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FIBROCELL SCIENCE, INC.

FORM 8-K
(Current report filing)

Filed 09/26/17 for the Period Ending 09/26/17

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SIC Code	2834 - Pharmaceutical Preparations
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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): September 26, 2017

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 or Rule 12b-2 of the Securities Exchange Act of 1934. 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 September 26, 2017, Fibrocell Science, Inc. (the "Company") issued a press release announcing the interim results of the Phase 1/2 Clinical Trial of FCX-007 Gene Therapy for Recessive Dystrophic Epidermolysis Bullosa. A copy of the press release is furnished herewith as Exhibit 99.1.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated September 26, 2017

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: September 26, 2017

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release dated September 26, 2017

FIBROCELL

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

- FCX-007 well-tolerated through 12 weeks post-administration with encouraging safety and positive early trends noted in wound healing and pharmacology signals -

- Data Safety Monitoring Board recommends continued enrollment and dosing -

EXTON, PA - September 26, 2017 - Fibrocell Science, Inc. (NASDAQ: FCSC), a gene therapy company focused on transformational autologous cell-based therapies for skin and connective tissue diseases, today reported interim results in its Phase 1/2 clinical trial of FCX-007 for the treatment of recessive dystrophic epidermolysis bullosa (RDEB).

Three adult non-collagenous (NC)1+ patients have been dosed with a single intradermal injection session of FCX-007 in the margins of and across targeted wounds, as well as in separate intact skin sites. Five wounds were treated on the three subjects, ranging in size from 4.4cm ^{2} to 13.1cm ^{2}.

Data from these patients show FCX-007 was well-tolerated through 12 weeks post-administration. There were no serious adverse events and no product related adverse events reported.

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 single intradermal injection session of FCX-007, at four weeks post-administration 100% (5/5) of wounds were $\geq$ 75% healed. At 12 weeks post-administration, 80% (4/5) of wounds were $\geq$ 70% healed.

Various pharmacology signals for vector DNA, type VII collagen (COL7) mRNA, or COL7 protein expression were detected throughout the data set in each patient for one or more assays up to 12 weeks post-administration (qPCR, electron microscopy or immunofluorescence). Anchoring fibrils have not been detected to date, whereas expressed COL7 mRNA and COL7 protein have been confirmed in multiple patient samples including one that detected linear expression of COL7 at the basement membrane zone.

“I am pleased with the interim data collected for the first three patients in the trial,” said Alfred Lane, MD, Chief Medical Advisor of Fibrocell and Professor of Dermatology and Pediatrics (Emeritus) at the Stanford University School of Medicine. “Safety is paramount in any new gene therapy candidate, and the detection of linear COL7 expression at the basement membrane zone is encouraging as it indicates the potential of FCX-007 to produce COL7 in the proper location of the skin structure. We believe increases in dosing and expression will enhance the consistency of effect as we continue clinical analysis and expand the treated patient population.”

The Data Safety Monitoring Board for the trial reviewed the interim data and concluded that safety and potential benefit were established, and allowed continuation of enrollment and dosing. With data from the first three patients meeting the primary trial objective of safety, the Company plans to increase expression and dosing FCX-007.

“FCX-007 to date has shown encouraging safety and positive early trends in pharmacology and wound healing with only a single injection session of cells,” stated John Maslowski, President and Chief Executive Officer of Fibrocell. “These interim results are a positive step towards our ultimate goal of bringing relief to patients and families suffering from this debilitating disease. In the coming months, we look forward to performing additional dosing and enhancing COL7 expression, and working with the FDA to further advance the program.”

Fibrocell will present on Wednesday, October 4 at the annual Partnering Forum, part of the Cell & Gene Meeting on the Mesa to be held October 4-6 in La Jolla, California. Webcast information for this presentation will be provided in a future press release.

Fibrocell is developing FCX-007 in collaboration with Intrexon Corporation (NYSE: XON), a leader in synthetic biology.

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 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 (FDA).

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 will assess the pharmacology of FCX-007 through evaluation of COL7 expression and the presence of anchoring fibrils, as well as the efficacy of FCX-007 through evidence of wound healing. Assessments are performed at 4, 12, 25 and 52 weeks post-administration of FCX-007. Twelve patients are targeted to be treated with FCX-007 consisting of six adults in the Phase 1 portion of the trial and six patients in the Phase 2 portion of the trial. Prior to conducting clinical trials on pediatric patients in the Phase 2 portion of the trial, Fibrocell is required to obtain allowance from the FDA by submitting evidence of FCX-007 safety and benefit in adult patients and data from its completed pre-clinical toxicology study. To learn more about the FCX-007 Phase 1/2 clinical trial, please visit www.clinicaltrials.gov and search the identifier 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 in pre-clinical development of FCX-013, its product candidate for the treatment of moderate to severe localized scleroderma. Fibrocell's gene therapy portfolio is being developed in collaboration with Intrexon Corporation (NYSE: XON), a leader in synthetic biology. For more information, visit www.fibrocell.com or follow Fibrocell on Twitter at @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 expectations regarding the timing of the completion of adult patient enrollment, dosing and reporting of results for the Phase 1 portion of its Phase 1/2 clinical trial of FCX-007; Fibrocell's plans to increase dosing of FCX-007 and Fibrocell's expectations of the potential results associated therewith; 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: 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 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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