

**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 18, 2018

 **FIBROCELL**
FIBROCELL SCIENCE, INC.
(Exact Name of Registrant as Specified in its Charter)

DELAWARE
(State or Other Jurisdiction of Incorporation or
Organization)

001-31564
(Commission File No.)

87-0458888
(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). 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 2.02 Results of Operations and Financial Condition.

On April 18, 2018, Fibrocell Science, Inc. (the “Company”) disclosed in a press release preliminary financial data of cash and cash equivalents of approximately \$12.2 million, as of March 31, 2018. The preliminary financial data included in the press release and this Current Report on Form 8-K have been prepared by, and are the responsibility of, the Company’s management. The Company’s independent registered public accounting firm, PricewaterhouseCoopers LLP, has not audited, reviewed, compiled or performed any procedures with respect to the preliminary financial data. Accordingly, PricewaterhouseCoopers LLP does not express an opinion or any other form of assurance with respect thereto.

Item 8.01 Other Events.

On April 18, 2018, the Company issued a press release announcing that its Board of Directors is conducting a comprehensive review of strategic alternatives focused on maximizing shareholder value. A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated April 18, 2018.

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/ John M. Maslowski

John M. Maslowski
President and Chief Executive Officer

Date: April 18, 2018



Fibrocell Announces Review of Strategic Alternatives

EXTON, PA – April 18, 2018 – Fibrocell Science, Inc. (NASDAQ: FCSC), a gene therapy company focused on transformational autologous cell-based therapies for skin and connective tissue diseases, today announced that its Board of Directors is conducting a comprehensive review of strategic alternatives focused on maximizing stockholder value. Fibrocell has engaged Canaccord Genuity LLC as its strategic financial advisor to assist with this review process.

The Board of Directors has established a Special Committee to explore and evaluate potential strategic alternatives which may include a sale of the Company, a business combination, a merger or reverse merger with another company, a strategic investment into the Company, a sale, license or other disposition of corporate assets of the Company or continuing with the current business plan. Fibrocell has not set a timetable for completion of the review process. No decision has been made as to whether the Company will engage in a transaction or transactions, and there can be no assurance that this process will result in any transaction, or the terms or timing of any potential transaction. Fibrocell does not intend to discuss or disclose further developments regarding the strategic review process unless and until its Board of Directors has approved a specific action or otherwise determined that further disclosure is appropriate or required by law.

In parallel with this review process, Fibrocell intends to continue advancing its Phase 1/2 clinical trial of FCX-007 by reporting additional interim data on the adult patients in the Phase 1 portion of its Phase 1/2 clinical trial and provide a trial update in the second quarter of 2018. The Company also expects to complete enrollment of Phase 2 patients in the third quarter of 2018. In addition, Fibrocell expects to initiate enrollment in a Phase 1/2 clinical trial of FCX-013 in the third quarter of 2018.

In its strategic review, the Board of Directors is considering Fibrocell's clinical programs for rare skin diseases with unmet needs, and other assets which include:

- **Two clinical trial programs based on the Company's proprietary, ex vivo gene-modified fibroblast platform**
 - FCX-007 for the treatment of Recessive Dystrophic Epidermolysis Bullosa (RDEB)
 - Interim results from three adult patients in the Phase 1 portion of the Phase 1/2 clinical trial showed well tolerated safety and noted positive early trends in pharmacology and wound healing
 - Obtained allowance from the U.S. Food and Drug Administration (FDA) to initiate enrollment of pediatric patients in the Phase 2 portion of the Phase 1/2 trial
 - FCX-013 for the treatment of moderate to severe Localized Scleroderma
 - Obtained Investigational New Drug Application (IND) allowance from FDA

- **Multiple FDA designations with potential regulatory advantages**
 - Regulatory advantages include more frequent communications with FDA, eligibility for Accelerated Approval and Priority Review, and Rolling Review
 - FCX-007 and FCX-013 received Rare Pediatric Disease Designations from the FDA and have the potential to receive Priority Review Vouchers upon market authorization
- **An FDA-approved autologous fibroblast cell therapy**
 - LAVIV® (azficel-T) is indicated for the improvement in the appearance of moderate to severe nasolabial fold wrinkles in adults
 - The platform includes several active INDs for evaluation in other indications, including treatment of moderate to severe acne scarring
- **In-house manufacturing expertise and infrastructure for Fibrocell's multi-product, cell and gene therapy facility**
 - Offers extensive expertise and experience culturing autologous dermal fibroblasts—including commercial scale—for cell and gene therapy products
 - Site features 13,000 square foot cGMP cell therapy manufacturing facility with an infrastructure to support production of FCX-007 and FCX-013, including its existing capacity to serve the U.S. RDEB market

As of March 31, 2018, Fibrocell had cash and cash equivalents of approximately \$12.2 million which the Company believes will be sufficient to fund operations into the first quarter of 2019. The preliminary financial data included in this press release have been prepared by, and are the responsibility of, the Company's management. The Company's independent registered public accounting firm, PricewaterhouseCoopers LLP, has not audited, reviewed, compiled or performed any procedures with respect to the preliminary financial data. Accordingly, PricewaterhouseCoopers LLP does not express an opinion or any other form of assurance with respect thereto.

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 trial for the treatment of recessive dystrophic epidermolysis bullosa (RDEB). Fibrocell is also developing FCX-013, the Company's 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 <http://www.fibrocell.com> or follow Fibrocell on Twitter at [@Fibrocell](https://twitter.com/Fibrocell).

Trademarks

Fibrocell, the Fibrocell logo and Fibrocell Science are trademarks of Fibrocell Science, Inc. and/or its affiliates. All other names may be trademarks of their respective owners.

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 exploration of strategic alternatives; the timing of dosing and reporting of interim data for its Phase 1/2 clinical trial of FCX-007; the completion of enrollment in the Phase 2 portion of its Phase 1/2 clinical trial of FCX-007; the initiation of the Phase 1 portion of its Phase 1/2 clinical trial for FCX-013; the potential for FCX-007 and FCX-013 to receive Priority Review Vouchers upon market authorization; the potential advantages of Fibrocell's product candidates; the sufficiency of the Company's cash and cash equivalents to fund operations into the first quarter of 2019; 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: uncertainties associated with being able to identify, evaluate and complete any strategic transaction or alternative; the impact of the announcement of the Board of Directors' review of strategic alternatives, as well as any strategic transaction or alternative that may be pursued, on the Company's business, including its financial and operating results and its employees; 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 or FCX-013; 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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