

Fibrocell Science, Inc.
Form 8-K
June 08, 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): June 8, 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):

- 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 7.01 – Regulation FD Disclosure.

On June 8, 2015, Fibrocell Science, Inc. ("Fibrocell") issued a press release announcing positive in vitro pre-clinical data for Fibrocell's lead orphan gene-therapy drug candidate, FCX-007, for the treatment of recessive dystrophic epidermolysis bullosa ("RDEB"). A copy of the press release is furnished herewith as Exhibit 99.1 and incorporated by reference herein.

Item 8.01 – Other Events.

On June 8, 2015, Fibrocell announced positive in vitro pre-clinical data for Fibrocell's lead orphan gene-therapy drug candidate, FCX-007, for the treatment of recessive dystrophic epidermolysis bullosa. The data showed that FCX-007 cells were successfully produced on cGMP-scale by expanding lentivirus-collagen type VII-transduced (LV-COL7-transduced) RDEB patient fibroblasts from a biopsy sample. The results showed:

- The integrated transgene copy number per cell was dose-dependent using a replication-defective, self-inactivating (SIN) lentiviral vector;
- The COL7 expression from the FCX-007 cells was confirmed by three different analytical methods: qRT-PCR, immunofluorescence staining and ELISA;
- The structure of the COL7 expressed by the FCX-007 cells was shown to be predominantly trimeric by immunoprecipitation/SDS-PAGE/Western blot analysis. Naturally-occurring COL7 primarily has this characteristic trimeric structure which is believed to be integral to the creation of anchoring fibrils of necessary strength; and
- The COL7 produced from the FCX-007 cells was demonstrated to be functional by binding to Laminin 332 both in an in vitro binding assay and by correction of the hypermotility phenotype of RDEB cells in an in vitro migration assay. In normal skin, COL7 anchoring fibrils bind to Laminin 332, extracellular matrix proteins, and other collagens to mediate attachment of the dermis to the epidermis.

Preliminary two- and six-week toxicology results using FCX-007 cells in a human skin graft model demonstrated no findings of toxicology in RDEB human skin xenograft severe combined immunodeficiency (SCID) mice.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated June 8, 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: June 8, 2015

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated June 8, 2015