

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): February 14, 2017

FORTRESS BIOTECH, INC.

(Exact Name of Registrant as Specified in Charter)

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

Item 8.01. Other Events.

Attached hereto as Exhibit 99.1 and incorporated herein by reference is a presentation including an updated corporate overview of Fortress Biotech, Inc.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Presentation of February 2017.

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 14, 2017

/s/ Lindsay A. Rosenwald

Name: Lindsay A. Rosenwald, M.D.

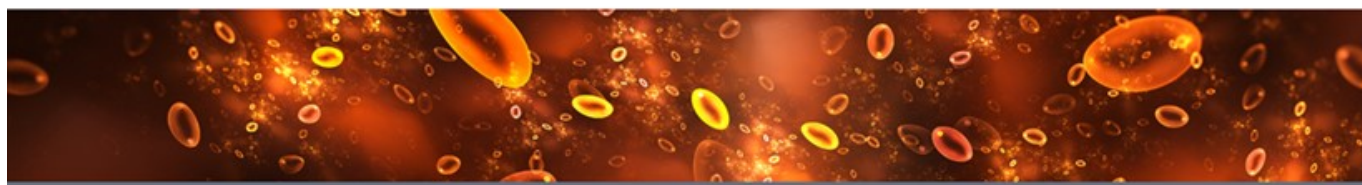
Title: Chairman of the Board of Directors,
President and Chief Executive Officer

Corporate Presentation

Lindsay A. Rosenwald, MD

President and CEO

Chairman of the Board



February 2017

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. 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 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.



Fortress Biotech: Our Unique Approach

What we do: Acquire, develop and commercialize novel biopharmaceutical products in all stages of development and across multiple therapeutic areas directly within Fortress Biotech and through our subsidiaries.

Our business strategy: Build subsidiaries around marketed products and product candidates that create a pipeline providing our shareholders with a diversified long-term revenue stream.

Product candidates



Fortress Biotech: Creating Opportunity

Business Advantages

- Unique business model and company structure
- Seek out the best product candidates
- Move fast to get products to market
- Extensive experience in structuring deals
- Take advantage of time-sensitive opportunities
- Top tier, focused and experienced management team

Financial Advantages

- Strong capital position
- Access to additional capital
- Efficient plan to fund subsidiaries
- Multiple revenue streams (sales, equities, royalties, fees)
- Super-majority voting shares of each subsidiary



Experienced Leadership

Lindsay A. Rosenwald, MD
President and CEO
Chairman of the Board

- Co-Portfolio Manager and Partner of Opus Point Partners
- Prolific and successful investor in the life sciences industry for over 20 years previously as Chairman of Paramount BioCapital

Michael S. Weiss
Executive Vice Chairman
Co-Vice Chairman of the Board

- Co-Portfolio Manager and Partner of Opus Point Partners, LLC
- Executive Chairman and CEO of TG Therapeutics
- Previously Chairman and CEO of Keryx Biopharmaceuticals

George C. Avgerinos, PhD
Senior Vice President, Operations

- Former Divisional VP, Global Process and Manufacturing Sciences, Abbvie
- Over 30 years experience in biopharmaceutical process development including leading Humira's™ process and manufacturing, world's biggest selling pharmaceutical product

Lucy Lu, MD
Executive Vice President
Chief Financial Officer

- Former Senior Analyst at Citi Investment Research
- Over 10 years of biotech equity research experience

Eric K. Rowinsky, MD
Co-Vice Chairman of the Board

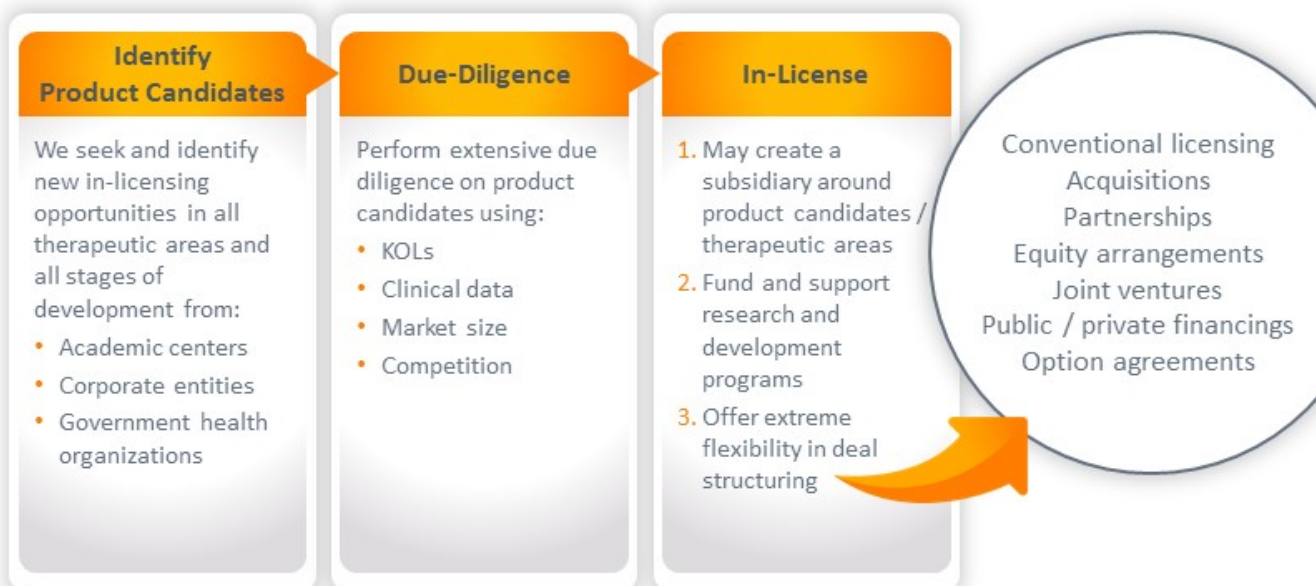
- Executive Vice President, Chief Medical Officer and Head of Research and Development, Stemline Therapeutics, Inc.
- Currently serves on board of Biogen, Inc.
- Oncologist and former Chief Medical Officer at ImClone Systems, Inc.



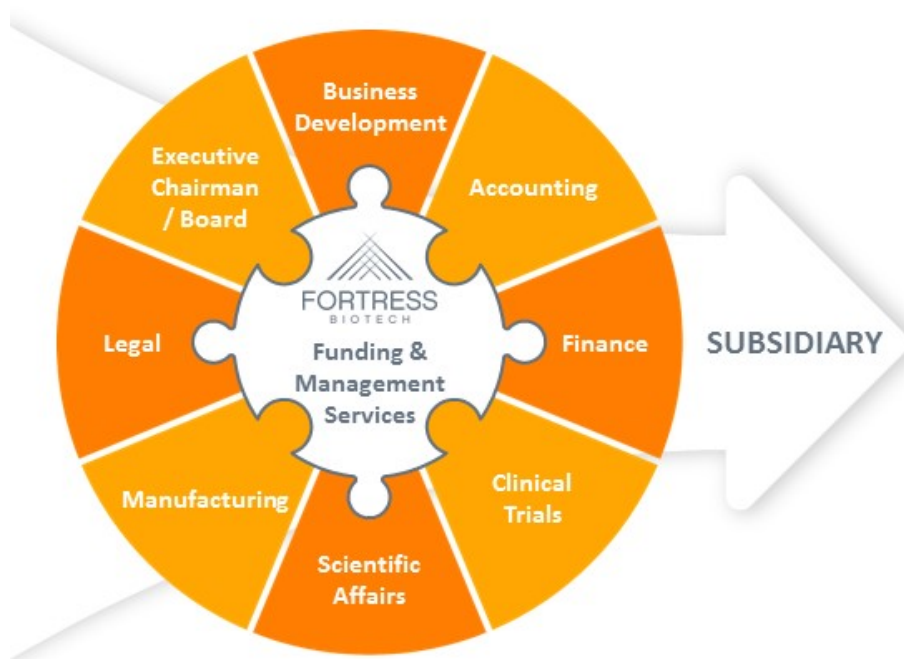
Diversified Portfolio of Subsidiaries



Provide Efficient Way To Develop / Commercialize A Product



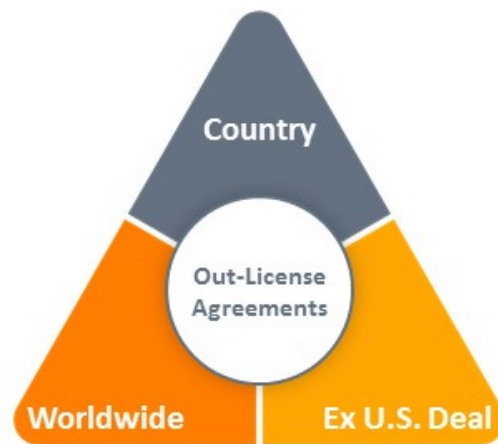
Fortress: Offer Subsidiaries Accelerated Drug Development



1. Expertise in each therapeutic area
2. Knowledge of the development process
3. Pooled resources
4. Cost efficient operations structure
5. Top-tier focused management team
6. Access to capital



Out-License Strategy Adds To Market Size



- Supports portfolio / capital needs
- Provides revenue to find more assets
- Monetizes pipeline



Hematology / Oncology Pipeline

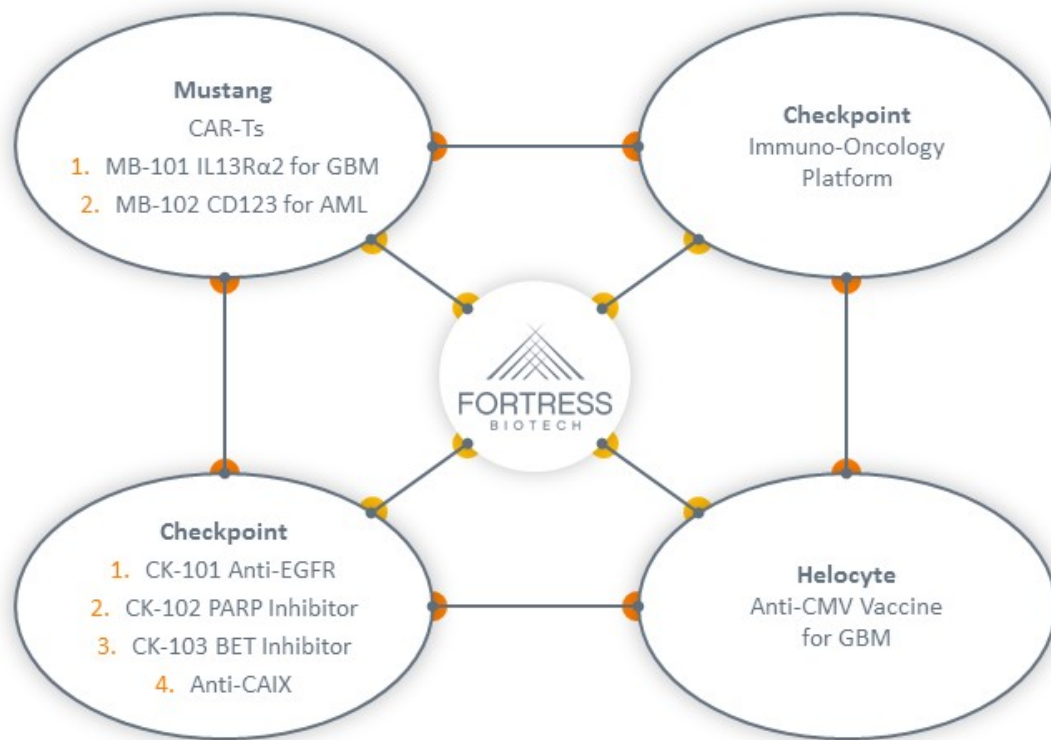
Subsidiary	Product Candidate	Indication	Stage of Development				
			Preclinical	Phase 1	Phase 2	Phase 3	Commercial
Caelum Biosciences	CAEL-101	AL Amyloidosis	█	█			
Checkpoint Therapeutics	Anti-PD-L1	Solid Tumor	█				
	Anti-GITR		█				
	Anti-CAIX		█				
	CK-101 EGFR Inhibitor		█	█			
	CK-102 PARP Inhibitor		█	█			
Mustang Bio	MB-101 IL13Rα2-specific CAR	Malignant Glioma	█	█			
	MB-102 CD123 CAR	AML; BPDCN	█	█			
Fortress Biotech	CNDO-109	AML; MDS	█	█			



Diversified Pipeline Across Different Therapeutic Areas

Subsidiary	Product Candidate	Indication	Stage of Development				
			Preclinical	Phase 1	Phase 2	Phase 3	Commercial
Cellvation	CEVA101	MNCs for Pediatric TBI	█	█	█		
	CEVA101	MNCs for Adult TBI	█	█	█		
	CEVA102	NextGen for Pediatric TBI	█				
	CEVA102	NextGen for Adult TBI	█				
	CEVA-D	Bioreactor – Device	█	█			
Helocyte	Triplex	CMV Control Allo-Stem Cell	█	█	█		
	PepVax	CMV Control Allo-Stem Cell	█	█	█		
	Triplex	CMV Control Solid Organ Tumor	█	█	█		
	Triplex	Glioblastoma Multiforme	█	█	█		
	Triplex	Hematological Malignancies	█	█	█		
	Triplex plus Mustang CAR-T	Glioblastoma Multiforme	█	█	█		
	Triplex plus Mustang CAR-T	Hematological Malignancies	█	█	█		
	Pentamer	Congenital CMV	█				
Escala Therapeutics	ManNAc	GNE Myopathy	█	█	█		
	ManNAc	Nephropathies	█	█			
Avenue Therapeutics	IV Tramadol	Post Surgical Pain	█	█	█		
Journey Medical Corporation	Targadox	Acne	█	█	█	█	█
	Ceracade	Eczema Emollient	█	█	█	█	█
	Luxamend	Wound Cream	█	█	█	█	█
	Dermasorb HC	Atopic Dermatitis	█	█	█	█	█

Significant Synergies Between & Among Subsidiaries



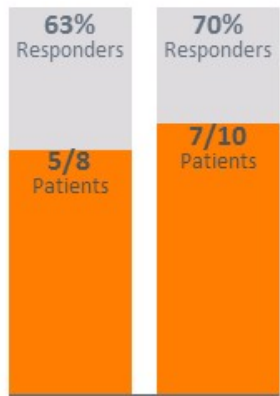
Rare & Life-Threatening Conditions



CAEL-101 is a novel antibody in Phase 1b clinical trials that is being developed for patients with AL Amyloidosis

Focus	Developing treatments toward rare and life threatening diseases that lack effective therapies
Market Size	30,000-45,000 patients in the US and EU; 4,500 newly diagnosed patients per year AL amyloidosis is the largest of systemic amyloidosis including both ATTR and AA
Product Candidate	CAEL-101, a pioneering antibody being developed to specifically target AL fibrils and dissolve amyloid deposits
Clinical Trials	Interim Phase 1 data of 21 patients, CAEL-101 is well-tolerated and safe showing no dose limiting toxicity: 67% of patients with organ response independent of light chain sub-type
Milestones	Phase 1a/1b expected to complete 1Q2017 Phase 2 expected to commence 1H2018
Licensors & Scientific Advisor	Columbia University: January 2016 Suzanne Lentzsch, M.D., Ph.D., Professor of Medicine at Columbia University Medical Center, Scientific Advisory Board Chair and Primary Investigator on Phase 1a/1b study
CEO	Michael Spector (25+ years of leadership experience in pharmaceutical and biotechnology)

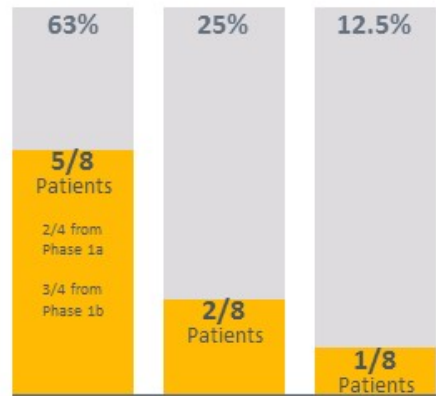
CAEL-101 Phase 1a/1b Organ Response Rates



PHASE 1A
8 Weeks
Single Dose

PHASE 1B
12 Weeks
4 Weekly Doses

**Overall Responders
Best Organ Response**

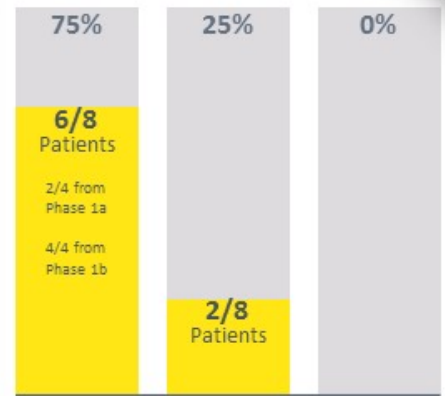


RESPONDER
>30% and >300 pg/ml decrease in NT-proBNP

STABLE

PROGRESSOR
>30% and >300 pg/ml increase in NT-proBNP

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



RESPONDER
>30% decrease in proteinuria or a decrease to <0.5 g/24 hours

STABLE

PROGRESSOR
>25% worsening in EGFR

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

Immuno-Oncology

Building a platform to combine targeted agents with immuno-oncology agents to maximize anti-cancer effect and develop first-in-class or best-in-class combination treatments

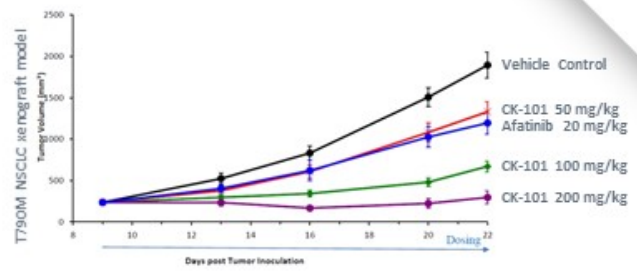
Focus	Acquire and develop novel immuno-oncology and targeted cancer agents alone and in combination to treat patients with solid tumors
Market Size	Anti-PD-(L)1 >\$30B, Anti-GITR > \$1B, CK-101 EGFR > \$3B, CK-103 BET > \$500M
Product Candidates	Two immuno-oncology "I/O" antibodies, licensed from Dana Farber Four targeted anti-cancer agents
Clinical Trials	CK-101 (EGFR Inhibitor) Phase 1/2 study ongoing
Milestones	Mid- 2017: Anti-PD-L1 IND expected 2H 2017: CK-101 (EGFR Inhibitor) Phase 2 expected initiation 2H 2017: CK-103 (BET Inhibitor) target IND filing 1H 2018: Anti-GITR target IND expected
TGTX Collaboration	Joint development of anti-PD-L1 and anti-GITR mAbs, and BET inhibitor program with Checkpoint developing solid tumor indications and TG in liquid tumors
Funding	~\$40M (9/30/16) to support development programs through 2018
CEO	James Oliviero (15+ years of leadership experience in pharmaceutical and biotechnology, previously senior management of Keryx, achieving a new drug approval)

CK-101, 3rd Generation EGFR Pre-Clinical Efficacy

Cell Line	IC ₅₀ (nM)		
	A431	H1975	HCC827
Mutation	EGFR Wild-Type	EGFR Mutant L858R / T790M	EGFR Mutant Exon 19 del
Afatinib	34	23	1
Tagrisso	280	2	3
CK-101	689	5	10

In vitro, CK-101 showed:

- Strong efficacy for T790M and other EGFR mutations
- Good selectivity for mutant over wild-type EGFR A431/H1975 ratio ~ 100 fold



In mice, CK-101 showed strong activity against T790M mutated NSCLC with increasing dose



Aggressive Forms of Cancer

Robust CAR-T platform technology in partnership with pioneers in CAR-T technologies from City of Hope, recently raising a \$94.5M private placement financing

Focus	Two lead CAR-T programs targeting IL13R α 2 and CD123, for the treatment of Glioblastoma Multiforme and AML/BPDCN, respectively
Market Size	In U.S., Japan and five major EU markets per year... ~30,000 newly diagnosed GBMs (malignant brain tumor) ~30,000 newly diagnosed cases of AML (acute myeloid leukemia)
Product Candidates	MB-101 IL13R α 2-specific CAR-T cells which have no current competition MB-102 CD123-specific CAR-T cells which have been validated in ultra orphan indication
Clinical Trials	Two Phase 1 trials ongoing with preliminary safety data from at least 6 patients in both CAR-T programs
Milestones	Phase 1 data readouts early 2018 NEJM case study demonstrates MB-101 achieved complete remission in patient with recurrent GBM
Licensors	City of Hope
Scientific Advisors	Dr. Stephen Forman, City of Hope Dr. Christine Brown, City of Hope

Phase 1 Clinical Trials With MB-101 & MB-102 Are Ongoing

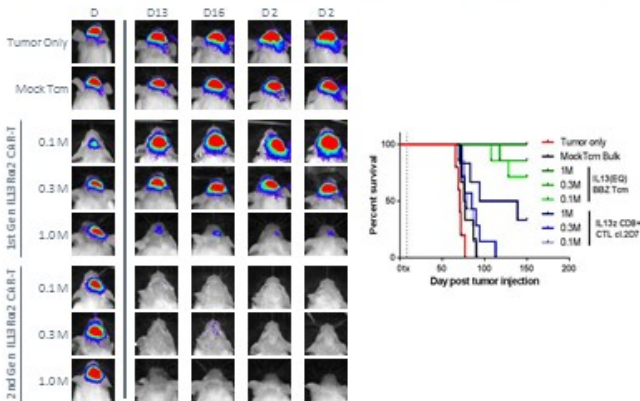
MB-101 is Ongoing

Patient Population	Rel/Ref GBM – Arm 1: Resectable / Arm 2: Non-resectable
Planned Enrollment	12/arm
Study Objectives	Asses the feasibility, safety and determine MTD

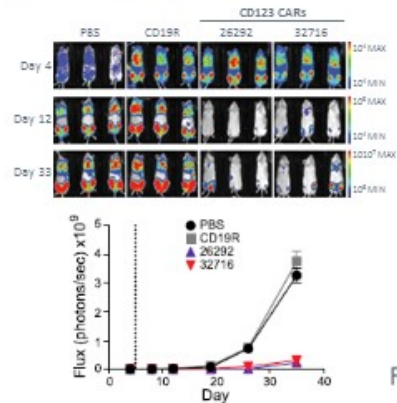
MB-102 is Open & Recruiting Patients

Patient Population	Rel/Ref AML
Planned Enrollment	18
Study Objectives	Asses the feasibility, safety and determine MTD of Single Infusion

MB-101 CAR-T is more potent than 1st generation IL13-targeted CAR-T



MB-102 (CD123) – Antitumor activity against human Acute Myeloid Leukemia



CEVA101: Severe Traumatic Brain Injury



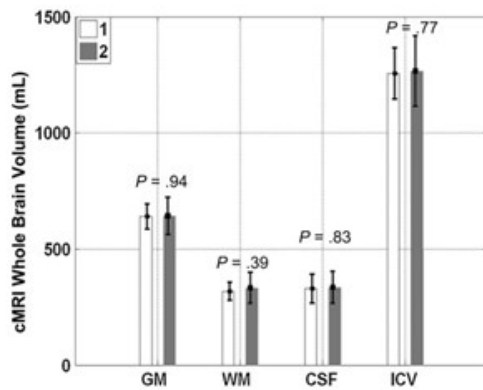
No approved reparative therapy for treatment of severe TBI. Now have CEVA101, a biologic, that minimizes the secondary injury associated with TBI.

Focus	Develop novel biologic therapies for TBI treatment
Market Size	200,000 adults / 50,000 children with TBI
Product Candidate	CEVA101: Autologous bone-marrow derived mononuclear cells
Clinical Trials	Two ongoing Phase 2 studies, one adult and one pediatric Phase 1 in Adult TBI: Published in <i>Stem Cells</i> , November 2016
Milestone	Phase 2 data in Children by 1H2018, in Adults by 1H2019 Potential for accelerated approval in Japan Potential for pediatric voucher
Licensors	Two technology platforms from University of Texas Health Science Center
Funding	NIH/DOD Grant Funding: \$10M, low capital requirement
CEO	Frank Taffy (15+ years of experience at Forest Labs and Life Tech in corporate development and operations)



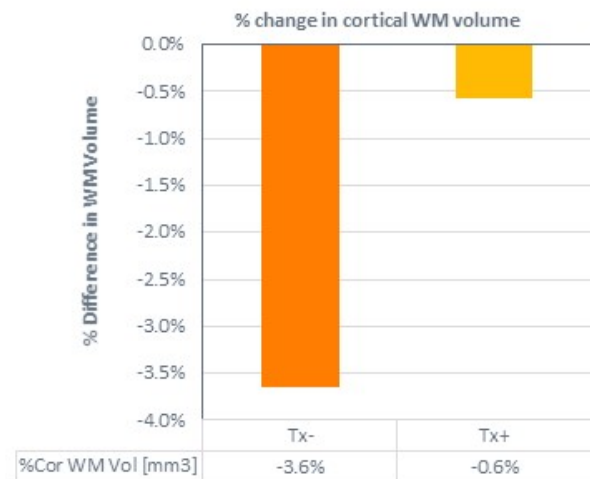
Structural Preservation Through Cell Therapy

**CEVA101 Phase 1:
Volumetric Preservation in Pediatric TBI**



- Post-TBI MRI at Month 1 (Scan 1) versus Month 6 (Scan 2)
- Preservation of Grey Matter (GM), White Matter (WM), Intracranial Volume (ICV)

**CEVA101 Phase 1:
Volumetric Preservation in Adult TBI**



Cytomegalovirus (CMV): Common Virus



Three novel biologic immunotherapies (two in Phase 2) targeting \$billion orphan market

Focus	Develop novel immunotherapies for the prevention and treatment of CMV that can cause life-threatening disease in those with weak immune systems
Market Size	CDC estimates 50-80% infected with Cytomegalovirus (CMV) by age of 40 CMV in Allogeneic Stem Cell Transplant: U.S. Incidence ~8,000 / EU Incidence ~15,000 CMV in Allogeneic Solid Organ Transplant: U.S. Incidence ~8,000 / EU Incidence ~15,000
Product Candidates	PepVax: HLA-restricted, single antigen CMV vaccine Triplex: First universal, multi-antigen CMV vaccine
Clinical Trials	PepVax: Phase 2 ongoing, multi-center, double-blind trial for stem cell transplant (n=96) Phase 1b showed safe, effective and Published in Lancet Dec 2015 Triplex: Phase 2 ongoing, multi-center, double-blind trial for stem cell transplant (n=115) Phase 1 showed safe, immunogenic. Presented ASH 2015. Published in Blood Nov 2016
Upcoming Milestones	Triplex: Phase 2 topline 100 day data by 2H2017 PepVax: Phase 2 topline data by 1H2018
Licensors	City of Hope
Funding	Total budget (thru 1H2019): ~ \$30M (Including \$8M NCI grant funding)
CEO	Frank Taffy (15+ years of experience at Forest Labs and Life Tech in corporate development and operations)

Phase 1 Studies: Journal Publications



Phase 1b

(Completed, Published in *The Lancet*)

Design	Single-Center (City of Hope) Study in 36 Allogeneic HSCT CMV(+)Recipients Randomized (1:1) between Vaccine Arm (VA) and Observation Arm (OA)
Dosing Schedule	Two subcutaneous vaccinations after transplant <ul style="list-style-type: none"> • Day 28 • Day 56
1^o Endpoint	Overall safe and well-tolerated Published in <i>The Lancet Haematology</i> (12/28/2015)
2^o Endpoint	<ul style="list-style-type: none"> • Increase in CD8+T-cells • Reduced CMV Reactivation, 6% vs.33%,p=0.044 • Reduced Relapse, 6% vs. 28%, p=0.015 • Reduced Death, Ovs. 39%

Phase 1

(Completed, Published in *Blood*)

Design	Single-Center (City of Hope) Dose Escalation (three levels) in 24 Healthy Volunteers (CMV +/-)
Dosing Schedule	Two IM injections four weeks apart Last patient dosed 4/2015
1^o Endpoint	Safe and well-tolerated in all dose cohorts Presented at <i>ASH</i> (December 2015) Published in <i>Blood</i> (November 2016)
2^o Endpoint	↑pp65-, IE1-, IE2-specific CD8 and CD4 T-cells Particularly pronounced increase in T-cells in those with low baseline levels

	Vaccine (n=18)	Observation (n=18)
Patients with serious adverse events	4 (22%)	9 (50%)
Disease relapse	1 (6%)	5 (28%)
Death	0 (0%)	7 (39%)
CMV viraemia (≥500 gc/mL)	1 (6%)	6 (33%)



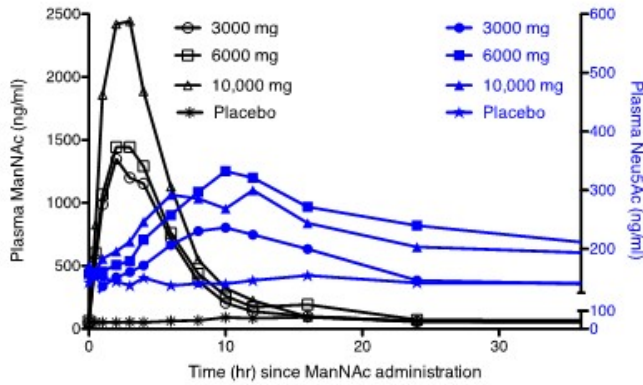
Rare & Orphan Diseases

GNE Myopathy has no approved therapies. FDA granted ManNAc orphan designation.

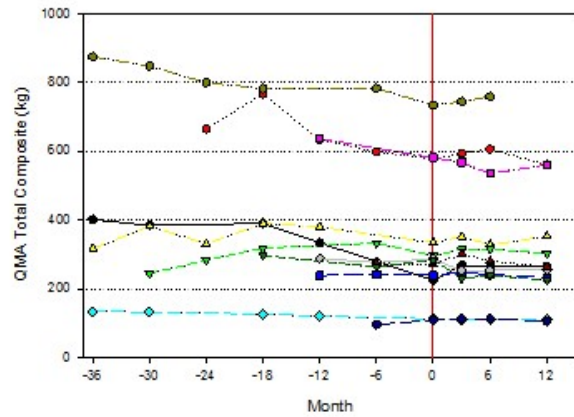
Focus	Develop and commercialize bid oral treatment for GNE Myopathy and primary podocyte nephropathies. No other company has this focus.
Market Size	GNE Myopathy: U.S. – 400 and WW – 2000 diagnosed Nephropathy (including diabetic): ~220,000 WW
Product Candidate	ManNAc=N-Acetyl-D-Mannosamine, a naturally-occurring monosaccharide and precursor to sialic acid
Clinical Trials	In collaboration with NIH on 3 clinical studies GNE Myopathy: Natural History study ongoing ,Phase 2 open label ongoing, Phase 1 completed Primary Podocyte Nephropathies: Phase 1 trial in progress (recruiting)
Upcoming Milestone	Phase 2 GNE Myopathy trial ongoing and Phase 3 planned for 2017
Licensors	Acquired from New Zealand Pharmaceuticals Ltd which is the exclusive global supplier of ManNAc
CEO	Hootan Khatami, MD (12+ years of pharmaceutical and biotechnology experience at Genzyme/Sanofi, Roche/Genentech, Merck & Daiichi Sankyo)

ManNAc Clinical Data

Phase 1 PK Results: ManNAc + Neu5Ac



Open Label Phase 2 Study



- 12 subjects on ManNAc were also previously in the Natural History Study
- Nearly all had evidence of preservation of muscle strength after 12 months on ManNAc

IV Tramadol For Acute Post Surgical Pain

IV Tramadol may be used in all types of inpatient and outpatient surgeries and as part of a multimodal analgesic plan for major surgery

Focus	Development of IV tramadol for the treatment of post-surgical pain
Market Size	IV analgesics sells ~\$1bn IV acetaminophen sells ~\$250MM Oral tramadol prescriptions increased from 23.3MM (2008) to 43.8MM (2013) Outside U.S.: IV tramadol widely used---EU accounts for 10% of IV analgesic use in post-op setting
Product Candidate	Intravenous (IV) Tramadol, an opioid without the typical side effects of narcotics , for the treatment of moderate to moderately severe pain
Regulatory Path	505b(2)
Status	Phase 3 program (bunionectomy and abdominoplasty) ready and expected to be initiated in 2017 Phase 3 confirmed at end of Phase 2 meeting with FDA
Milestones	Phase 3 Data 2018
Clinical Efficacy	Parenteral tramadol has been tested in several, randomized, double-blind, parallel-group, comparative studies. Relieved moderate to severe post-op pain associated several types of surgeries (abdominal, orthopedic, and cardiac surgery).
Funding	~\$30M to complete Phase 3
CEO	Lucy Lu, MD (CFO, Fortress Biotech and previously Citi biotechnology equity research analyst)

Survey of Anesthesiologists: Favorable View of IV Tramadol

Overall Impression

Favorable initial impression of Tramadol as a potential new IV analgesic	77%
Believes that IV Tramadol is an improvement over current post-op pain meds	97%
Believes that IV Tramadol is better than morphine on safety	87%
Believes that IV Tramadol is similar or better than morphine on efficacy	67%

Patients Taking	Switch To IV Tramadol	Add IV Tramadol
IV Morphine	40%	41%
IV NSAIDS	26%	37%
IV Acetaminophen	24%	35%

Survey of 30 U.S. Anesthesiologists. Conducted through LEERINK and available upon request.

Innovative Dermatology Products

Team of industry experts successfully launched four dermatology products

Focus	Identify and rapidly commercialize innovative, differentiated dermatology products through efficient and potent sales and marketing model
Product Candidates	Targadox: Doxycycline--acne Dermisorb: Hydrocortisone--atopic dermatitis Luxamend: Wound cream Ceracade: Skin barrier emulsion--dermatitis
Market	3,000 top prescribing dermatologists
CEO	Claude Maraoui (25+ years commercializing dermatology products; previously Vice President of Sales at Medicis)

TARGADOX™
(doxycycline hyclate USP) **50mg tablets**

Dermisorb™ **HC**
(Hydrocortisone USP, 2%) Lotion
COMPLETE KIT
Co-Promote with Crown Laboratories

Luxamend™
Wound Cream

Ceracade™
Skin Barrier Emulsion



Fortress Subsidiaries Are Creating A Pipeline of Therapies For Life-Threatening Diseases

Accelerated Drug
Development Model

Diversified
Pipeline

Experienced,
Proven Leadership

