibrocell Science, Inc. and/or its affiliates. All other names may be trademarks of their respective owners.

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 exploration of strategic alternatives; the timing of dosing and reporting of interim data and trial updates for its Phase 1/2 clinical trial of FCX-007; the completion of enrollment in the Phase 2 portion of its Phase 1/2 clinical trial of FCX-007; the potential for FCX-007 to receive Priority Review Vouchers upon market authorization; the potential advantages of Fibrocell's product candidates; 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 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; that interim clinical trial results are not necessarily indicative of final clinical results and final clinical trial results may not be positive with regard to safety or efficacy of FCX-007; uncertainties and delays relating to the initiation, enrollment and completion of pre-clinical studies and clinical trials; whether pre-clinical study and 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 collaboration with Precigen, Inc., a wholly owned subsidiary of Intrexon Corporation; 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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