

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): October 20, 2016

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**FORTRESS BIOTECH, INC.**

(Exact Name of Registrant as Specified in Charter)

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<b>Delaware</b> (State or Other Jurisdiction of Incorporation)	<b>001-35366</b> (Commission File Number)	<b>20-5157386</b> (IRS Employer Identification No.)
<b>2 Gansevoort Street, 9th Floor, New York, New York</b> (Address of Principal Executive Offices)		<b>10014</b> (Zip Code)

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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 October 2016.

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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: October 20, 2016

/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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**FORTRESS**  
BIOTECH

**CORPORATE OVERVIEW**

NASDAQ: FBIO

October 2016

## 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: our growth strategy; results of research and development activities; uncertainties relating to preclinical and clinical testing; 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; competition; as well as other risks described in our SEC filings. 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.



# FORTRESS BIOTECH COMPANIES



Acute settings  
(pain)



Multiple  
cancers/Epigene  
tics/Antibodies



Orphan  
diseases



Infectious  
diseases  
(CMV)



Dermatology  
(marketed  
products)



CAR-T/  
Immuno-oncology  
(brain cancer,  
leukemia)





## OVERVIEW & BUSINESS STRATEGY

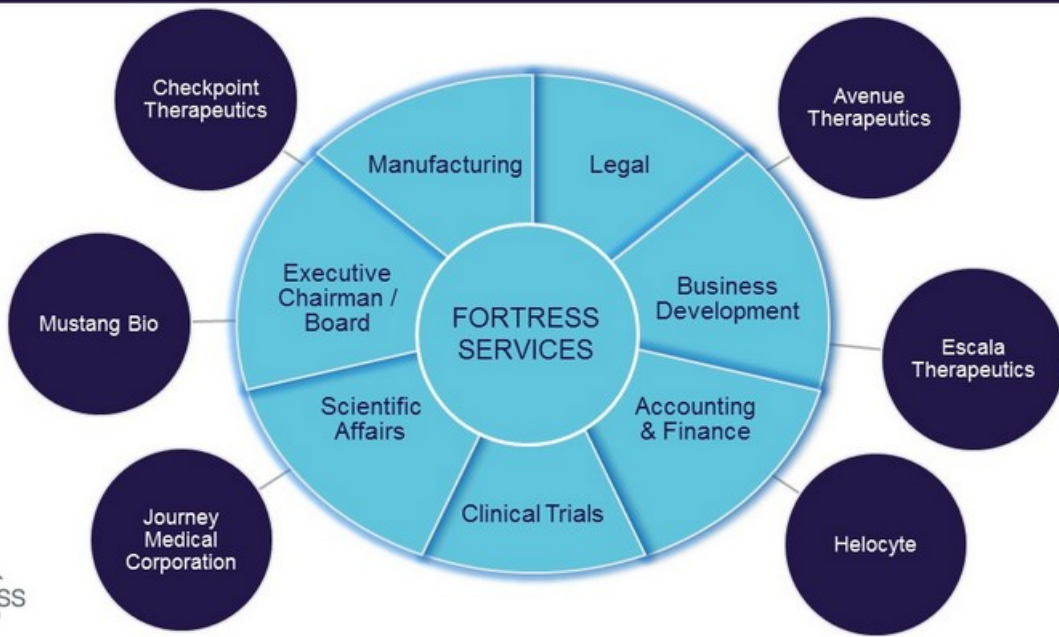
Acquire, develop and commercialize a diversified portfolio of products directly and through subsidiary companies (known as “Fortress Companies”)

Multiple sources of return for FBIO, direct sales, royalties, equity stakes and service fees

FBIO holds super-majority voting shares of each Fortress Company



# FORTRESS BIOTECH BUSINESS MODEL





# VALUE PROPOSITION

**IN JUST  
2 YEARS,  
FORTRESS HAS  
ACCOMPLISHED:**

- **CAR-T Program Including Solid Tumor (GBM) Complete Response**
- **CMV Vaccine Program: In 2 Phase 2 Clinical Trials: Positive randomized trial recently published in the Lancet Hematology**
- **Internal Immuno-Oncology program makes Fortress one of the only Life Sciences Companies with its own internal I/O and CAR-T Programs**
- **Other Phase 2 and Phase 3 Programs soon to launch**
- **A business development engine with 15 full time B/D staff and growing**

## PIPELINE PRODUCTS

PRODUCT CANDIDATE	COMPANY	STAGE OF DEVELOPMENT				
		Preclinical	Phase I	Phase II	Phase III	Commercial
Dermasorb HC <i>(Co-Promote)</i>	Journey Medical Corporation	COMMERCIAL				
Luxamend <i>(Wound Cream)</i>	Journey Medical Corporation	COMMERCIAL				
Ceracade <i>(Eczema Emollient)</i>	Journey Medical Corporation	COMMERCIAL				
Targadox	Journey Medical Corporation	COMMERCIAL				
Triplex (CMV Control) Allogeneic Stem Cell Transplant Recipients	Helocyte, Inc.	PHASE II				
PepVax (CMV Control) Allogeneic Stem Cell Transplant Recipients	Helocyte, Inc.	PHASE II				
Triplex (AIDS) ART	Helocyte, Inc.	PHASE II				
Triplex (CMV Control) Allogeneic Solid Organ Transplant Recipients	Helocyte, Inc.	PHASE I				
Triplex (Recurrent GBM)	Helocyte, Inc.	PHASE I				
Triplex (with Mustang CAR-Ts) <i>Hematological Malignancies</i>	Helocyte, Inc.	PHASE I				
Triplex (with Mustang CAR-Ts) GBM	Helocyte, Inc.	PHASE I				
Pentamer (Congenital CMV Prev)	Helocyte, Inc.	PRECLINICAL				

## PIPELINE PRODUCTS

PRODUCT CANDIDATE	COMPANY	STAGE OF DEVELOPMENT				
		Preclinical	Phase I	Phase II	Phase III (Pending)	Commercial
IV Tramadol	Avenue Therapeutics	PHASE III				
CNDO-109	Fortress Biotech	PHASE I				
Argus NeuroOptics	Fortress Biotech	PHASE II				
Anti-PD-L1	Checkpoint Therapeutics	PRECLINICAL				
Anti-GITR	Checkpoint Therapeutics	PRECLINICAL				
Anti-CAIX	Checkpoint Therapeutics	PRECLINICAL				
CK-101 EGFR Inhibitor	Checkpoint Therapeutics	PHASE III ongoing				
CK-102 PARP Inhibitor	Checkpoint Therapeutics	PHASE Ib planned				
CK-103 BET Inhibitor	Checkpoint Therapeutics	PRECLINICAL				

FORTRESS  
BIOTECH

## PIPELINE PRODUCTS

PRODUCT CANDIDATE	COMPANY	STAGE OF DEVELOPMENT				
		Preclinical	Phase I	Phase II	Phase III	Commercial
ManNAc (GNE Myopathy)	Escala Therapeutics	PHASE II				
ManNAc (Nephropathies)	Escala Therapeutics	PHASE I				
CD123 CAR (AML)	Mustang Bio	PHASE I				
IL13Ra2-specific CAR (Malignant Glioma)	Mustang Bio	PHASE I				
CGRP	Fortress Biotech	PRECLINICAL				
Oncolytic Virus Program	Fortress Biotech	PRECLINICAL				





**MUSTANGBIO** 

A FORTRESS BIOTECH COMPANY



## GBM, A SIGNIFICANT UNMET MEDICAL NEED

Glioblastoma (GBM) is the most common primary malignant brain tumor

GBM most aggressive form of brain tumor with extremely poor prognosis and overall survival (OS)

- Median OS from diagnosis is ~15 months
- Recurrent/Relapsed survival is ~5-7 months
- 5 year survival of only 5%

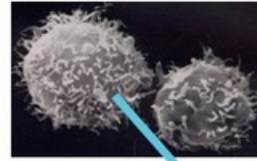
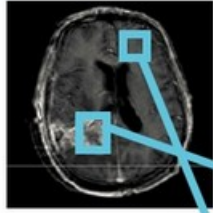
~30,000 newly diagnosed GBMs annually in the US, Japan and five major EU markets

## CAR-T PROGRAM (MUSTANG BIOTECH)

- ⊕ **Chimeric Antigen Receptor (CAR) T Cell technology from City of Hope (COH)**
  - Based on the research of Stephen Forman and Christine Brown, pioneers of CAR-T technology
- ⊕ **First two CAR-T's in the clinic, targeting**
  - IL13Ra2
  - CD123(IL3)
- ⊕ **Research collaboration between Mustang and COH to identify additional CAR-T clinical candidates**



## GBM – CART MB-101 – IL13R $\alpha$ 2 AN IDEAL TARGET FOR CAR-T



TARGET ANTIGEN	NORMAL BRAIN	GBM	T CELLS
TNF R	+/-	+++	+++
Her 2	-	+++	-
EGFR	++	++++	-
EGFRvIII	-	++++ (<30%)	-
IL-13R $\alpha$ 2	-	++++ (>90%)	-



## RESECTION ARM - ICT TREATMENT SUMMARY

PATIENT #	TX ARM / DOSE	IL13RA2 IHC	MANUF CAR T CELLS	TREATMENT DOSE	NOTES
UPN097	Resection / Dose 1	110	64% CAR 16 days	Cycles 1, 2: 2M, 10M	PD; Off-study due to rapid tumor progression
<b>UPN109</b>	<b>Resection / Dose 1</b>	<b>80</b>	<b>64% CAR 18 days</b>	Cycles 1, 2, 3 (ICT): 2M, 10M, 10M Cycles 4, 5, 6 (ICT): 10M, 10M, 10M Cycles 1, 2, 3 (ICV): 2M, 10M, 10M Cycles 4, 5 (ICV): 10M, 10M Cycles 6-9 (ICV): 10M	<b>CR Duration 7 ½ months</b>
UPN117	Resection / Dose 1	200+	60% CAR 15 days	Cycles 1, 2, 3: 2M, 10M, 10M	PD; Off-study due to rapid tumor progression
UPN122	Resection / Dose 1	150+	95% CAR 14 days	Cycles 1, 2, 3: 2M, 10M, 10M Cycles 4, 5, 6: 10M, 10M, 10M	SD* (6 cycles)
UPN125	Resection / Dose 2	200+	73.5% CAR 15 days	Cycles 1, 2, 3: 10M, 50M, 50M Cycles 4, 5, 6: 50M, 50M, 50M	SD* (6 cycles)
UPN131	Resection / Dose 2	130	81.3% CAR 14 days	Cycles 1, 2: 10M, 50M*, 50M	SD* (3 cycles)

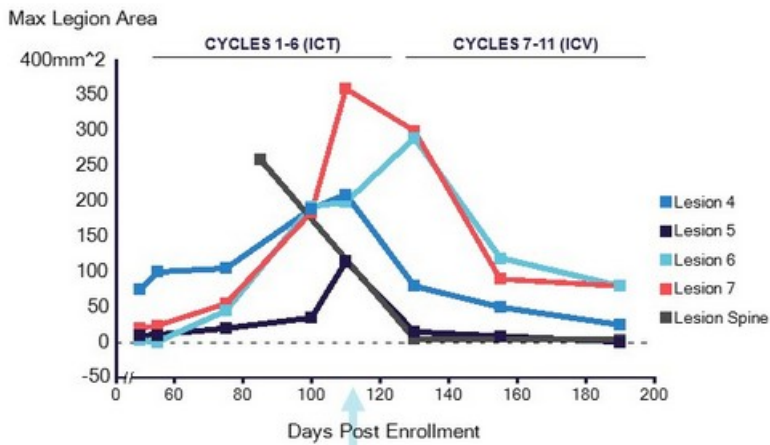


\* Preliminary data, currently under QA review

### DOSE SCHEDULE 1:

Well-tolerated in all patients treated  
No grade 3 or higher toxicities  
No CRS or Neurotoxicity  
Grade < 2 fevers, headaches, myalgia, chills

## PROGRESSION OF NEW TUMORS DISTANT FROM CAR-T CELL INFUSION SITE



FIRST DOSE OF  
"SYSTEMIC" THERAPY



### UPN 109

50 YEAR OLD MALE

#### GBM - PRIMARY DIAGNOSIS

- IDH1 wt; MGMT-hypomethylated
- SOC therapy: surgery, radiation, temozolamide, Novacure device (i.e. tumor treating fields)

#### RECURRENT IL13RA2+ GBM DISPLAYED POOR PROGNOSTIC FEATURES

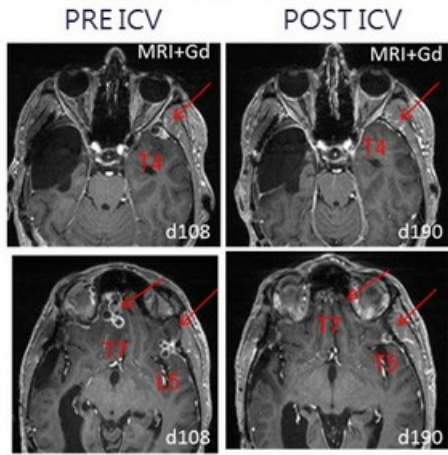
- Multifocal
- Highly proliferative

#### TREATMENT - IL13RA2-CAR T CELLS

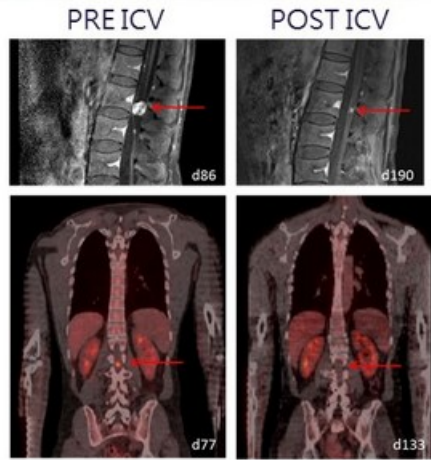
- 6 intracavitary infusions (ICT)
- 5 intraventricular infusions (ICV)

# ICV DELIVERY OF IL13BBζ T CELLS MEDIATES REGRESSION OF MULTIFOCAL GBM

## REGRESSION OF DISTANT CRANIAL METASTASES

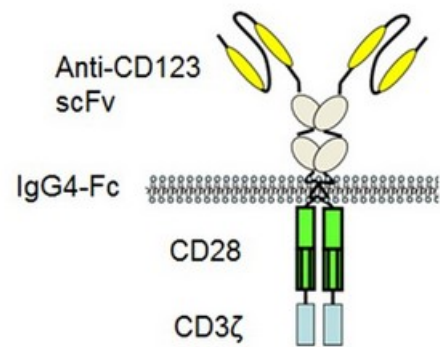


## REGRESSION OF SPINE METASTASES



## MB-102 – CAR-T TARGETING CD123 EXPRESSING TUMORS

- + CD123 is expressed on cells of myeloid lineage and is overexpressed on AML, ALL and BPDCN (Blastic Plasmacytoid Dendritic Cell Neoplasm)
- + Human proof of principle with fusion toxin directed at target in BPDCN
- + Limited CAR-T competition (Novartis, Juno and Kite not in or near clinic)
- + Currently in early clinical development



Wang et al. 2011 Blood Mardros et al. 2013 Blood Jonnalagadda et al. 2014 Mol Ther



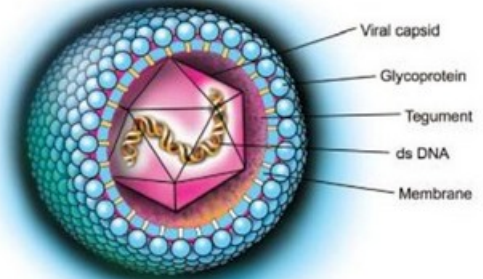


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## PEPVAX FOR POST-ASCT (HELOCYTE)

- **Antigen target applicable to ~35% of Patients**
- **Healthy volunteer Phase 1 completed**
  - Safe, well tolerated at all dose levels
  - Immunogenic
- **Phase 1b published in Lancet, Dec. 2015**
- **Multicenter Phase 2 in 96 Patients**
  - Data by 1H2018
  - NCI Funding: >\$5M





**Phase 1b in 36 Stem Cell Transplant Recipients: published with editorial (12/2015)**

	Vaccine (n=18)	Observation (n=18)	P
<b>Patients with serious adverse events</b>	<b>4 (22%)</b>	<b>9 (50%)</b>	0.16
Patients with serious adverse events related to vaccine	1	NA	..
Grade 3-4 adverse events	54	91	0.2
Patients with acute GVHD 28 days after HCT	..	..	0.74
Grade I	1 (6%)	1 (6%)	..
..Grade II	6 (33%)	5 (28%)	..
Grade III-IV	0	0	..
<b>Disease relapse</b>	<b>1 (6%)</b>	<b>5 (28%)</b>	0.015
<b>Death</b>	<b>0</b>	<b>7 (39%)</b>	..
<b>CMV viraemia (&gt;500 gc/ml)</b>	<b>1 (6%)</b>	<b>6 (33%)</b>	0.044
CMV disease (gastrointestinal)	1 (6%)	1 (6%)	0.76
Duration of pre-emptive CMV treatment (days)	15	263	0.015



Data are number (%), p value are two-sided, unless otherwise stated. Patients were followed up for at least 180 days after HCT, or until May 31, 2015. CMV = cytomegalovirus. gc = genomic viral copies. GVHD=graft versus host disease. HCT=haemopoietic celtransplantation. NA = not applicable. Fisher's exact test. S=500 gc/ml. CMV viraemia



## TRIPLEX FOR POST-ASCT (HELOCYTE)



- 3 Antigen targets applicable to ~100% of Patients
- CMV MVA DNA Vaccine (pp65, IE1, IE2)

**HEALTHY VOLUNTEER PHASE 1  
PRESENTED AT ASH 2015**

- **Safe, well tolerated at all dose levels**
- **Immunogenic**

**Phase 2 (Enrolling As Of 11/2015)**

- **Multicenter Phase 2 in 115 Patients**
- **NCI Funding: >\$2M**





# CHECKPOINT THERAPEUTICS

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### ANTI-PD-L1 MAB

- ✓ A fully human antagonistic antibody that binds PD-L1
- ✓ 1<sup>st</sup> Gen Maintains ADCC
- ✓ Developing 2<sup>nd</sup> Gen as first glycoengineered PD-L1
- ✓ IND expected 1H17

### ANTI-GITR MAB

- ✓ A fully human agonistic antibody binding GITR resulting in downregulation of T-regs
- ✓ Pre-clinical data demonstrates synergy with anti-PD-L1
- ✓ IND expected before YE17





### EGFR Mutations – Validated Target

- Success of 1<sup>st</sup> generation EGFR's have led to acquired resistance through further mutations to EGFR (T790M)
- One 3<sup>rd</sup> generation EGFR inhibitor (Tagrisso™) is approved for patients with lung cancer with T790M mutation



### CK-101 has potential safety advantages

- AZN's drug, Tagrisso™, has significant skin tox due to also targeting wild-type EGFR
- CK-101 has limited targeting of wild-type



## CK-101, 3RD GENERATION EGFR RATIONALE

### STRONG EFFICACY OF CK-101 AGAINST CANCER CELLS CARRYING T790M AND DEL19 EGFR MUTATIONS

IC<sub>50</sub> (NM), MTT ASSAY

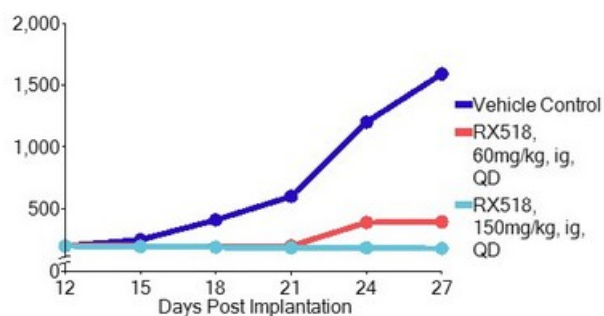
CELL LINE	A431	H1975	HCC827
Mutation	EGFR WT	L858R/ T790M	Del 19
Erlotinib	392	2,500	9.3
AZD9291	64	2.2	1.5
CO-1686	383	18	15
RX518	267	9	2.6

- Good selectivity for mutant:
    - A431/H1975 ratio ~ 30 fold
- CK-101(RX518): No efficacy for EGFR wt cell line (A431)...



Source: NeuPharma, data on file

Tumor Volume (mm<sup>3</sup>)



- ... Strong efficacy in EGFR L858R/T790M (H1975) xenograft model



## CK-101, 3RD GENERATION EGFR STATUS



**In Phase 1/2 clinical trials**



**Will explore accelerated approval strategy, similar to AZN**






**Develop as a monotherapy and in combination with synergistic I/O agents**

Targeting first-in-class combination as AZN terminated combo program and CLVS is shutting program






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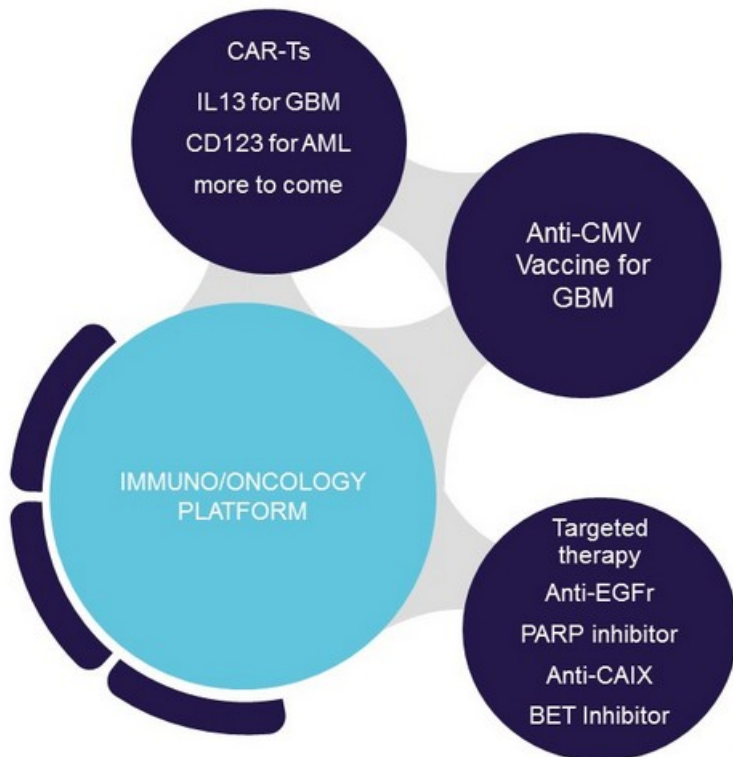
### BACKGROUND

-  Oral tramadol is one of the most prescribed pain medications in the U.S.
-  IV tramadol approved and widely used outside the U.S.
-  IV acetaminophen sells ~\$250MM - ~25% of total dollar market with approximately 3% of the volume

### BENEFITS

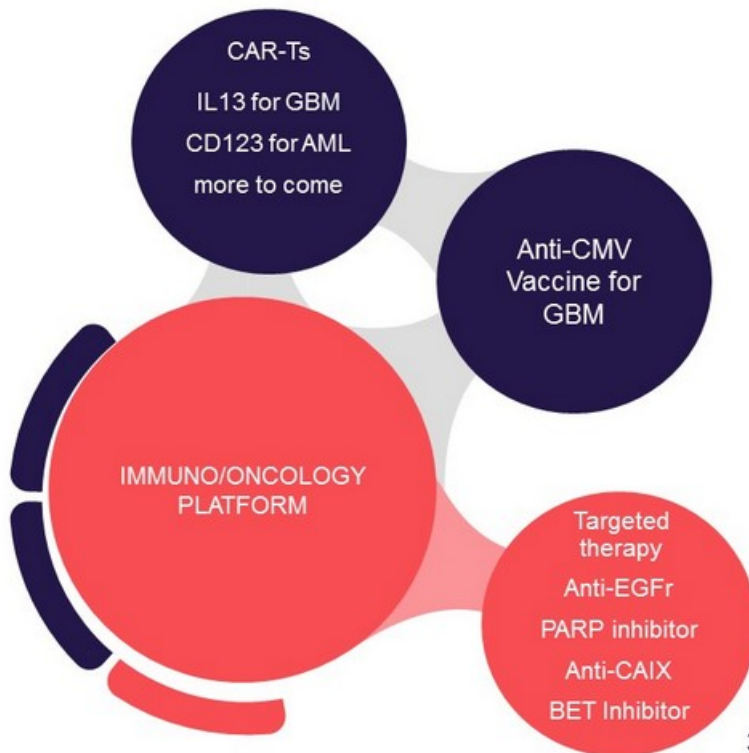
-  Fits important niche, more potent pain relief than acetaminophen and NSAIDs.
-  Less side effects than other opioids
-  Phase 3 ready

# SYNERGY AMONG THE PIPELINE

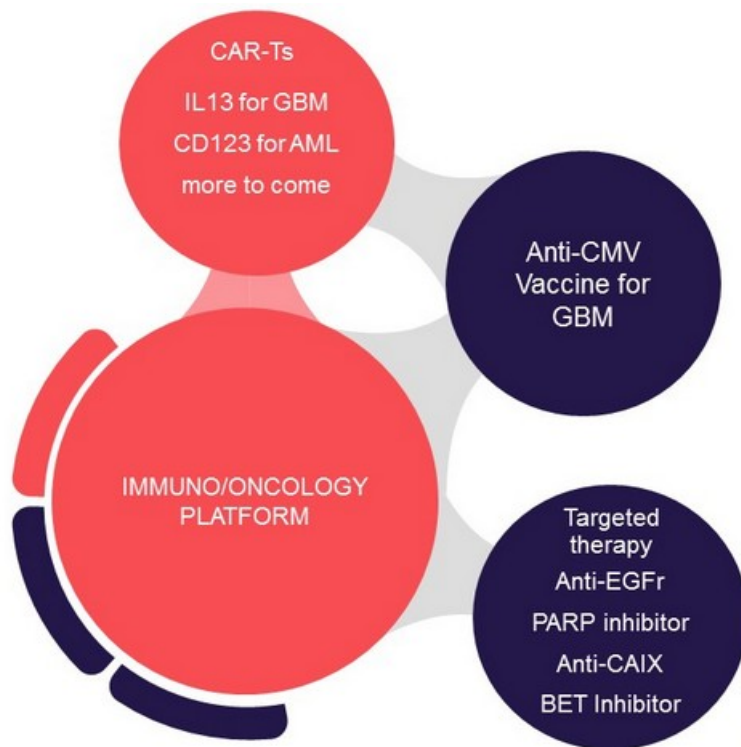




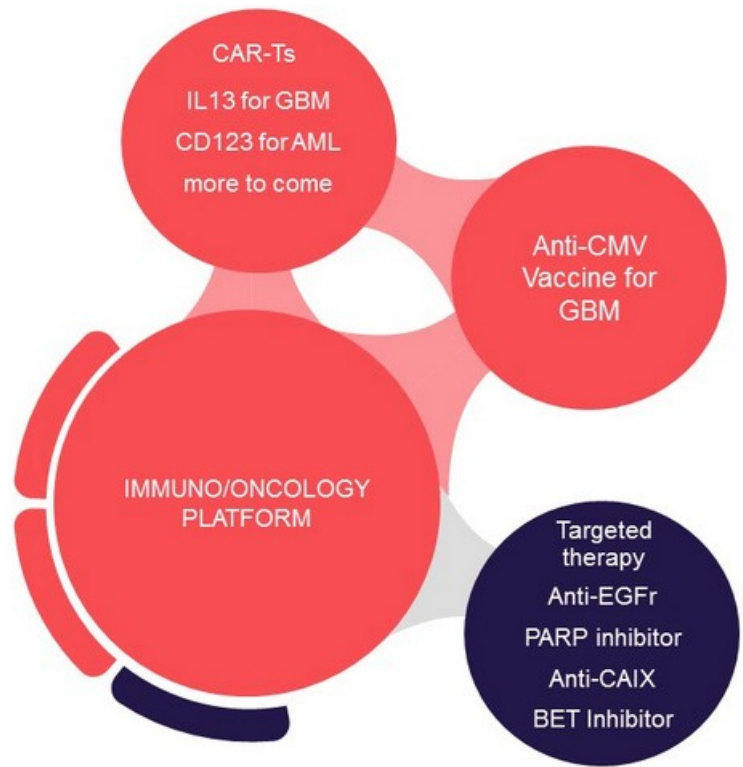
# SYNERGY AMONG THE PIPELINE



# SYNERGY AMONG THE PIPELINE



# SYNERGY AMONG THE PIPELINE



## OTHER PROGRAMS

- Rare Disease Program...ManNac Phase 2
- NK Program
- Anti-CAIX Program
- PARP Inhibitor Program
- CK- 103 BET Inhibitor
- Our business development engine identifies multiple opportunities weekly



## KEY TAKE HOME MESSAGES

Diverse pipeline with multiple shots on goal  
and multiple revenue streams (sales, equity, royalties, fees)

CAR-T program with **solid tumor response reported**

Emerging I/O pipeline with differentiating features and **multiple combinations possible**

Vaccine program for CMV with **human proof of concept** and large Phase II data expected  
in 12-18 months. Recent science also suggests important role of CMV in brain tumors

IV Tramadol for post-surgical acute pain **Phase III clinical trials** begin next 2-3 quarters