

March 15, 2016



## **Fortress Biotech Reports Financial Results for the Fourth Quarter and Year Ended December 31, 2015**

NEW YORK, March 15, 2016 (GLOBE NEWSWIRE) -- Fortress Biotech, Inc. (NASDAQ:FBIO) announces its financial results for the fourth quarter and year ended December 31, 2015.

Dr. Lindsay A. Rosenwald, Fortress Biotech's Chairman, President and CEO, said, "2015 was a transformational year for Fortress Biotech both strategically and operationally. We continued to make progress executing our unique business plan of creating a portfolio of marketed and development-stage products under one umbrella. We believe this combination will enhance shareholder value. As a result of our aggressive efforts in 2015, Fortress Biotech now has several subsidiaries, or Fortress Companies, focused on a number of important, growing therapeutic areas. We plan to expand the number of Fortress Companies and expect to see continued advancement of our current pipeline as well as revenue growth in 2016 and beyond."

### **Financial Highlights:**

- At December 31, 2015, Fortress Biotech's consolidated cash and marketable securities totaled \$98.2 million compared to \$65.5 million at September 30, 2015 and \$69.8 million at December 31, 2014, an increase of \$32.7 million for the fourth quarter and an increase of \$28.4 million for the year. This total excludes restricted cash of \$14.6 million.
- Revenue totaled \$0.9 million at December 31, 2015.
- License acquisitions totaled \$11.4 million for the year ended December 31, 2015.
- Research and development expenses were \$18.4 million for the year ended December 31, 2015, compared to \$10.2 million for 2014. Noncash stock-based compensation expenses included in research and development were \$5.8 million for the year ended December 31, 2015 and \$1.1 million for 2014.
- General and administrative expenses were \$21.6 million for the year ended December 31, 2015, compared to \$10.4 million for 2014. Noncash stock-based compensation expenses included in general and administrative expenses were \$8.5 million for the year ended December 31, 2015 and \$4.4 million for 2014.
- For the year ended December 31, 2015, Fortress Biotech reported a net loss of \$48.4 million, or \$1.24 per share, compared to a net loss of \$20.4 million, or \$0.56 per share, for 2014.

## **Recent Corporate Events:**

### **Avenue Therapeutics, Inc.**

- In February 2015, Fortress Biotech purchased an exclusive license to an intravenous formulation of Tramadol for the U.S. market from Revogenex Ireland Limited. Fortress transferred the license and rights to Avenue during the first quarter of 2015.

### **Checkpoint Therapeutics, Inc.**

- In March 2015, Checkpoint Therapeutics, Inc. (“Checkpoint”) licensed a portfolio of fully human immuno-oncology targeted antibodies generated at the Dana-Farber Cancer Institute (“Dana Farber”). The portfolio includes antibodies targeting programmed-death ligand 1 (“PD-L1”), glucocorticoid-induced TNFR-related protein (“GITR”) and carbonic anhydrase 9 (“CAIX”). Additionally, Fortress assigned its license from NeuPharma, Inc. for a small molecule inhibitor of epidermal growth factor receptor mutations to Checkpoint, effective March 2015.
- In connection with the license agreement with Dana-Farber, Checkpoint entered into a collaboration agreement with TG Therapeutics, Inc. (“TGTX”) to develop and commercialize the Anti-PD-L1 and Anti-GITR antibody research programs in the field of hematological malignancies. Further, in connection with the NeuPharma license, Checkpoint entered into an option agreement with TGTX for a global collaboration in connection with the future development of the certain licensed compounds. Both programs are currently in preclinical development.
- In December 2015, Checkpoint licensed the exclusive worldwide rights to develop and commercialize a PARP (poly (ADP-ribose) polymerase) inhibitor from Teva Pharmaceutical Industries Ltd.’s subsidiary, Cephalon, Inc.
- Also in 2015, Checkpoint raised net proceeds of approximately \$51.5 million from a series of private placement financings.

### **Escala Therapeutics, Inc.**

- In July 2015, Escala Therapeutics, Inc. acquired from New Zealand Pharmaceuticals Limited a license from the National Institutes of Health and cooperative research and development agreements for the development of oral N-acetyl-D-mannosamine, a key compound in the sialic biosynthetic pathway for the treatment of hyposialylation disorders, including GNE myopathy and various forms of nephropathy.

### **Helocyte, Inc.**

- In April 2015, Helocyte, Inc. (“Helocyte”) entered into an agreement with the City of Hope National Medical Center (“COH”) to secure exclusive worldwide rights for two T-cell immunotherapeutic vaccines, known as Triplex and PepVax, for controlling cytomegalovirus (“CMV”) in allogeneic hematopoietic stem cell transplant (“HSCT”) and solid organ transplant recipients. Triplex entered into a Phase 2 clinical study in

February 2016 and PepVax is expected to enter Phase 2 clinical studies later this year. Both programs are supported by grants paid and payable to COH from the National Cancer Institute.

- In connection with the licensing of Triplex and PepVax, Helocyte further entered into an option agreement with COH for exclusive worldwide rights to Pentamer, a universal immunotherapeutic vaccine being developed for the prevention of CMV transmission in utero, and exercised this option on April 28, 2015.
- In December 2015, the results of the PepVax Phase 1b study in allogeneic HSCT CMV(+) recipients were published in *Lancet Haematology*.
- In February 2016, Helocyte entered into a Clinical Trial Agreement with the COH to support a Phase 2 Study of its Triplex vaccine for CMV control in allogeneic stem cell transplant recipients. The Phase 2 study is additionally supported by grants from the National Institutes of Health / National Cancer Institute. Helocyte expects data to emerge from this Phase 2 study in the first half of 2017.

### **Journey Medical Corporation**

- In March 2015, Journey Medical Corporation (“JMC”) entered into a license and supply agreement to acquire rights to distribute a dermatological product for the treatment of acne.
- In October 2015, JMC entered into a co-promotion agreement to sell a 2% topical lotion, Dermasorb HC™, for the treatment of corticosteroid-responsive dermatoses.
- In January 2016, JMC entered into a product license and supply agreement with a third party to distribute a topical cream to promote wound healing for surgical treatments such as cryosurgery, Mohs surgery and biopsies.
- Additionally in January 2016, JMC entered into a distribution agreement with a third party to promote an emollient for the treatment of eczema.
- Both new products will be marketed under the Journey brand.

### **Mustang Bio, Inc.**

- In March 2015, Fortress formed Mustang Bio, Inc. (“Mustang”) to develop immunotherapies based on Chimeric Antigen Receptor T-Cells (“CAR-T”) and Mustang entered into a license agreement with the COH to acquire such technology. In connection with the license agreement, Mustang also entered into a sponsored research agreement with COH in which Mustang will fund continued research at COH related to CAR-T.
- In the second half of 2015, Mustang entered the clinic with novel CAR-T studies for brain tumors and acute myeloid leukemia.

### **About Fortress Biotech**

Fortress Biotech, Inc. (“Fortress” or “the Company”) is a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products. Fortress plans to develop and commercialize products both within Fortress and through subsidiary companies, also known as Fortress Companies. In addition to its internal development programs, the Company will leverage its biopharmaceutical business expertise and drug development capabilities to help the Fortress Companies

achieve their goals. Additionally, the Company will provide funding and management services to each of the Fortress Companies and, from time to time, the Company and the Fortress Companies will seek licensing, partnerships, joint ventures and/or public and private financings to accelerate and provide additional funding to support their research and development programs. For more information, visit [www.fortressbiotech.com](http://www.fortressbiotech.com).

### Forward-Looking Statements

This press release 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 are: risks related to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; our ability to identify, acquire, close and integrate product candidates successfully and on a timely basis; risks relating to the results of research and development activities; 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 required by law.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Balance Sheets**  
(\$ in thousands except for share and per share amounts)

	<u>As of December 31,</u>	
	<u>2015</u>	<u>2014</u>
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 98,182	\$ 49,759
Marketable securities, at fair value	-	20,002
Prepaid expenses and other current assets	1,597	702
Total current assets	<u>99,779</u>	<u>70,463</u>
Property and equipment, net	309	52
Restricted cash	14,586	14,586
Long-term investments, at fair value	2,485	4,160
Intangible asset - license	1,250	-
Other assets	201	64
<b>Total assets</b>	<b><u>\$ 118,610</u></b>	<b><u>\$ 89,325</u></b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 1,868	\$ 366
Accrued expenses	8,570	3,683

Interest payable	27	28
Derivative warrant liability	114	-
Total current liabilities	<u>10,579</u>	<u>4,077</u>
Notes payable, long-term (net of debt discount of \$835 and \$6 at December 31, 2015 and December 31, 2014, respectively)	23,174	14,003
Other long-term liabilities	584	722
<b>Total liabilities</b>	<b><u>34,337</u></b>	<b><u>18,802</u></b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity</b>		
Convertible Preferred stock, \$.001 par value, 129,767 Series C shares authorized, 0 shares issued and outstanding as of December 31, 2015 and December 31, 2014, respectively	-	-
Common Stock, \$.001 par value, 100,000,000 shares authorized, 47,147,032 and 46,494,034 shares issued and outstanding as of December 31, 2015 and December 31, 2014, respectively	47	46
Additional paid-in-capital	246,955	212,205
Accumulated deficit	(190,156 )	(141,728 )
Total stockholders' equity attributed to the Company	<u>56,846</u>	<u>70,523</u>
Non-controlling interests	27,427	-
Total stockholders' equity	<u>84,273</u>	<u>70,523</u>
<b>Total liabilities and stockholders' equity</b>	<b><u>\$ 118,610</u></b>	<b><u>\$ 89,325</u></b>

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Statement of Operations**  
(\$ in thousands except for share and per share amounts)

	<b>For the Years Ended December 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>2013</b>
Revenue	\$ 273	\$ -	\$ -
Revenue - from a related party	590	-	-
Total revenue	<u>863</u>	<u>-</u>	<u>-</u>
<b>Operating expenses</b>			
Research and development	18,402	10,239	25,682
Research and development – licenses acquired	11,408	-	-
General and administrative	21,584	10,413	10,098
Total operating expenses	<u>51,394</u>	<u>20,652</u>	<u>35,780</u>
Loss from operations	(50,531 )	(20,652 )	(35,780 )
Other income (expenses)			
Interest income	245	662	545
Interest expense	(1,484 )	(1,338 )	(1,923 )
Change in fair value of subsidiary's warrant liabilities	(438 )	-	-
Change in fair value of investments	(1,675 )	942	-
Total other income (expenses)	<u>(3,352 )</u>	<u>266</u>	<u>(1,378 )</u>
<b>Net loss</b>	<b><u>(53,883 )</u></b>	<b><u>(20,386 )</u></b>	<b><u>(37,158 )</u></b>
Less: net loss attributable to non-controlling interests	5,455	-	-
<b>Net loss attributable to common stockholders</b>	<b><u>\$ (48,428 )</u></b>	<b><u>\$ (20,386 )</u></b>	<b><u>\$ (37,158 )</u></b>

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Source: Fortress Biotech, Inc.