

FREE WRITING PROSPECTUS

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August 24, 2020



# Fortress Biotech

CORPORATE PRESENTATION

August 2020

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The issuer has filed a registration statement (including a prospectus) and a preliminary prospectus supplement with the SEC for the offering to which this communication relates. Before you invest, you should read the prospectus in that registration statement, the preliminary prospectus supplement, and other documents the issuer has filed with the SEC for more complete information about the issuer and this offering. You may get these documents for free by visiting EDGAR on the SEC Web site at [www.sec.gov](http://www.sec.gov). Alternatively, the issuer, any underwriter or any dealer participating in the offering will arrange to send you the preliminary prospectus supplement and prospectus if you request it by emailing [info@fortressbiotech.com](mailto:info@fortressbiotech.com).



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## 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. For such forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. 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 Securities and Exchange Commission 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.



## Summary of Expected Offering Terms

Security:	9.375% Series A Cumulative Redeemable Perpetual Preferred Stock
Current Nasdaq Symbol:	FBIOP
Number of Preferred Shares Currently Outstanding:	2,693,806
Monthly Dividends:	\$0.1953125
Dividend Payment Dates:	Monthly on the last calendar day of each month
Liquidation Preference:	\$25.00
Maturity/Mandatory Redemption:	None
Optional Redemption:	At the Company's option any time on or after December 15, 2022
Use of Proceeds:	General corporate purposes, which may include research and development expenditures, clinical trial expenditures, manufacture and supply of product, and working capital.
Potential Tax Treatment:	Any portion of a distribution that exceeds our current and accumulated earnings and profits will first be applied to reduce a U.S. holder's tax basis in the Series A Preferred Stock, but not below zero. Distributions in excess of our current and accumulated earnings and profits and in excess of a U.S. holder's tax basis in its shares will be taxable as gain from the disposition of the Series A Preferred Stock.
Joint Bookrunning Managers:	The Benchmark Company ThinkEquity, a division of Fordham Financial Management, Inc.



# The Opportunity



Near-term Key Catalysts that will Create Value Opportunities

ONE



Robust Pipeline with 25+ Development-stage Biotech Product Candidates<sup>1</sup>

TWO



Solid Track Record of Execution

THREE



Valuation Dislocation

FOUR



Near-term Revenue Growth

FIVE

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

## Fortress Biotech Programs\*

Commercial	Late Clinical	Early Clinical	Preclinical
Targadox®	Cosibelimab	MB-102	ATVS-001 Gene Therapy
Ximino®	MB-107 / MB-207	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	KRAS G12D ONCOlogues
		BAER-101	Multiple Other ONCOlogues

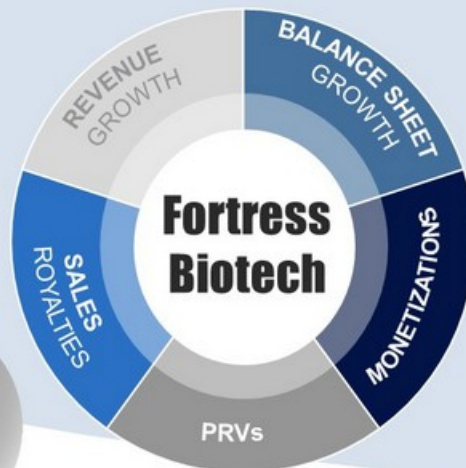
Dermatology	Gene Therapy	Oncology / Hematology	Pain	Rare Diseases	Traumatic Brain Injury	Vaccines	CNS Disorders
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\*Includes product candidates in development at Fortress, at its majority-owned and majority-controlled subsidiaries and at entities in which it holds minority ownership positions.

Generating Cash Flow & Shareholder Value

Creating value  
**in five ways**

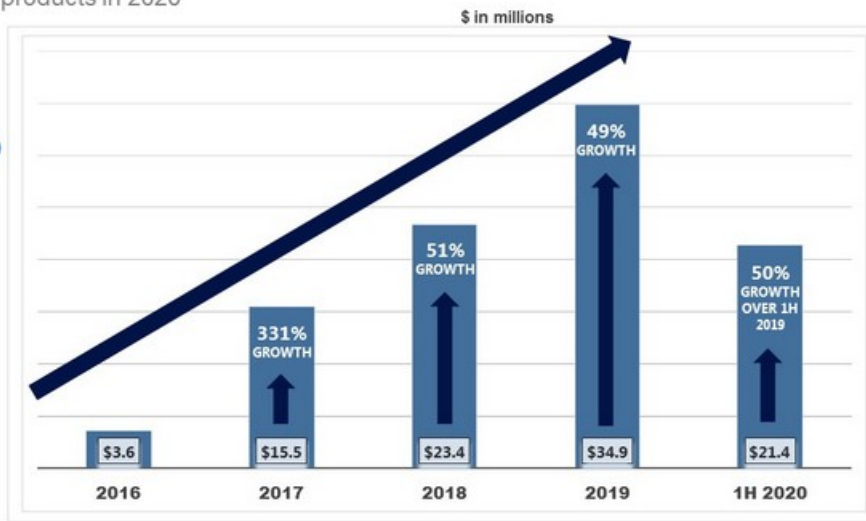


# Dermatology Product Revenue Growth

Expect to acquire 1 to 2 new products in 2020

## Reaching >70%

of market via top 5,000  
prescribing dermatologists





# 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>○ Relatively de-risked assets</li><li>○ High value / need</li><li>○ Low acquisition cost</li><li>○ Known buyers</li></ul>



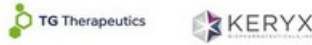
<sup>1</sup>Includes employees and product candidates in development at Fortress, at its majority-owned and majority-controlled partners.

# 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



## Top-tier Academic & Commercial Partners



## Near-term Monetization Opportunities



### Contingent Acquisition By Cipla

- Upon FDA approval and other conditions<sup>1</sup>
- \$180 Million aggregate cash purchase; (est. \$13.92/share)<sup>1</sup>; *FBIO 29% or eligible to receive ~\$48M of the distribution net of fees*
- Potential additional payments pursuant to Contingent Value Rights; *CVR payout of 10-20% of gross profits*<sup>2</sup>
- FBIO stands to realize ~\$48M in addition to value of CVRs



### Contingent Exclusive Acquisition Option Granted To Alexion (Jan. 2019)

- Alexion purchased minority stock position in Caelum for \$30M, with up to an additional \$110M in funding due upon achievement of development milestones
- Additionally, up to \$500M payable to Caelum shareholders in connection with Alexion option exercise:
  - \$150M upfront
  - Up to \$350M in contingent approval / sales milestone payments
- FBIO owns ~40% of Caelum and is eligible to receive ~43% of upfront and approval/sales milestone proceeds in event of Alexion exercise of contingent option



<sup>1</sup>subject to conditions described in Avenue public filings  
<sup>2</sup>Fortress to receive ~1/3 of CVR royalty if certain net sales thresholds are met

## Near-term Value Creating Pipeline

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				PDUFA action date of October 10, 2020	29% Avenue** 10-20% CVR Royalty on gross profits****	~\$790M
<b>MB-107 &amp; MB-207 Gene Therapy</b>	XSCID (newly diagnosed) XSCID (previously transplanted)				File IND for MB-207 (previously transplanted patients) in 4Q 2020	25% Mustang 4.5% Royalty	~\$200M
<b>CUTX-101 Copper Histidine</b>	Menkes disease				Rolling NDA submission expected to start in 4Q 2020 and be completed in 1H 2021	79% Cyprium 4.5% Royalty	~\$175M
<b>COSIBELIMAB Anti-PD-L1 mAb</b>	Recurrent or metastatic cancers				P1 Registration-enabling expansion cohorts ongoing; potential to support 1 or more BLA filings	21% Checkpoint 4.5% Royalty	\$300M - \$500M (Initial indication CSCC)
<b>CK-101 Mut.-EGFR inh.</b>	EGFR* NSCLC				Initiate Registration Study	21% Checkpoint 4.5% Royalty	\$300M - \$600M
<b>CAEL-101 mAb 11-1F4</b>	Amyloid light chain amyloidosis				Initiate pivotal Phase 3 program 2H 2020	43% Caelum***	
<b>BAER-101 α2/3-subtype-GABA A PAM</b>	CNS Disorders				Preclinical POC data to support IND in Refractory Epilepsy anticipated 2020	67% Baergic 4.5% Royalty	~\$200M - \$300M (refractory epilepsy)

\*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.

\*\*FBIIO is eligible to receive ~22% of the proceeds upon the second-stage closing of the InvivoGen transaction net of fees, and currently owns 23% of Avenue's issued and outstanding capital stock.

\*\*\*FBIIO 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.

\*\*\*\*FBIIO receives ~1/3 of the CVR Royalty on gross profits based on certain net sales thresholds.

\*Based on most recent internal forecasts and assuming approval in all denoted indications.

Registration-enabling

## Early Clinical Pipeline

Candidate*	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Next Milestone	Partnership % / Royalty†	Potential Peak Sales Revenue*
MB-102	AML, BPDCN, and hrMDS					First patient expected to be treated in Mustang IND trial 3Q 2020	25% Mustang; 4.5% Royalty	\$500M - \$700M
CEVA-101	Traumatic Brain Injury (pediatric and adult)					Phase 2 Data in Peds expected 2H 2020 Phase 2 Data in Adults expected 2022	78% Cellvation; 4.5% Royalty	\$1B+ in US / EU
MB-101	Glioblastoma (GBM)					COH expected to file IND for Phase 1 combination trial with MB-108 4Q2020	25% Mustang; 4.5% Royalty	\$500M - \$700M
MB-106	B-Cell Non-Hodgkin Lymphoma, and CLL					First data disclosure from FHCRC Phase 1 trial expected 4Q2020	25% Mustang; 4.5% Royalty	\$750M - \$1,000M
MB-103	GBM and Metastatic Breast Cancer to Brain					First data disclosure from COH Phase 1 trials expected in 2021	25% Mustang; 4.5% Royalty	\$400M - \$500M
MB-108	Glioblastoma (GBM)					COH expected to file IND for Phase 1 combination trial with MB-101 4Q2020	25% Mustang; 4.5% Royalty	\$200M (used only with MB-101)
MB-104	Multiple Myeloma (MM)					First data disclosure from COH Phase 1 trial expected 2021	25% Mustang; 4.5% Royalty	\$500M - \$700M
MB-105	Prostate & Pancreatic Cancers					First data disclosure from COH Phase 1 prostate cancer trial expected 1Q 2021	25% Mustang; 4.5% Royalty	\$500M - \$700M
Triplex	Cytomegalovirus (CMV)					Initiate Phase 2 study in kidney transplant	81% Helocyte; 4.5% Royalty	\$500M+ in US / EU

## Pre-Clinical Pipeline

Candidate*	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Next Milestone	Partnership % / Royalty†	Potential Peak Sales Revenue*
ATVS-001 Gene Therapy	AMD, PNH, and aHUS					Non-human primate long-term toxicology data and additional POC in Dry AMD	62% Aevitas; 4.5% Royalty	>\$1B
AAV-ATP7A Gene Therapy	Menkes Disease					Nominate candidate for clinical development in 2021	79% Cyprium; 4.5% Royalty	~\$100M - \$400M
CEVA-102	Traumatic Brain Injury (TBI)					Initiate Phase 1 Study in 2021	78% Cellvation; 4.5% Royalty	\$1B+ in US / EU
ConVax	Cytomegalovirus Prevention & Control					Initiate Phase 1 Study in 2021	81% Helocyte; 4.5% Royalty	\$1B+ in US / EU
ONCOlogues	KRAS G12D					Finalize KRAS G12D in-vivo dataset	80% Oncogenity; 4.5% Royalty	>\$10B
ONCOlogues	Other Genetically Driven Cancers & Coronaviruses					POC in genetic disorders (non-oncology) and coronaviruses	80% Oncogenity; 4.5% Royalty	Multiple >\$1B opportunities

\*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.  
†Based on most recent internal forecasts and assuming approval in all denoted indications



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

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

- FBIO eligible to receive up to \$48M upfront in contingent acquisition of Avenue
- CVR Payout of 10-20% of gross profits<sup>2</sup>
- PDUFA goal action date of 10/10/2020

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

- Eligible to receive 43% of up to \$500M (upfront and approval / sales milestones) in event of Alexion exercise of contingent option
- Initiate pivotal Phase 3 program in 2H20

### Journey Medical

- Generated \$34.9M in net revenue for the full year 2019; a 49% increase over 2018
- Generated \$21.4M in revenue in the first half of 2020, a 50% increase over the first half of 2019
- Expect to acquire 1 to 2 new revenue-generating dermatology products in 2020

### MB-107 & MB-207<sup>1</sup>

- Expect to commence Phase 2 registration trial for newborns with XSCID shortly
- File IND for Phase 2 registration trial in previously transplanted patients, expected Q4 2020

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

- Interim data update for cosibelimab expected in 2H 2020; Complete enrollment in cosibelimab registration-enabling CSCC expansion cohort expected year-end 2020
- Potential initiation of CK-101 global registration study for treatment of lung cancer

### ONCOlogues Platform

- KRAS G12D pre-IND completion

### PRVs (Priority Review Vouchers)

- Filing for at least 2 PRVs anticipated (CUTX-101, MB-107 (newly diagnosed) and MB-207 (previously transplanted))<sup>1</sup>
  - Data suggests PRVs may be worth ~\$75M to ~\$110M, each

<sup>1</sup>IV Tramadol, CAEL-101, Cosibelimab, CK-101, CUTX-101, MB-107 (newly diagnosed XSCID), MB-207 (previously transplanted XSCID) and ONCOlogues are product candidates in development at FBIO partner companies

<sup>2</sup>Fortress to receive ~1/3 of CVR royalty if certain net sales thresholds are met



# MB-107 & MB-207\*

XSCID "Bubble Boy" Disease



## Fortress Biotech Near-Term Value Creating Pipeline Assets

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

**Status** Phase 2

**Next Steps** File IND for Phase 2 registration trial in previously transplanted patients, Q4 2020 (new designation – MB-207)

**PRVs** PRVs for each of the 2 patient populations, ~\$75M to ~\$110M for each PRV

- 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 for MB-107 granted by FDA in August 2019; Rare Pediatric Disease Designation for MB-107 granted by FDA in August 2020
- Published clinical results demonstrate\*\*:
  - Multilineage engraftment of transduced cells
  - Reconstitution of functional T cells and B cells
  - Normalization of NK-cell counts

\*Product candidates in development at Mustang Bio, Inc., an entity which was founded by Fortress and in which Fortress still maintains a large ownership position.

\*\*Mamcarz E et al. *N Engl J Med*. 2019; 380: 1525-1534; also, Mamcarz E et al. *Blood*. 2019;134(Suppl1): 2058.

# CUTX-101

Menkes Disease



## Fortress Biotech Near-Term Value Creating Pipeline Assets

<b>Est. Market</b>	Estimated Peak Sales of \$175M
<b>Status</b>	Phase 3 enrollment complete
<b>Next Steps</b>	Rolling NDA submission expected to start in 4Q 2020 and be completed in 1H 2021
<b>PRV</b>	Eligible for PRV ~\$75M to ~\$110M

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

# COSIBELIMAB\*

Anti-PD-L1



## Fortress Biotech Near-Term Value Creating Pipeline Assets

**Est. Market** PD-L1 mAbs: \$40b+ / year

**Status** Registration-enabling Phase 1

**Next Data** Anticipated 2H 2020

**Next Steps** Complete enrollment in 2021

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

\*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.

# CK-101\*

Third-Gen EGFR Inhibitor



## Fortress Biotech Near-Term Value Creating Pipeline Assets

**Est. Market** \$6b+ / year

**Status** Phase 1

**Next Steps** Initiate registration trial

\*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®

# 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>	FDA accepted NDA submission for review
<b>Next Steps</b>	PDUFA action date of October 10, 2020
<b>CVRs</b>	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 if certain net sales thresholds are met

- o Uniquely positioned to address need for new post-operative pain therapies amid opioid crisis
- o Potential to replace conventional narcotics in wide range of patients
- o Two-stage acquisition agreement with Cipla minimizes dilution and provides substantial upside to shareholders; First stage closed in February 2019
- o 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 2

**Next Data** Phase 2 safety data readout anticipated 3Q 2020

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

\*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.

- Granted Orphan Drug designations in the U.S. and EU
- 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

# ONCOlogues\*

Gene-Silencing at the DNA Level



## Fortress Biotech Near-Term Value Creating Pipeline Assets

<b>Est. Market</b>	Various Gene-Silencing Markets >\$1B each KRAS G12D estimated >\$10B
<b>Status</b>	Pre-Clinical
<b>Next Steps</b>	Finalize KRAS G12D in-vivo dataset POC in genetic disorders (non-oncology) POC in coronaviruses Additional Oncogene targets Finalize clinical formulation

- Delivery platform allows PNAs to enter cell membrane & nucleus, displacing mutant DNA strand, preventing mutant mRNA transcription
- ONCOlogues work higher upstream than traditional antisense and small molecule approaches, targeting the root of genetic disease
- KRAS G12D remains a complete unmet need and plays a heavy role in devastating cancers, including: ~35% of pancreatic, ~12% of colorectal, and ~5% of endometrial and NSCLC
  - KRAS G12C for NSCLC is considered ~\$4B market opportunity with ~40K patients in the US/EU
  - KRAS G12D has ~180K patients in the US/EU within pancreatic, colorectal, endometrial and NSCLC
- Single Stranded RNA viruses, like COVID-19, are easily targeted by ONCOlogues

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



# BAER-101

CNS Disorders



## Fortress Biotech Near-Term Value Creating Pipeline Assets

**Est. Patient Population** ~1M refractory epilepsy patients per year in U.S.

**Status** Phase 1 in CNS Disorders

**Next Steps** Finalization of pre-clinical proof-of-concept data for BAER-101 to support IND in Refractory Epilepsy anticipated 2020

- High affinity, selective modulator of GABA  $\alpha$  receptor system
- Selective positive allosteric modulator (PAM) for GABA $\alpha$ 2/3, minimizing adverse events that are typically seen with benzodiazepines, which are non-selective agonists
- Established safety profile
- Epilepsy is among the most prevalent neurological disorders, affecting ~1% of the world population (~3M in the U.S.)

\*Product candidates in development at Baergic Bio, Inc., an entity which was founded by Fortress and in which Fortress still maintains a large ownership position.

## Key Takeaways



Near-term Key Catalysts that will Create Value Opportunities

ONE



Robust Pipeline with 25+ Development-stage Biotech Product Candidates<sup>1</sup>

TWO



Solid Track Record of Execution

THREE



Valuation Dislocation

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Near-term Revenue Growth

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

# FORTRESS BIOTECH

## Financial Snapshot

NASDAQ	FBIO
Shares outstanding as of 6/30/20:	86,113,331
Market Cap as of 8/17/20:	~\$279.0 million
Consolidated cash as of 6/30/20:	\$199.9 million <sup>1</sup>
FBIO standalone cash as of 6/30/20:	\$86.3 million <sup>2</sup>
Value of FBIO ownership of public partner companies as of 8/17/20:	~\$109.1 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 ATXI, CKPT and MSIO



# Investment Highlights

- World class management team with extensive experience in all facets of biotech with multiple successful exits;
- Implementing revenue generating model focusing on low risk and low cost portfolio acquisition using strategic partners for funding;
- Deep existing portfolio with multiple opportunities for cash generation, well in excess of preferred dividend.

