

September 29, 2021



Fortress Biotech Announces Receipt of Notice of Option Exercise from AstraZeneca to Fully Acquire Caelum Biosciences, a Company Founded by Fortress Biotech

Option exercise triggers upfront payment of approximately \$150 million to Caelum shareholders, of which approximately \$64 million is payable to Fortress Biotech¹

AstraZeneca intends to advance and accelerate the Phase 3 development of CAEL-101 for light chain (AL) amyloidosis

HSR waiting period has expired for the acquisition of Caelum

NEW YORK and BORDENTOWN, N.J., Sept. 29, 2021 (GLOBE NEWSWIRE) -- Fortress Biotech, Inc. (NASDAQ: FBIO) ("Fortress"), an innovative biopharmaceutical company focused on acquiring, developing and commercializing or monetizing promising biopharmaceutical products and product candidates cost-effectively, and a company it founded, Caelum Biosciences, Inc. ("Caelum"), a clinical-stage biotechnology company developing treatments for rare and life-threatening diseases, today announced that AstraZeneca's Alexion notified Caelum that it has exercised its option to acquire Caelum, pursuant to the Development, Option and Stock Purchase Agreement in place between Fortress, Caelum, Alexion and the other parties thereto (as amended, the "DOSPA"). In addition, the waiting period under the Hart-Scott-Rodino ("HSR") Antitrust Improvements Act of 1976, as amended, has expired in connection with such acquisition. Expiration of the waiting period under the HSR Act satisfies one of the conditions precedent for consummation of the acquisition.

Under terms of the DOSPA, upon closing of the acquisition, which is expected to take place on October 5, 2021, Alexion will purchase all of the outstanding shares of Caelum and will pay Caelum the agreed option exercise price of approximately \$150 million. Distributions will be made to all existing Caelum stockholders. The agreement also provides for additional potential payments to Caelum stockholders totaling up to \$350 million, payable upon the achievement of regulatory and commercial milestones. Fortress is eligible to receive approximately 43 percent of all proceeds from the transaction.

“The acquisition of Caelum is a positive development and monetization opportunity for our shareholders, while validating the Fortress business model,” said Lindsay A. Rosenwald, M.D., Fortress’ Chairman, President and Chief Executive Officer. “We believe in CAEL-101’s potential to be a best-in-class treatment for AL amyloidosis and look forward to the continued progression of CAEL-101 in the CARES Phase 3 clinical program under the leadership of the renowned team at Alexion.”

Michael Spector, Co-Founder, President and Chief Executive Officer of Caelum, said, “I am proud to have been a co-founder of Caelum in 2017 with Fortress Biotech. Caelum formed a collaboration with Alexion Pharmaceuticals in 2019 to develop CAEL-101 for patients with AL amyloidosis, and we achieved significant milestones together through the on-going Phase 3 program. The acquisition of Caelum is an important step for patients with AL amyloidosis, as our partners at Alexion have the resources required to expedite the development of CAEL-101. Treatments that target amyloid deposits remain an important unmet medical need.”

[The Cardiac Amyloid Reaching for Extended Survival \(CARES\) clinical program](#) is evaluating CAEL-101, and enrollment is ongoing in two parallel Phase 3 studies – one in patients with Mayo stage IIIa disease and one in patients with Mayo stage IIIb disease (ClinicalTrials.gov Identifier: [NCT04512235](#) and [NCT04504825](#)). The company also has a Phase 2 clinical study that is evaluating the safety and tolerability of CAEL-101 in patients with AL amyloidosis (ClinicalTrials.gov Identifier: [NCT04304144](#)).

About CAEL-101

CAEL-101 is a potentially first-in-class monoclonal antibody (mAb) designed to improve organ function by reducing or eliminating amyloid deposits in the tissues and organs of patients with AL amyloidosis. The antibody is designed to bind to misfolded light chain protein and amyloid and shows binding to both kappa and lambda subtypes. CAEL-101 has received Orphan Drug Designation from both the U.S. Food and Drug Administration and the European Commission as a potential therapy for patients with AL amyloidosis. Additionally, the U.S. FDA granted Fast Track Designation to CAEL-101 for AL amyloidosis in June 2021.

About AL Amyloidosis

AL amyloidosis is a rare systemic disorder caused by an abnormality of plasma cells in the bone marrow. Misfolded immunoglobulin light chains produced by plasma cells aggregate and form fibrils that deposit in tissues and organs. This deposition can cause widespread and progressive organ damage and high mortality rates, with death most frequently occurring as a result of cardiac failure. Approximately 20,000 people across the US, France, Germany, Italy, Spain and the UK live with AL amyloidosis classified as Mayo stage IIIa or IIIb disease.

About Fortress Biotech

Fortress Biotech, Inc. (“Fortress”) is an innovative biopharmaceutical company that was ranked in Deloitte’s 2019 and 2020 Technology Fast 500™, annual rankings of the fastest-growing North American companies in the technology, media, telecommunications, life sciences and energy tech sectors, based on percentages of fiscal year revenue growth over three-year periods. Fortress is focused on acquiring, developing and commercializing high-potential marketed and development-stage drugs and drug candidates. The company has seven marketed prescription pharmaceutical products and over 25 programs in development at Fortress, at its majority-owned and majority-controlled partners and at partners it founded

and in which it holds significant minority ownership positions. Such product candidates span six large-market areas, including oncology, rare diseases and gene therapy, which allow it to create value for shareholders. Fortress advances its diversified pipeline through a streamlined operating structure that fosters efficient drug development. The Fortress model is driven by a world-class business development team that is focused on leveraging its significant biopharmaceutical industry expertise to further expand the company's portfolio of product opportunities. Fortress has established partnerships with some of the world's leading academic research institutions and biopharmaceutical companies to maximize each opportunity to its full potential, including Alexion Pharmaceuticals, Inc., AstraZeneca, City of Hope, Fred Hutchinson Cancer Research Center, St. Jude Children's Research Hospital, Nationwide Children's Hospital and Sentyln Therapeutics, Inc. For more information, visit www.fortressbiotech.com.

About Caelum Biosciences

Caelum Biosciences, Inc. ("Caelum") is a clinical-stage biotechnology company developing treatments for rare and life-threatening diseases. Caelum's lead asset, CAEL-101, is a novel antibody for the treatment of patients with amyloid light chain ("AL") amyloidosis. In 2019, Caelum entered a collaboration agreement with Alexion Pharmaceuticals, Inc. ("Alexion") under which Alexion acquired a minority equity interest in Caelum and an exclusive option to acquire the remaining equity in the company. In July 2021, Alexion was acquired by AstraZeneca, triggering a six-month period in which AstraZeneca had the option to acquire Caelum. Caelum was founded by Fortress Biotech, Inc. (NASDAQ: FBIO). For more information, visit www.caelumbio.com.

Forward-Looking Statements

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. As used below and throughout this press release, the words "we", "us" and "our" may refer to Fortress individually or together with one or more partner companies, as dictated by context. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; uncertainties relating to preclinical and clinical testing; risks relating to the timing of starting and completing clinical trials; our dependence on third-party suppliers; risks relating to the COVID-19 outbreak and its potential impact on our employees' and consultants' ability to complete work in a timely manner and on our ability to obtain additional financing on favorable terms or at all; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as may be required by law, and we claim the protection of the safe harbor for forward-looking statements contained in

the Private Securities Litigation Reform Act of 1995. The information contained herein is intended to be reviewed in its totality, and any stipulations, conditions or provisos that apply to a given piece of information in one part of this press release should be read as applying *mutatis mutandis* to every other instance of such information appearing herein.

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¹ Ten percent of the upfront option exercise fee would be held in escrow to satisfy potential indemnification obligations, if any.



Source: Fortress Biotech, Inc.