Section 1: 8-K (8-K)

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): **January 30, 2019**

Fortress Biotech, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-35366**	**20-5157386**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2 Gansevoort Street, 9th Floor
New York, New York 10014
(Address of Principal Executive Offices)

(781) 652-4500
(Registrant's telephone number, including area code)

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:

☐ Written communications pursuant to Rule 425 under the Securities Act.
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act.
☐ Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

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 1.01 Entry into a Material Definitive Contract.

On January 30, 2019, Caelum Biosciences, Inc. ("Caelum"), a subsidiary of Fortress Biotech, Inc. (the "Company"), entered into a Development, Option and Stock Purchase Agreement (the "DOSPA") and related documents by and among Caelum, Alexion Therapeutics, Inc. ("Alexion"), Fortress and the Caelum security holders parties thereto (including Fortress, the "Sellers"). As of the date hereof and following the First Stage Purchase (as defined below), the Company owns approximately 40% of the issued and outstanding capital stock of Caelum.

Development, Option and Stock Purchase Agreement

The DOSPA broadly comprises four transactional components: (i) an initial purchase by Alexion of a number of shares of Caelum preferred stock equal to 19.9% of Caelum's total capitalization, for consideration of $30 million (the "First-Stage Purchase"); (ii) subsequent potential development funding payments due upon the satisfaction of certain development milestones achieved by CAEL-101, Caelum's lead product candidate, that in the aggregate comprise $30 million; (iii) an Alexion option to purchase all of the equity of the Sellers for $150M or $200M, depending on BLA (as defined below) approval timing (the "Second-Stage Acquisition"); and (iv) in the event of exercise of the Option (as defined below), certain contingent earn-out payments made to the Sellers upon the achievement of certain regulatory and commercial milestones of up to $325 million.

First-Stage Purchase

The first component of the DOSPA is an equity subscription by Alexion of $30 million in exchange for a number of shares of Caelum Class B Preferred Stock ("Class B Preferred Stock") representing 19.9% of the company's outstanding capitalization. The Class B Preferred Stock will carry identical rights and privileges as Caelum's common stock, except that it will have a liquidation preference (meaning that, in the event of a "liquidation event" of Caelum (e.g., bankruptcy, sale of the company), the holders of the Class B Preferred Stock will be entitled to receive distributions prior to the holders of Caelum common stock).

The DOSPA also grants Alexion anti-dilution protection such that, if, during the period between execution of the DOSPA until exercise of the Option (the "Pre-Closing Period"), Alexion's equity interest in the company is reduced below 19.9% of Caelum's fully diluted capitalization, then Caelum must issue to Alexion a number of shares of Class B Preferred Stock to restore Alexion's equity interest in Caelum to 19.9%.

Within 30 days following execution of the DOSPA (and simultaneous closing of the First-Stage Purchase), Caelum and Alexion will establish a Joint Steering Committee (the "JSC"), which will comprise an equal number of representatives from Caelum and Alexion and shall manage and oversee all activities contemplated by the Development Plan for CAEL-101 (which itself is targeted for finalization within 90 days following First-Stage Closing). In the event of a disagreement between members of the JSC with respect to any aspect of the Development Plan, Caelum shall have the right to make the final decision; *provided*, *however*, that the unanimous consent of the JSC shall be required in connection with: (i) the seeking of accelerated approval by the FDA of a biologic license application ("BLA") for CAEL-101; (ii) the selection of any Caelum vendors; (iii) any decisions with respect to any active pharmaceutical ingredient and drug product specifications; (iv) the commencement of any analytical or manufacturing process; and (v) the selection of any principal investigators for clinical trials.

In addition to Alexion's presence on the JSC, Alexion, Caelum and the Sellers will also execute a stockholders' agreement, which affords Alexion the right to appoint a director to the Caelum board (the "Alexion Appointee"). A provision in the DOSPA enumerates certain consent rights, or corporate actions that Caelum may not take without the consent of such Alexion Appointee. These actions include any:

(1) amendment of Caelum's charter or bylaws;
(2) establishment of any new subsidiary, division or line of business;
(3) repurchase, split, combination or reclassification of any Caelum securities, or the declaration of any dividend or distribution;
(4) issuance, offer, sale, pledge, disposition or encumbrance of any Caelum securities (other than in accordance with current equity plans);
(5) acquiring or merging with or into any other entity;
(6) initiating any bankruptcy proceedings;
(7) transferring, selling or licensing any Caelum assets;
(8) incurring any indebtedness;
(9) materially modifying or waiving the terms of any company contracts;
(10) settling any litigation, tax dispute or other dispute;
(11) entering into any joint venture;
(12) transferring, abandoning or encumbering any intellectual property; or
(13) disclosing to any person or entity any IND, BLA or other regulatory documents, other than in the ordinary course of business.

The above veto rights will expire automatically upon expiration, if any, of the Option Period (as defined below).

Subsequent Development Funding Payments

The DOSPA obligates Alexion to make subsequent development funding payments to Caelum upon the achievement of certain regulatory milestones: (i) $5 million upon the demonstrated equivalence of the clinical supply of CAEL-101 from Patheon Biologics LLC, (Caelum's manufacturer of CAEL-101 ("Patheon"), under Patheon's newly-adopted processes to previously-supplied CAEL-101 from Patheon, provided that the related IND has been appropriately updated without objection from the FDA and that such batch of CAEL-101 has proper identification, quality, purity and strength; (ii) $10 million upon the first patient dosing in a Phase 2 clinical trial; and (iii) $15 million upon the enrollment of 50% of the total number of patients to be enrolled in a Phase 2 clinical trial, per the applicable protocol.

Option Exercise – Second-Stage Acquisition

From the period beginning 12 months after execution of the DOSPA and ending three months after delivery by Caelum to Alexion of all data held by Caelum reasonably required to demonstrate "proof of concept" in a Phase 2 clinical trial for CAEL-101 (the "Option Period"), Alexion will have an option to purchase all of Caelum's outstanding capital stock (the "Option"). Because the Sellers, which include each holder of any equity security in Caelum (including options, restricted stock units and warrants), will be signatories to the DOSPA, Alexion will be able to, upon exercise of the Option, acquire 100% of the equity interests of Caelum via stock purchase. The upfront payment required by Alexion in order to exercise the Option is $150 million (the "Baseline Purchase Price"); *provided, however*, that, if Caelum receives accelerated BLA approval following completion of the Phase 2 clinical trial prior to the Second-Stage Acquisition, then the Baseline Purchase Price shall be increased by an additional $50 million (the "Supplemental Purchase Price").

The DOSPA also permits Alexion to consummate the Second-Stage Acquisition in the format of a merger or an asset sale, and the Sellers agree in connection therewith to cooperate with Alexion in executing any agreements, documents or certificates reasonably required to consummate the Second-Stage Acquisition under either such structure.

In connection with, and effective immediately following, the Second-Stage Acquisition, each of the Sellers, severally and not jointly, based on each Seller's pro rata share, will indemnify Alexion for any losses incurred by Alexion in connection with: (i) breaches of any representations and warranties ("R&W") made by Caelum or the Sellers in the DOSPA; (ii) breaches of any covenants made by Caelum or the Sellers in the DOSPA; or (iii) certain tax liabilities of Caelum incurred prior to or as a result of the Second-Stage Acquisition. Under this several and not joint liability paradigm, the maximum liability faced by any individual Seller is his or her portion of damages measured pro rata across the entire Caelum stockholder base. Alexion's only recourse, however, in satisfaction of indemnifiable claims is payment from the Escrow Fund (as defined below) or withholding from the Earn-Out Payments (as defined below); *provided, however*, that in the case of indemnifiable claims pertaining to certain fundamental R&W, Alexion will conceivably also be able to pursue individual Sellers for previously-paid amounts in satisfaction of indemnification obligations.

Concurrently with the closing of the Second-Stage Acquisition, Alexion will set aside $15 million from the Baseline Purchase Price ($20 million if the Supplemental Purchase Price payment is triggered) for the establishment of an escrow account to be used to satisfy any amounts owed to Alexion pursuant to the aforementioned indemnification provided by the Sellers (the "Escrow Fund"). The portion of the Escrow Fund that is not used to satisfy any indemnification obligations within the two-year period following the Second-Stage Acquisition will be distributed pro rata to the Sellers following such two-year period.

Contingent Earn-Out Payments

The DOSPA also entitles all Sellers to their pro rata portion of contingent compensation totaling up to $325 million, upon the achievement of certain regulatory and commercial milestones and payable as follows:

(1) $50 million upon obtaining BLA approval for CAEL-101 for a broad patient population following completion of a pivotal clinical trial (*provided* that such payment will be $75 million if the Supplemental Purchase Price was not previously paid);
(2) $25 million following the first calendar year in which net sales of CAEL-101 exceed $250 million;
(3) $50 million following the first calendar year in which net sales of CAEL-101 exceed $500 million;
(4) $75 million following the first calendar year in which net sales of CAEL-101 exceed $750 million; and
(5) $100 million following the first calendar year in which net sales of CAEL-101 exceed $1 billion.

Fortress will be appointed the shareholder representative ("Representative") in connection with verifying Alexion's calculations of net sales for the purposes of determining whether or not one of the above sales milestones has been achieved. Fortress, as Representative will also be charged with distributing un-drawn portions of the Escrow Fund to the Sellers, accepting valid notice on behalf of all Sellers with respect to notifications made under the DOSPA and handling (on behalf of the Sellers) indemnification claims among the Sellers, Alexion and third parties.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

FORTRESS BIOTECH, INC.

(Registrant)

Date: January 31, 2019

By: */s/ Lindsay A. Rosenwald, M.D.*
Lindsay A. Rosenwald, M.D.
Chairman, President and Chief Executive Officer

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