

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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FORM 8-K

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CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 28, 2017

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**FORTRESS BIOTECH, INC.**  
(Exact Name of Registrant as Specified in Charter)

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**Delaware**

(State or Other Jurisdiction  
of Incorporation)

**001-35366**

(Commission File Number)

**20-5157386**

(IRS Employer  
Identification No.)

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**2 Gansevoort Street, 9th Floor, New York, New York**

(Address of Principal Executive Offices)

**10014**

(Zip Code)

Registrant's Telephone Number, Including Area Code: **(781) 652-4500**

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 (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))
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**Item 8.01. Other Events.**

Attached hereto as Exhibit 99.1 and incorporated herein by reference is a corporate presentation regarding Caelum Biosciences, Inc., a subsidiary of Fortress Biotech, Inc.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Corporate presentation of Caelum Biosciences, Inc. dated February 2017.

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SIGNATURE

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 thereunto duly authorized.

FORTRESS BIOTECH, INC.

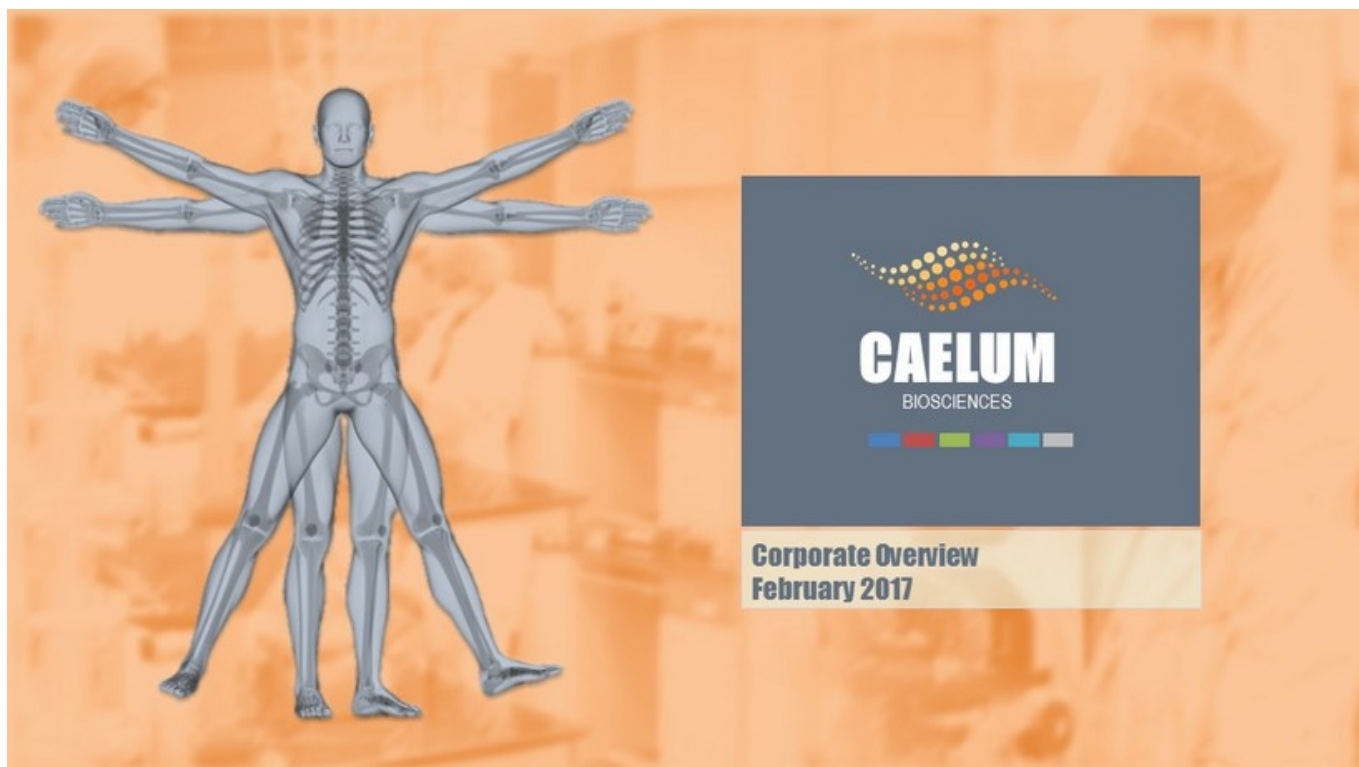
Date: February 28, 2017

/s/ Lindsay A. Rosenwald

Name: Lindsay A. Rosenwald, M.D.

Title: Chairman of the Board of Directors,  
President and Chief Executive Officer

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# Forward Looking Statements

Statements in this presentation that are not descriptions of historical facts are forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. We have attempted to identify forward-looking statements by terminology including “anticipates,” “believes,” “can,” “continue,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “should,” or “will” or the negative of these terms or other comparable terminology. 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 are risks relating to: results of research and development activities; uncertainties relating to preclinical and clinical testing; our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; our dependence on third party suppliers; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; our ability to attract, integrate, and retain key personnel; the early stage of products under development; our need for substantial funds; government regulation; patent and intellectual property matters; and competition. We expressly disclaim any obligation or undertaking to update or revise any statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances after the date of this presentation.

## About Us

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Caelum Biosciences, a Fortress Biotech Company, is a clinical stage biotechnology company developing treatments for rare and life-threatening conditions. Caelum's lead asset, CAEL-101, is a novel antibody in Phase 1b clinical trials that is being developed for patients with AL Amyloidosis.

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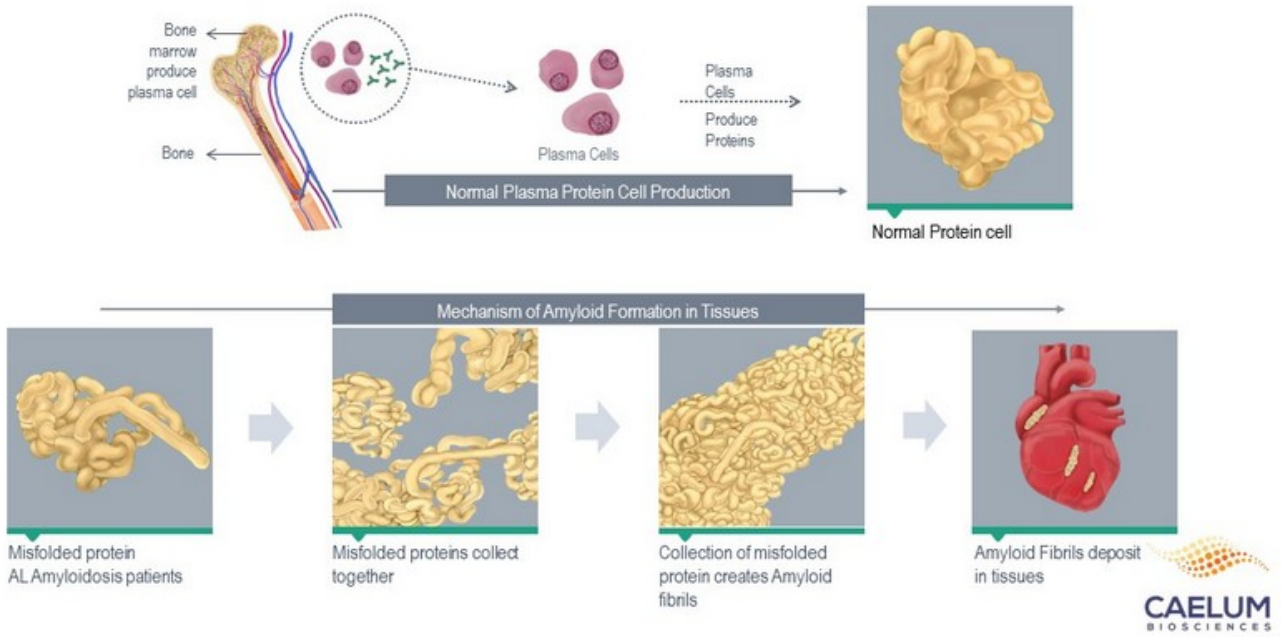
Michael Spector, CEO

# CAEL-101 Opportunity Overview in AL Amyloidosis

- ✓ AL Amyloidosis effects major organs leading to a high mortality
- ✓ 30,000-45,000 patients in the US and EU, 4,500 newly diagnosed patients per year
- ✓ Pioneering antibody developed to specifically target AL Fibrils
- ✓ Potential Best-in-Class treatment to dissolve amyloid deposits
- ✓ CAEL-101 well-tolerated and sustained organ response in Phase 1
- ✓ Preparing for Phase 2
- ✓ Broad protection through regulatory exclusivity and IP

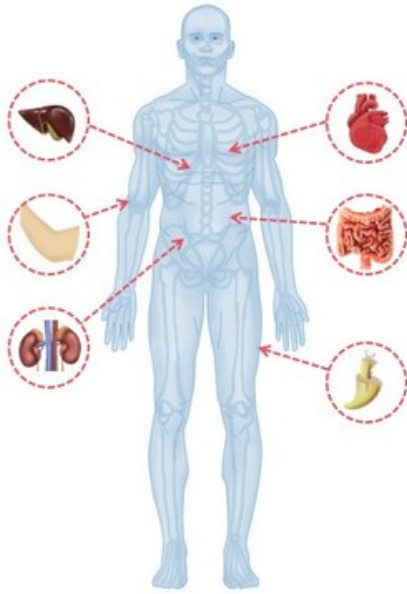



# Amyloid Fibrils Formation in Tissue






# AL Amyloidosis Impact on Organs & Tissue



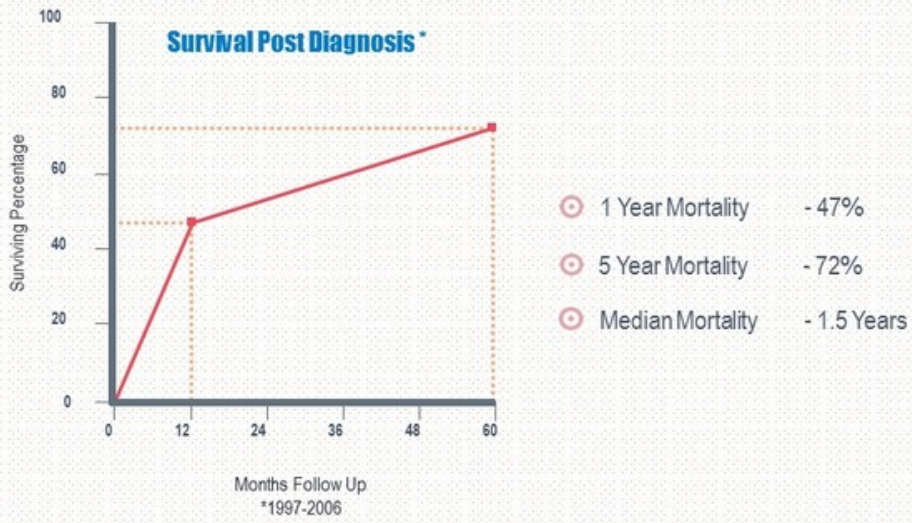
 65%-75% of patients - leads to heart failure and high mortality

 60%-80% of patients - leads to end-stage kidney disease

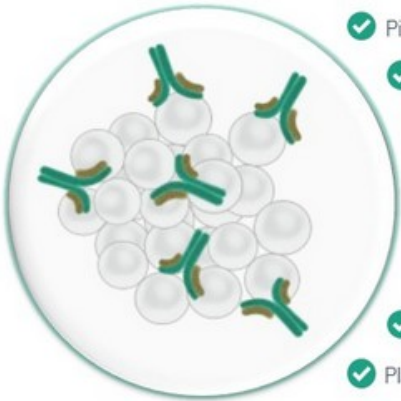
 20%-45% of patients - peripheral neuropathy leading to pain, numbness, and weakness

 5%-35% - Other organs

# AL Amyloidosis Mortality Remains High

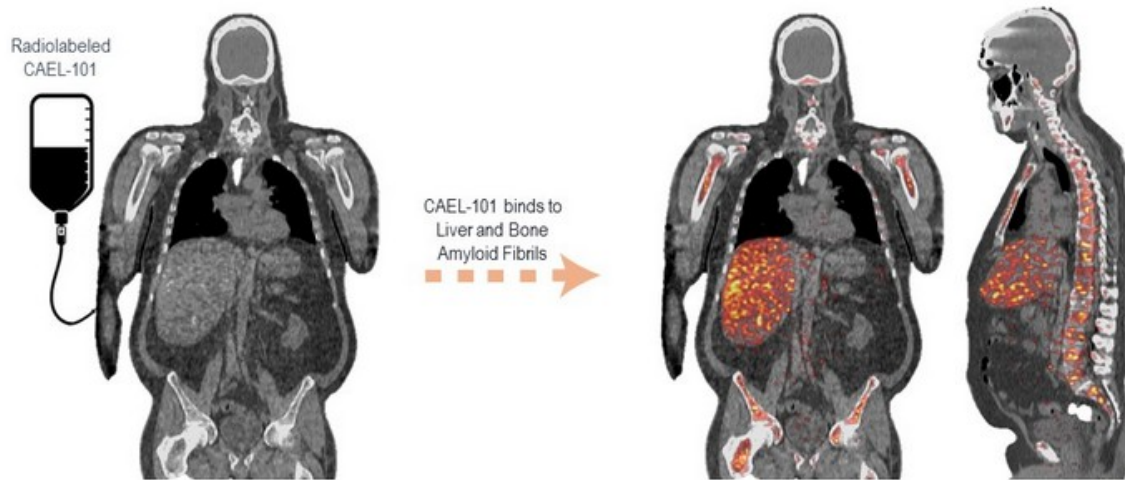


# CAEL-101 Summary



- ✓ Pioneering antibody that lead to new treatment discovery
- ✓ κ Bence Jones protein isolated and used to develop CAEL-101
- ✓ Dissolves human AL λ and κ in preclinical studies
- ✓ Interim Phase 1 data of 21 Patients, CAEL-101 is well-tolerated and safe showing no dose limiting toxicity
- ✓ Interim Phase 1 data demonstrates 67% of Patients with organ response independent of light chain sub-type
- ✓ Sustained organ response even after a single dose
- ✓ Planning for Phase 2 underway

# Specificity of Antibody Binding

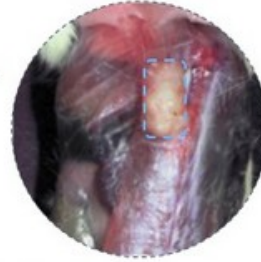


# Amyloidomas Dissolved in CAEL-101 Treated Mice With Human AL $\lambda$ and $\kappa$

Human Amyloid deposits injected in Mice



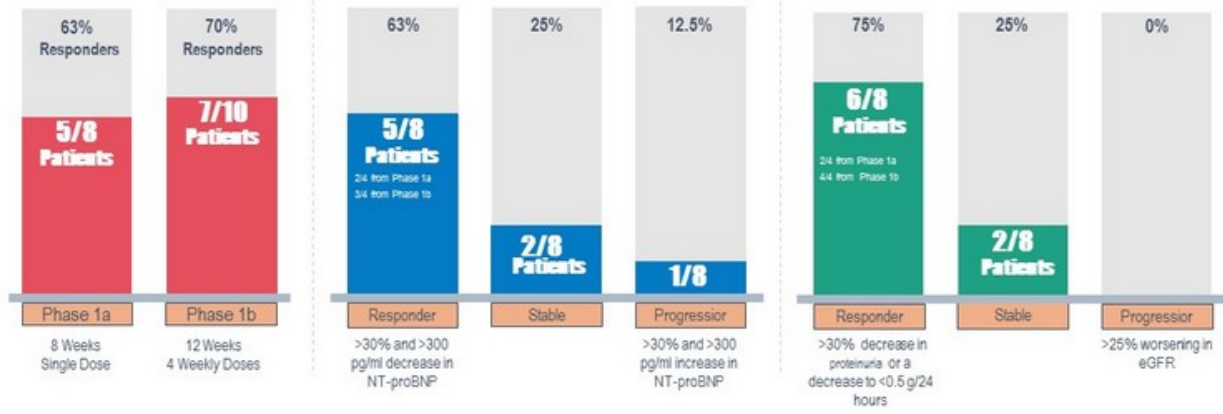
Untreated Mice



CAEL-101 Treated Mice



# CAEL-101 Phase 1a/1b Organ Response Rates



**Overall Responders  
Best Organ Response**

**Cardiac Response Phase  
1a & 1b (n=8)**

**Renal Response Phase 1a &  
1b (n=8)**



# Marked and Sustained Cardiac Response After a Single Dose

Cardiac response (NT-proBNP) in a patient during Phase 1a/b clinical trial of CAEL-101 antibody



## PATIENT 3 PROFILE

- ❖ Refractory  $\lambda$  AL Amyloidosis
- ❖ Baseline NT-proBNP approx. 13,000 ng/L
- ❖ Previous treatments: 1
- ❖ Best Hematologic response to chemotherapy: VGPR
- ❖ No Organ response to chemotherapy
- ❖ Persistently elevated NT-proBNP
- ❖ NYHA Class III

## Organ response to T1-TF4

- ❖ NYHA Class I
- ❖ NT-proBNP Reduction to below 4,000 ng/L

# Marked and Sustained Renal Response After a Single Dose

24 hour urine protein in a patient before and during Phase 1a/b clinical trial of CAEL-101 antibody



## **PATIENT PROFILE**

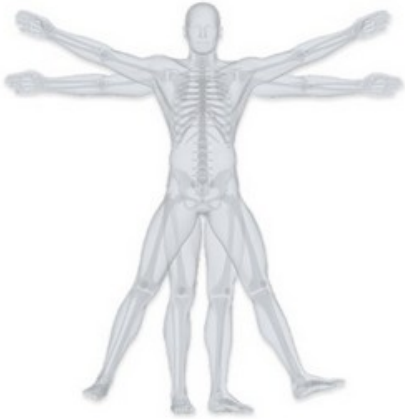
- ❖ Refractory  $\lambda$  AL Amyloidosis
- ❖ Baseline 24-hr urine protein in mg/24hr: approx. 10,000
- ❖ Previous treatments: 6
- ❖ No Organ response to chemotherapy
- ❖ Persistence of significant proteinuria

## **Organ response to CAEL-101**

- ❖ 24 hour urine protein in mg/24 hr: approx. 3,000



# CAEL-101 Highlights



- Pioneering antibody
- Promising Phase 1a/1b data
  - No dose limiting toxicity
  - Marked and sustained responses even after a single dose
  - Organ activity independent of light chain sub-type
- Phase 2 to commence in 2018
- Experienced Leadership Team

# Key Leadership



**Lindsay Rosewald, MD**  
Executive Chairman

- Prolific biotechnology entrepreneur
- Chairman and CEO of Fortress Biotech
- 20+ years founding and capitalizing numerous public and private biotechnology and life sciences companies



**Michael Spector**  
Chief Executive Officer

- 25+ years of leadership experience in pharmaceuticals and biotechnology
- Launched several new biotech and specialty pharmaceutical companies
- Worked on 4 Continents in R&D and General Management roles



**Suzanne Lemtzsch, MD**  
Scientific Advisory Board Chair

- Professor of Medicine at Columbia University Medical Center, New York
- Director of the Multiple Myeloma and Amyloidosis Service at Columbia University and at New York Presbyterian Hospital