Fibrocell Science, Inc.
Form 8-K
April 16, 2019

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 16, 2019

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))
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 o

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. o

Item 1.01 Entry into a Material Definitive Agreement.

On April 12, 2019, Fibrocell Science, Inc. (the "Company") entered into a co-development and license agreement (the "Agreement") with Castle Creek Pharmaceuticals, LLC ("CCP") with respect to the development and commercialization of the Company's lead gene therapy candidate, FCX-007 (the "Product"), for the treatment of recessive dystrophic epidermolysis bullosa ("RDEB").

Under the terms of the Agreement, CCP will receive an exclusive license to commercialize the Product in the United States. CCP will be responsible for the first $20 million in development costs prior to the initial Biologics License Application ("BLA") filing with U.S. Food and Drug Administration ("FDA") and manufacturing costs undertaken prior to commercial launch of the Product. If such spending exceeds $20 million, CCP will be responsible for 70% of the excess costs and Fibrocell will cover 30% of the remaining additional expenses. The Company will maintain responsibility for the development (including pre-launch manufacturing) of the Product through initial BLA approval of the Product, and CCP will be responsible for all post-approval development and commercialization activities for the Product. The parties have agreed to negotiate the terms of a manufacturing and supply agreement that will set forth the terms under which the Company will supply CCP commercial quantities of the Product. A joint development committee consisting of representatives from the Company and CCP will oversee the development of FCX-007 pursuant to an agreed-upon development plan and budget.

The Company will receive an upfront payment of $7.5 million, and will receive an additional $2.5 million for the first patient enrolled in the Phase 3 clinical trial and $30 million upon BLA approval and commercial manufacturing readiness. The Company is also eligible to receive up to $75 million in sales milestones, consisting of $25 million upon the achievement of $250 million in cumulative Product net sales and an additional $50 million upon the achievement of $750 million in cumulative Product net sales. In addition, CCP will pay the Company a 30% share of the gross profits from Product sales. The Company will retain sole ownership of the Rare Pediatric Disease Priority Review Voucher, which may be granted upon market approval of the Product.

As part of the Company's existing exclusive channel collaboration agreement with Intrexon Corporation ("Intrexon"), the Company will pay Intrexon 50% of all upfront, milestone and profit share payments from CCP. Payments to Intrexon do not include funds received by the Company from CCP in connection with the development and manufacturing costs or payments for supply of the Product.

Unless earlier terminated, the Agreement will expire on the later of (a) expiration of the last-to-expire valid claim of any Product patent rights in the United States and (b) forty years from the date of initial BLA approval of the Product. CCP has the right to terminate the Agreement at will upon 180 days' prior written notice. CCP may also terminate the Agreement at any time, upon 180 days' prior written notice to the Company, in the event (i) CCP determines, in its reasonable discretion, that further development or commercialization of the Product is not commercially viable or (ii) CCP determines that development or commercialization of the Product must be terminated because of safety issues outside of CCP's reasonable control Either party may, subject to specified cure periods, terminate the Agreement in the event of the other party's uncured material breach, and either party may terminate the Agreement under specified circumstances relating to the other party's insolvency.

The foregoing description of the Agreement does not purport to be complete and is qualified it its entirety by reference to the Agreement, which the Company intends to file as an exhibit to its Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019.

Item 8.01 Other Events.

On April 15, 2019, Fibrocell Science, Inc. (the "Company") issued a press release announcing an agreement with Castle Creek Pharmaceuticals to develop and commercialize FCX-007. A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated April 15, 2019.

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/ John M. Maslowski

John M. Maslowski

President and Chief Executive Officer

Date: April 16, 2019