

Fibrocell Science, Inc.
Form 8-K
April 18, 2016

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): April 15, 2016

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-4(c))
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Item 2.02 Results of Operations and Financial Condition.

On April 18, 2016, Fibrocell Science, Inc. (“Fibrocell”) reported unaudited cash and cash equivalents of \$13.1 million as of March 31, 2016. Fibrocell’s actual cash and cash equivalents as of March 31, 2016 may differ due to the completion of its closing procedures with respect to the first quarter ended March 31, 2016, final adjustments, and other developments that may arise between now and the time the financial results for the quarter are finalized.

Item 7.01 Regulation FD Disclosure.

Press Release

On April 18, 2016, Fibrocell issued a press release to provide a regulatory update for FCX-007, its lead gene-therapy product candidate for the treatment of recessive dystrophic epidermolysis bullosa (RDEB). A copy of the press release is furnished herewith as Exhibit 99.1.

Corporate Presentation

On April 18, 2016, Fibrocell posted an updated corporate presentation on its website, www.fibrocell.com. A copy of this presentation is furnished herewith as Exhibit 99.2 and is incorporated by reference herein.

Item 8.01 Other Events.

Development Program Update

On April 15, 2016, Fibrocell received allowance from the U.S. Food and Drug Administration (FDA) to initiate a Phase I/II clinical trial of FCX-007 in adults. The primary objective of the Phase I/II trial will be to evaluate the safety of FCX-007. The secondary objectives will be to (i) assess the mechanism of action of FCX-007 at weeks 12, 25, 52 and unscheduled visits through the evaluation of skin biopsies for COL7 expression and the presence of anchoring fibrils and (ii) assess the efficacy of FCX-007 through an intra-subject paired analysis of target wound area at weeks 4, 12, 25, 52 and unscheduled visits by comparing FCX-007 treated wounds to untreated wounds in Phase I and to wounds administered sterile saline in Phase II through the evaluation of digital imaging of wounds.

Fibrocell aims to enroll 12 subjects in this Phase I/II clinical trial consisting of six adults in the Phase I portion of the trial and, subject to FDA allowance, six pediatric subjects in the Phase II portion of the trial. Fibrocell expects to initiate the Phase I portion of the trial in the second quarter of 2016. Prior to conducting studies on pediatric subjects, Fibrocell is required to obtain allowance from the FDA and submit the following data:

• evidence of FCX-007 activity in adult subjects; and

a final report for its ongoing toxicology study of FCX-007 in severe combined immunodeficiency (SCID) mice, evaluated at one, three and six months following injection of FCX-007. One-month data from this study has already been submitted to the FDA.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated April 18, 2016
99.2	Corporate Presentation dated April 18, 2016

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/ Keith A. Goldan
Keith A. Goldan
SVP and Chief Financial Officer
Date: April 18, 2016

EXHIBIT INDEX

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