



# Fortress Biotech

CORPORATE PRESENTATION

November 2019

## Forward Looking Statements

This presentation 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 presentation, 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 related to our growth strategy; risks relating to the results of research and development activities; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; uncertainties relating to preclinical and clinical testing; our dependence on third party suppliers; our ability to attract, integrate, and retain key personnel; the early stage of products under development; our need for and continued access to 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. 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 presentation should be read as applying *mutatis mutandis* to every other instance of such information appearing herein.



## Fortress Biotech Programs\*

Commercial	Late Clinical	Early Clinical	Preclinical
Targadox	Cosibelimab	MB-102	ATVS-001 Gene Therapy
Ximino	MB-107	CK-101	AAV-ATP7A Gene Therapy
Exelderm	CAEL-101	MB-101	Anti-GITR
Ceracade	CUTX-101	MB-106	Anti-CAIX
Luxamend	CEVA-101	MB-103	CK-103
	IV Tramadol	MB-108	CEVA-102
	Triplex	MB-104	ConVax
		MB-105	

Rare Diseases

Vaccines

Pain

Gene Therapy

Traumatic Brain Injury

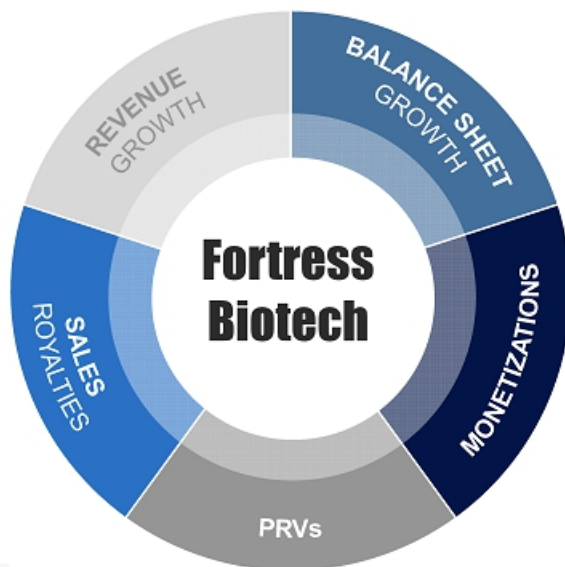
Oncology/ Hematology

Dermatology



\*Includes product candidates in development at Fortress, at its majority-owned and majority-controlled subsidiaries and at entities in which it holds minority ownership positions.

## Generating Shareholder Value



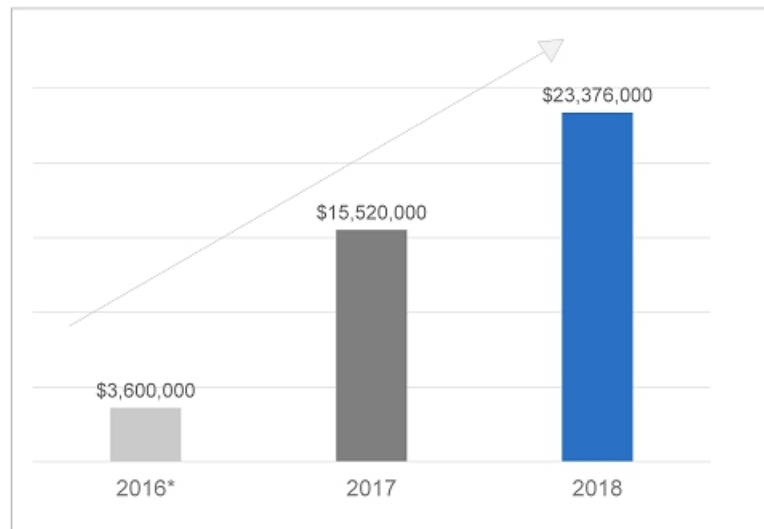
Creating value  
**in five ways**

## Dermatology Product Revenue Growth

Expect to in-license 1 to 3 new products in 2019

**Reaching >70%**

of market via top 5,000  
prescribing dermatologists



\*Sales commenced in Q4 2016

# Strategy

To build a pipeline of both development-stage / commercial-stage assets and leverage the most efficient course to move products forward with our partners.

**Identify**



**Develop**



**Monetize**



## How We Do It

Aim to increase the intrinsic value and decrease the overall risk of Fortress

Development Team	Programs	Secret Sauce
<ul style="list-style-type: none"><li>○ 10+ Business Development Professionals</li><li>○ 30+ Manufacturing Professionals<sup>1</sup></li><li>○ 25+ MDs and PhDs<sup>1</sup></li></ul>	<ul style="list-style-type: none"><li>○ Current portfolio includes: 5 revenue-generating dermatology products</li><li>○ 25+ development-stage biotech product candidates<sup>1</sup></li></ul>	<ul style="list-style-type: none"><li>○ De-risked assets</li><li>○ High value / need</li><li>○ Low acquisition cost</li><li>○ Known buyers</li></ul>



<sup>1</sup>Includes employees and product candidates in development at Fortress, at its majority-owned and majority-controlled partners.

# Management Profiles

## Lindsay Rosenwald, MD

Chairman, President, and CEO



## Michael S. Weiss

Co-Vice Chairman of the Board, Strategic Development



## Eric K. Rowinsky, MD

Co-Vice Chairman of the Board



## Robyn Hunter

Chief Financial Officer





## George C. Avgerinos PhD

Senior Vice President, Operations











## Near-term Monetization Opportunities

 <b>Contingent Acquisition By Cipla</b>	 <b>Contingent Exclusive Acquisition Option Granted To Alexion (Jan. 2019)</b>
<ul style="list-style-type: none"> <li>○ Upon FDA approval and other conditions<sup>1</sup></li> <li>○ \$180 Million aggregate cash purchase; \$166M net of fees (est. \$13.92/share)<sup>1</sup>; <i>FBIO 29% or eligible to receive ~\$48M of the distribution net of fees</i></li> <li>○ Potential additional payments pursuant to Contingent Value Rights; <i>CVR payout of 10-20% of gross profits<sup>2</sup></i></li> <li>○ FBIO stands to realize ~\$48M in addition to value of CVRs</li> </ul>	<ul style="list-style-type: none"> <li>○ Alexion purchased minority stock position in Caelum for \$30M, with additional \$30M in funding due upon achievement of development milestones</li> <li>○ Additionally, up to \$500M payable to Caelum shareholders in connection with Alexion option exercise:               <ul style="list-style-type: none"> <li>• \$150M - \$200M upfront</li> <li>• Up to \$325M in contingent milestone payments</li> </ul> </li> <li>○ FBIO owns ~40% of Caelum and is eligible to receive ~43% of upfront and milestone proceeds</li> </ul>



<sup>1</sup>subject to conditions described in Avenue public filings  
<sup>2</sup>Fortress to receive ~1/3 of CVR royalty

## Near-term Value Creating Pipeline Assets

Candidate*	Indication	Phase 1	Phase 2	Phase 3	Next Milestone	Partnership % / Royalty†	Potential Peak Sales Revenue^
<b>IV Tramadol</b>	Moderate to moderately severe post-operative pain				File NDA by year-end 2019	29% Avenue** 10-20% CVR Royalty on gross profits****	~\$790M
<b>MB-107</b> Gene Therapy	XSCID				Initial meeting with FDA 4Q19; Transfer STJ IND to MBIO 1Q20	30% Mustang 4.5% Royalty	~\$200M
<b>CUTX-101</b> copper histidinate	Menkes disease				File NDA 2021	89% Cyprium 4.5% Royalty	~\$175M
<b>CK-101</b> Mut-EGFR Inh.	EGFR+ NSCLC				Initiate Reg. Study 2020	32% Checkpoint 4.5% Royalty	\$300M - \$600M
<b>COSIBELIMAB</b> Anti-PD-L1 mAb	recurrent or metastatic cancers				P1 Reg. Enabling expansion cohorts ongoing; potential to support 1 or more BLA filings	32% Checkpoint 4.5% Royalty	\$300M - \$500M (initial indication CSCC)
<b>CAEL-101</b> mAb 11-1F4	amyloid light chain amyloidosis				Initiate Phase 2/3 Study 2020	43% Caelum***	

\* Estimated as of 6-30-2019



\*Includes product candidates in development at Fortress, at its majority-owned and majority-controlled partners and at entities in which it holds minority ownership positions.  
 \*\*FBIO is eligible to receive ~29% of the proceeds upon the second-stage closing of the InvaGen transaction net of fees, and currently owns 23% of Avenue's issued and outstanding capital stock.  
 \*\*\*FBIO is eligible to receive ~43% of the proceeds from an Alexion acquisition option exercise, and currently owns ~40% of Caelum's issued and outstanding capital stock.  
 \*\*\*\*FBIO receives ~1/3 of the CVR Royalty on gross profits.  
 ^Based on internal forecasts

 Registration-enabling

# MB-107\*

XSCID “Bubble Boy” Disease



## Fortress Biotech Near-Term Value Creating Pipeline Assets

**Est. Market** \$200M / year

**Status** Registration-enabling Phase 2

**Next Steps** Initial meeting with FDA, Q4 2019;  
Transfer St. Jude IND to MBIO, Q1 2020

**Royalty to FBIO** 4.5%, with PRV ~\$75M to ~\$110M

\*Product candidate in development at Mustang Bio, Inc., an entity which was founded by Fortress and in which Fortress still maintains a large ownership position.  
\*\*Marricaz E et al. *N Engl J Med*. 2019; 380: 1525-1534

- Lentiviral vector gene therapy
- ~1 in 225k newborns per year (U.S.)
- ~400 patients living with XSCID post-transplant in the US and ~650 patients living with XSCID post-transplant in high and mid-income ex-U.S. countries
- RMAT Designation granted by FDA in August 2019
- Published clinical results demonstrate\*\*:
  - Multilineage engraftment of transduced cells
  - Reconstitution of functional T cells and B cells
  - Normalization of NK-cell counts

# CUTX-101

Menkes Disease



## Fortress Biotech Near-Term Value Creating Pipeline Assets

**Est. Market** Estimated Peak Sales of \$175M

**Status** Phase 3 enrollment complete

**Next Steps** File NDA in 2021

**Royalty to FBIO** 4.5%, with PRV ~\$75M to ~\$110M

- FDA granted Orphan Drug and Fast Track designations
- Would be the first FDA approved therapy in this indication
- Eligible for Rare Pediatric Disease Priority Review Voucher (valuation range ~\$75M to \$110M)

# CK-101\*

Third-Gen EGFR Inhibitor



## Fortress Biotech Near-Term Value Creating Pipeline Assets

<b>Est. Market</b>	\$6b+ / year
--------------------	--------------

<b>Status</b>	Phase 1
---------------	---------

<b>Next Data</b>	Clinical update expected by YE 2019
------------------	-------------------------------------

<b>Next Steps</b>	Initiate registration trial in 2020
-------------------	-------------------------------------

<b>Royalty to FBIO</b>	4.5%
------------------------	------

\*Product candidate in development at Checkpoint Therapeutics, Inc., an entity which was founded by Fortress and in which Fortress still maintains a large ownership position.

- Irreversible inhibitor against selective mutations of EGFR
- Potential to be effective in NSCLC patients with susceptible mutations as a monotherapy or in combination with anti-tumor immune potentiating therapies
- Interim P1 data presented at 2018 World Conference on Lung Cancer
- Potential emerging safety differentiation vs TAGRISSO®

# COSIBELIMAB\*

Anti-PD-L1



## Fortress Biotech Near-Term Value Creating Pipeline Assets

<b>Est. Market</b>	PD-L1 mAbs: \$40b+ / year
<b>Status</b>	Registration-enabling Phase 1
<b>Next Data</b>	2H 2020
<b>Next Steps</b>	Complete enrollment in 2020
<b>Royalty to FBIO</b>	4.5%

\*Product candidate in development at Checkpoint Therapeutics, Inc., an entity which was founded by Fortress and in which Fortress still maintains a large ownership position.

- Fully human IgG1 monoclonal antibody
- Potential therapy for lung cancer, endometrial cancer, colorectal cancer and cutaneous squamous cell carcinoma
- Potentially differentiated vs marketed PD-(L)1s
- Interim P1 data showed efficacy in multiple tumor types w/ well tolerated safety profile
- Enrolling cohorts intended to support potential BLA submissions
- Exploring possible partnerships and collaborations

# IV Tramadol\*

Post-operative pain management

## Fortress Biotech Near-Term Value Creating Pipeline Assets

<b>Est. Market</b>	Estimated Peak Sales of \$790M**
<b>Status</b>	Announced Positive Topline Data from 2 <sup>nd</sup> Pivotal Phase 3 Trial
<b>Next Steps</b>	File NDA by year-end 2019
<b>Royalty to FBIO</b>	CVRs worth 10-20% of gross profits**

\*Product candidate in development at Avenue Therapeutics, Inc., an entity which was founded by Fortress and in which Fortress still maintains a large minority ownership position

\*\*Based on internal forecasts Fortress to receive ~1/3 of CVR royalty

- Uniquely positioned to address need for new post-operative pain therapies amid opioid crisis
- Potential to replace conventional narcotics in wide range of patients
- Two-stage acquisition agreement with Cipla minimizes dilution and provides substantial upside to shareholders; First stage closed in February 2019
- Strong IP position on proprietary dosing regimen expected to protect exclusivity in the U.S. until 2036

# CAEL-101\*

AL Amyloidosis



## Fortress Biotech Near-Term Value Creating Pipeline Assets

**Est. Patient Population** 30k to 45k patients in U.S. and EU

**Status** Phase 1 Complete

**Next Data** 2021

**Next Steps** Phase 2/3 study initiation 2020

- Granted Orphan Drug designation
- No FDA, EMEA, or PMDA approved therapies in this indication
- ~30k - 45k patients in U.S. and EU
- ~4.5k newly-diagnosed patients (U.S.) per year
- Potentially understated market size given AL Amyloidosis often misdiagnosed

\*Product candidate in development at Caelum Biosciences, Inc., an entity which was founded by Fortress and in which Fortress still maintains a large minority ownership position.



## Top-tier Academic & Commercial Partners



## Potential Near-term Value-Creating Events for FBIO Shareholders

### IV Tramadol<sup>1</sup> & Cipla

- FBIO eligible to receive up to \$48M in contingent acquisition of Avenue
- CVR Payout of 10-20% of gross profits<sup>2</sup>
- NDA Filing anticipated by year-end 2019

### CAEL-101<sup>1</sup> & Alexion

- Eligible to receive 43% of up to \$500M (upfront and sales milestones) in event of Alexion exercise of contingent option
- Initiate pivotal trial in 1H20

### Journey Medical

- Generated \$23.5M in net revenue in 2018, \$5.5M in cash
- Generated \$14.3M in net revenue in the first half of 2019
- Expected to in-license 1 to 3 new products in 2019

### MB-107<sup>1</sup>

- Initial meeting with FDA Q4 2019
- IND transfer from St. Jude to MBIO expected Q1 2020

### Cosibelimab and CK-101<sup>1</sup>

- Complete enrollment in cosibelimab registration-enabling expansion cohorts 2020
- CK-101 data read out, Initiate global registration study for treatment of lung cancer

### PRVs (Priority Review Vouchers)

- Filing for 3 PRVs anticipated (CUTX-101, MB-107 and CEVA-101)<sup>1</sup>
- Data over last 24 months suggests these PRVs may be worth ~\$75M to ~\$110M, each



<sup>1</sup>IV Tramadol, CAEL-101, Cosibelimab, CK-101, CUTX-101, MB-107, and CEVA-101 are product candidates in development at FBIO partner companies

<sup>2</sup>Based on internal forecasts Fortress to receive ~1/3 of CVR royalty

# FORTRESS BIOTECH

## Financial Snapshot

### NASDAQ

Shares outstanding as of 9/30/19:

Market Cap as of 10/31/19:

Consolidated cash as of 9/30/19:

FBIO standalone cash as of 09/30/19:

Value of FBIO ownership of public partner  
companies as of 10/31/19:

### FBIO

70,335,534

~\$99.2 million

\$156.0 million<sup>1</sup>

\$55.9 million<sup>2</sup>

~\$77.7 million<sup>3</sup>

1 Consolidated cash, cash equivalents, short-term investments (certificates of deposit) and restricted cash

2 Fortress' cash, cash equivalents, short-term investments (certificates of deposit) and restricted cash (excludes public partner companies)

3 Approximate value of Fortress' holdings in ATKI, CKPT and MBIO

