Fibrocell Science, Inc.
Form 8-K
July 20, 2015

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 THE EARLIEST EVENT REPORTED): July 20, 2015

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):

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

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

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

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

Item 7.01 – Regulation FD Disclosure.

On July 20, 2015, Fibrocell Science, Inc. ("Fibrocell") issued a press release announcing, among other things, that it had submitted an Investigation New Drug Application ("IND") with the U.S. Food and Drug Administration ("FDA"). A copy of the press release is furnished herewith as Exhibit 99.1 and incorporated by reference herein.

Item 8.01 – Other Events.

On July 20, 2015, Fibrocell submitted an IND with the U.S. Food and Drug Administration ("FDA") for FCX-007 for the treatment of recessive dystrophic epidermolysis bullosa ("RDEB"). Fibrocell expects to initiate a Phase I/II clinical trial by the end of 2015 to evaluate the safety, mechanism of action, and efficacy of FCX-007 for the treatment of RDEB.

Also on July 20, 2015, Fibrocell reported positive proof-of-concept data from in vivo pre-clinical studies of FCX-007 that showed:

- the presence of COL7 in the dermal-epidermal junction of the RDEB cultured grafts in RDEB human skin xenograft severe combined immunodeficiency (SCID) mice; and
- no apparent systemic distribution of the vector in normal human skin xenograft SCID mice.

Cautionary Note About Forward-Looking Statements

Statements in this Form 8-K about the initiation and timing of a Phase I/II clinical trial of FCX-007 for the treatment of RDEB are “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934. These statements are not guarantees of future performance and involve risks and uncertainties including:

- the outcome of regulatory review of the IND;
- regulatory approval to commence the Phase I/II clinical trial;
- Institutional Review Board approval of our trial protocol to conduct the Phase I/II clinical trial at prospective trial sites;
- reaching agreement on acceptable terms with prospective trial sites to conduct the Phase I/II clinical trial;
- the enrollment of patients in the Phase I/II clinical trial;
- manufacturing delays affecting supplies for the Phase I/II clinical trial;
- varying interpretation of research data; and
- the performance of Fibrocell’s partners and other third parties.

These and additional factors that could cause actual results to differ materially from those reflected in forward-looking statements are discussed under the heading “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2014 and in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2015. As a result, readers are cautioned not to place undue reliance on forward-looking statements. Furthermore, the forward-looking statements contained in this Form 8-K reflect Fibrocell’s beliefs and expectations only as of the date of this report. Fibrocell undertakes no obligation to update or revise forward-looking statements whether as a result of new information, future developments or otherwise.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

Exhibit No.	Description
99.1	Press Release dated July 20, 2015

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/ Keith A. Goldan
	Keith A. Goldan
	SVP and Chief Financial Officer

Date: July 20, 2015

EXHIBIT INDEX

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99.1	Press Release dated July 20, 2015