Fibrocell Science, Inc.
Form 8-K
December 13, 2011

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

DECEMBER 13, 2011

Date of Report (date of Earliest Event Reported)

FIBROCELL SCIENCE, INC.

(Exact Name of Registrant as Specified in its Charter)

DELAWARE	**001-31564**	**87-0458888**
(State or Other Jurisdiction of	(Commission File No.)	(I.R.S. Employer Identification No.)

Incorporation or Organization)

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)).

Item 8.01 Other Events.

Fibrocell Science, Inc. (Company) was advised by the FDA that it was unable to grant the Company s request for orphan-drug designation for azficel-T for the repair of post burn contracture scars where surgery has failed, is contraindicated, or when donor sites for repair are not sufficient or desirable due to the physiological condition of the patient, based on the Company s application dated August 30, 2011. The ability to receive orphan-drug designation requires that population estimate for the designation is less than 200,000 in the U.S. Since the data presented to the FDA indicated that azficel-T can repair many kinds of dermal and subcutaneous defects, the FDA stated that the target population of azficel-T includes patients with wounds, scars and contractures induced by many sources. As such, the Company was unable to provide an accurate population estimate, was unable to provide evidence that the prevalence is less than 200,000, and did not provide a plausible rationale for limiting the use of azficel-T to those patients in the proposed indication.

SIGNATURE

Pursuant to the requirements of the Securities and 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.

Date: December 13, 2011

By: /s/ David Pernock
David Pernock,
Chief Executive Officer