



November 4, 2016

## **Anthera Pharmaceuticals Provides Business Update and Reports 2016 Third Quarter Financial Results**

- | Blisibimod topline data from the Phase 3 CHABLIS-SC1 Study in severe lupus patients is imminent
- | Data and Safety Monitoring Board recommendation to continue SOLUTION study with Sollpura™
- | FDA Type C meeting in September validated basis for BLA filing and manufacturing approach for Sollpura™
- | Closing of initial \$17 million registered direct offering
- | Appointed William Shanahan Jr., M.D., J.D. as Chief Medical Officer

HAYWARD, Calif., Nov. 04, 2016 (GLOBE NEWSWIRE) -- Anthera Pharmaceuticals, Inc. (Nasdaq:ANTH) today provided a business update and reported financial results for the third quarter ended September 30, 2016.

### **Recent Developments and Business Highlights:**

#### ***Blisibimod for the treatment of Systemic Lupus Erythematosus ("SLE")***

##### **| Topline Data from Phase 3 CHABLIS-SC1 Clinical Study**

We have been working diligently through the adjudication for the CHABLIS-SC-1 study, which completed the last patient visit in September. We currently plan to report topline efficacy and safety data prior to the 2016 American College of Rheumatology Annual Meeting taking place from November 11<sup>th</sup> to November 16<sup>th</sup>. Topline data from the CHABLIS-SC1 will include the primary endpoint evaluation, the Systemic Lupus Erythematosus Responder Index (SRI-6) as well as safety and tolerability data from the study. For more information on the CHABLIS-SC1 study, please visit [http://www.anthera.com/clinical-studies/chablis\\_sc/](http://www.anthera.com/clinical-studies/chablis_sc/).

##### **| Phase 3 CHABLIS 7.5 Clinical Study Enrollment and Clinical Site Activation On Track**

We continued further clinical site activation for, and enrollment in CHABLIS 7.5, our second Phase 3 clinical study. This study will evaluate the efficacy and safety of blisibimod in patients who, despite corticosteroid use, continue to have clinically-active lupus (SLE) and the presence of anti-double-stranded DNA and low complements which are known serological markers of lupus. For more information about the CHABLIS 7.5 study, visit [http://www.anthera.com/clinical-studies/chablis\\_7-5/](http://www.anthera.com/clinical-studies/chablis_7-5/).

#### ***Sollpura™ (liprotamase) for the treatment of Exocrine Pancreatic Insufficiency ("EPI")***

##### **| Phase 3 SOLUTION Clinical Study**

Following the completion of patient enrollment in our Phase 3 SOLUTION study, an independent Data and Safety Monitoring Board (DSMB) recommended continuation of the study without modification on August 3, 2016. Subsequent assessment by the DSMB on September 25, 2016, found no concerning safety signals. We expect to report topline efficacy data from the SOLUTION study before the end of 2016. For more information on the SOLUTION clinical study, please visit [http://www.anthera.com/clinical-studies/solution\\_study/](http://www.anthera.com/clinical-studies/solution_study/).

##### **| SIMPLICITY Clinical Study Enrollment on Track**

Enrollment in the SIMPLICITY study, which intends to evaluate the efficacy and safety of Sollpura™ supplied as a powder for oral solution, is on track. In this study, Sollpura™ is delivered in a convenient, easy-to-administer single use package. We completed enrollment of the initial cohort of patients 7 years of age and above, and following a review of safety and efficacy data by an independent DSMB, the study will allow for administration of Sollpura™ powder for oral solution to pediatric patients ranging in age from 28 days to less than 7 years. For more information on the study, please visit <http://www.anthera.com/clinical-studies/simplicity-study/>.

##### **| EASY Clinical Study**

During the third quarter of 2016, we initiated the EASY study, which provides continued access to Sollpura™ for patients who completed the SOLUTION study. We plan to continue the EASY study until Biologic License Application ("BLA") for Sollpura™ is approved by the U.S. Food and Drug Administration ("FDA").

##### **| Manufacturing to Support Commercial Readiness Accelerated**

We began acceleration of the manufacturing scale-up to support the commercial launch of Sollpura™ including the

completion of demonstration and registration batches at commercial launch scale. We had a Type-C meeting with the FDA in September to discuss the manufacturing approach for the Lipase-CLEC drug substance and the conversion of the filed Sollpura™ New Drug Application ("NDA") to a BLA. The FDA confirmed that Sollpura™ fits the regulatory definition of a biologic, supporting the conversion of the filed NDA to a BLA. Furthermore, preliminary agreement was reached on Anthera's approach to demonstration of comparability of drug substance manufactured by a new contract manufacturing organization ("CMO"), and the potential use of a comparability protocol to manage post-approval process scale up.

### ***Blisibimod for the treatment of IgA Nephropathy***

#### **Longer-Term Evaluation Continues in Phase 2 BRIGHT-SC Clinical Study**

In June 2016, an interim analysis of observed data from 57 patients, all of whom had the opportunity to complete 24 weeks of treatment, demonstrated a positive trend in lower proteinuria in blisibimod versus placebo treated patients over two years, supporting continuation of the study. Data from the 48-week evaluation is expected at the end of this year or in early first quarter of 2017. For more information about the BRIGHT-SC study, visit <http://www.anthera.com/clinical-studies/bright-sc/>.

### ***Management Update***

- On August 16, 2016, we appointed William Shanahan, M.D., J.D. as Chief Medical Officer. In this role, Dr. Shanahan will oversee the clinical development of the blisibimod and Sollpura™ programs. Dr. Shanahan joins Anthera with over 30 years of drug development experience, including 16 years as a chief medical officer.

### **Summary of Financial Results**

- Registered Direct Offering.** In September 2016, we executed a subscription agreement with Biotechnology Value Fund, L.P. and other affiliates of BVF Partners L.P. ("BVF"), and Rock Springs Capital, pursuant to which we may sell convertible preferred stock in two tranches. The initial tranche closed on September 14 and we received gross proceeds of \$17 million. The investors have an option for an additional \$28.3 million of convertible preferred stock at their discretion. Each share of preferred stock is convertible into shares of common stock at various prices in the future. The initial \$17 million of Series X convertible preferred stock received warrant coverage equal to 25% of the issued shares of common stock with an exercise price equal to 120% of the conversion price of the Series X convertible preferred stock.
- Cash Position.** We ended the third quarter of 2016 with cash and cash equivalents totaling \$32.6 million, compared to \$47 million as of December 31, 2015. The decrease in cash was mainly attributable to \$36.7 million used to fund our clinical development programs during the nine months ended September 30, 2016, offset by approximately \$23 million in net proceeds received from the sale of common and preferred stock.
- R&D Expense.** Research and development expenses for the three and nine months ended September 30, 2016 totaled \$14.1 million and \$35.7 million, respectively, compared to \$10.4 million and \$24.9 million for the corresponding periods in 2015. The increase is primarily due to cost associated with acceleration of the manufacturing scale-up timeline, including the production of demonstration and registration batches at commercial launch scale for Sollpura™ and the purchase and installation of manufacturing equipment at our contract manufacturers. Additionally, clinical development expense increased from prior year due to the initiation of three new clinical studies, namely the CHABLIS-7.5 study with blisibimod in severe lupus patients, the SIMPLICITY study with Sollpura™ in sachet formulation and the EASY study which provides continued access to Sollpura™ for patients who completed the SOLUTION study.
- G&A Expense.** General and administrative expenses for the three and nine months ended September 30, 2016 totaled \$2.5 million and \$7.3 million, respectively, compared to \$2.1 million and \$5.7 million for the corresponding periods in 2015. The increase is primarily due to higher non-cash stock-based compensation expense recognized during the three and nine months ended September 30, 2016.
- Net Loss.** Net loss for the three and nine months ended September 30, 2016 was \$16.5 million and \$42.5 million, respectively, compared to \$11.3 million and \$27.9 million for the corresponding periods in 2015. The increase in net loss is mainly attributable to the increase in manufacturing expense for Sollpura™ and clinical study expense for both Sollpura™ and blisibimod in 2016.
- Net Loss Applicable to Common Stockholders.** In connection with the September 2016 registered direct offering of convertible preferred stock, warrants and option to purchase future shares of convertible preferred stock, there is an in-the-money conversion feature (beneficial conversion feature, or BCF) that required separate financial statement recognition and was recorded as a discount to the preferred shares and was immediately accreted as a deemed dividend because the shares are immediately convertible. For the quarter and nine months ended

September 30, 2016, we recorded a deemed dividend of \$8.8 million.

## About Anthera Pharmaceuticals

Anthera Pharmaceuticals is a clinical-stage biopharmaceutical company focused on developing and commercializing products to treat serious and life-threatening diseases, including exocrine pancreatic insufficiency due to cystic fibrosis, lupus, lupus with glomerulonephritis, and IgA nephropathy. Additional information on the Company can be found at [www.anthera.com](http://www.anthera.com).

### Safe Harbor Statement

Any statements contained in this press release that refer to future events or other non-historical matters, including statements that are preceded by, followed by, or that include such words as "estimate," "intend," "anticipate," "believe," "plan," "goal," "expect," "project," or similar statements, are forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such statements are based on Anthera's expectations as of the date of this press release and are subject to certain risks and uncertainties that could cause actual results to differ materially, including but not limited to those set forth in Anthera's public filings with the SEC, including Anthera's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016. Anthera disclaims any intent or obligation to update any forward-looking statements, whether because of new information, future events or otherwise, except as required by applicable law.

[www.twitter.com/antherapharma](http://www.twitter.com/antherapharma)

<https://www.facebook.com/antherapharma/>

<https://www.linkedin.com/company/anthera-pharmaceuticals>

**ANTHERA PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except share and per share data)  
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Revenues:				
License fee revenue	\$ —	\$ 548	\$ 139	\$ 743
Collaborative revenue	—	185	6	524
Total revenues	—	733	145	1,267
Operating expenses:				
Research and development	\$ 14,096	\$ 10,359	\$ 35,686	\$ 24,893
General and administrative	2,504	2,091	7,318	5,694
Research award	—	(367)	(261)	(1,467)
Total operating expenses	16,600	12,083	42,743	29,120
Loss from operations	(16,600)	(11,350)	(42,598)	(27,853)
Other income (expense):				
Other income (expense)	\$ (47)	\$ 24	\$ (109)	\$ (28)
Change in fair value of warrant liability	169	—	169	—
Net loss	(16,478)	(11,326)	(42,538)	(27,881)
Deemed dividends attributable to preferred stock	(8,807)	—	(8,807)	—
Net loss applicable to common stockholders	\$ (25,285)	(11,326)	\$ (51,345)	(27,881)
Net loss per share—basic and diluted	\$ (0.61)	\$ (0.29)	\$ (1.25)	\$ (0.81)
Weighted-average number of shares used in per share calculation—basic and diluted	41,682,669	39,241,738	40,924,480	34,260,866

**ANTHERA PHARMACEUTICALS, INC.**  
**BALANCE SHEET DATA**  
(in thousands, except share data)

(unaudited)

	<b>September 30, 2016</b>	<b>December 31, 2015</b>
Cash and cash equivalents	\$ 32,570	\$ 46,951
Accounts receivable	\$ —	\$ 326
Total assets	\$ 34,486	\$ 48,125
Total deferred revenue	\$ —	\$ 138
Total warrant liability	\$ 3,509	—
Total liabilities, excludes deferred revenue & warrant liability	\$ 10,191	\$ 8,330
Series X contingently redeemable convertible preferred stock	\$ 9,553	\$ —
Option to purchase future shares of Series X-1 convertible preferred stock	\$ 3,689	\$ —
Common Stock and additional paid-in capital	\$ 410,920	\$ 391,688
Accumulated deficit	\$ (403,376)	\$ (352,031)
Total shareholders' equity	\$ 11,233	\$ 39,657
Common shares outstanding	41,955,126	40,004,037
Series X convertible preferred shares outstanding	17,000	—

CONTACT:

Nikhil Agarwal of Anthera Pharmaceuticals, Inc.

[nagarwal@anthera.com](mailto:nagarwal@anthera.com) or 510-856-5600 x5621

 Primary Logo

Source: Anthera Pharmaceuticals, Inc.

News Provided by Acquire Media