August 21, 2017

Albireo Reports Second Quarter 2017 Financial Results

— Plans to initiate A4250 Phase 3 trial by year end —

— Following successful equity financing in May, cash runway expected through at least 2019 —

BOSTON, Aug. 21, 2017 (GLOBE NEWSWIRE) -- Albireo Pharma, Inc. (NASDAQ:ALBO), a clinical-stage orphan pediatric liver disease company developing novel bile acid modulators, today reported its financial results for the second quarter and six months ended June 30, 2017 and provided a business update.

"The Phase 3 clinical program for A4250, our promising IBAT inhibitor for the treatment of children with progressive familial intrahepatic cholestasis (PFIC), is planned to commence by the end of 2017. This program is an important step towards our goal of providing a new, non-surgical treatment for children afflicted with this life-altering disease," said Ron Cooper, President and Chief Executive Officer of Albireo. "As we proceed with our Phase 3 plans for A4250, we were pleased to strengthen our balance sheet in the second quarter with the completion of an equity offering that resulted in approximately $48.5 million in new capital for Albireo."

Albireo reported a net loss of $6.2 million for the second quarter of 2017 compared with a net income of $2.1 million for the second quarter of 2016. For the six months ended June 30, 2017, Albireo reported a net loss of $12.8 million compared with a net loss of $1.1 million for the corresponding 2016 period. As of June 30, 2017, cash and cash equivalents totaled $62.6 million. Based on current operating plans, Albireo expects its current cash resources will be sufficient to meet its operating requirements through at least the end of 2019.

Recent Highlights and Corporate Update

A4250

- Continued to prepare for a planned Phase 3 clinical trial of A4250 in patients with PFIC, which Albireo expects to initiate by the end of 2017.
- Completed a successful Phase 2 open label, dose-finding clinical trial of A4250 in children with cholestatic liver disease and pruritus.
- Received notification that the abstract for the completed Phase 2 pediatric trial, titled "The ileal bile acid transport inhibitor A4250 reduced pruritus and serum bile acid levels in children with cholestatic liver disease and pruritus: final results from a multiple-dose, open-label, multinational study," has been accepted to The Liver Meeting® 2017, to be held October 20-24, 2017, in Washington, D.C.
- Announced the allowance of two new U.S. patents for A4250, including one with claims directed to a method of treatment for A4250 in PFIC and other specified liver cholestatic diseases. The regular term of this patent, which has since issued, expires in November 2031.

Elobixibat

- Albireo's licensee for elobixibat in Japan and other select countries in Asia, EA Pharma Co., Ltd., completed an open-label, multicenter clinical trial designed primarily to evaluate the long-term safety of elobixibat in Japanese patients with chronic constipation. Earlier this year, Albireo announced that EA Pharma has submitted an application to regulatory authorities in Japan for approval of elobixibat as a treatment for chronic constipation.

Corporate

- Completed an underwritten public offering of shares of common stock, with gross proceeds to Albireo of approximately $51.9 million and net proceeds of approximately $48.5 million, after deducting underwriting discounts and commissions and offering expenses.

Financial Results for the Three and Six Months ended June 30, 2017

Cash Position: Cash and cash equivalents totaled $62.6 million as of June 30, 2017.

Revenue: Revenue totaled $1,000 for the second quarter of 2017 compared with $8.0 million for the second quarter of 2016, a decrease of $8.0 million. For the six months ended June 30, 2017, revenue totaled $2,000 compared with $8.1 million for the corresponding 2016 period, a decrease of $8.1 million. The decrease for both 2017 periods was primarily due to a nonrefundable one-time payment of $8.0 million received from EA Pharma in April 2016 in connection with a renegotiated payment stream.

R&D Expenses: Research and development expenses totaled $3.0 million for the second quarter of 2017 compared with $2.7 million for the second quarter of 2016, an increase of $249,000. For the six months ended June 30, 2017, research and development expenses totaled $5.8 million compared with $4.3 million for the corresponding 2016 period, an increase of $1.5 million. The increase for both 2017 periods was driven primarily by increased costs associated with the development of A4250, partially offset for the three-month period by reductions in other project costs attributable to patent expenses.

G&A Expenses: General and administrative expenses totaled $3.7 million for the second quarter of 2017 compared with $3.0 million for the second quarter of 2016, an increase of $685,000. For the six months ended June 30, 2017, general and administrative expenses totaled $6.9 million compared with $4.3 million for the corresponding 2016 period, an increase of $2.6 million. The increase for both 2017 periods was principally attributable to an increase in personnel expense, including stock-based compensation expense, and other costs associated with being a public company.

Interest expense, net: Net interest expense totaled $152,000 for the second quarter of 2017 compared with $512,000 for the second quarter of 2016, a decrease of $360,000. For the six months ended June 30, 2017, net interest expense totaled $401,000 compared with $1.0 million for the corresponding 2016 period, a decrease of $637,000. The decrease for both 2017 periods was due to conversion of convertible loan notes issued in 2014 and 2015 into equity in connection with the completion of the share exchange transaction in November 2016 and lower interest paid under an existing loan facility in accordance with the terms of the facility.

Other (income) expense, net: Other (income) expense, net totaled $65,000 of income for the second quarter of 2017 compared with $290,000 of expense for the second quarter of 2016, a difference of $355,000. For the six months ended June 30, 2017, other (income) expense, net totaled $9,000 of expense compared with $135,000 of expense for the corresponding 2016 period, a decrease of $126,000. The difference for both 2017 periods resulted from differences in currency exchange rates in the two periods.

Non-operating income, net: Non-operating income, net totaled $585,000 for the second quarter of 2017 compared with $709,000 for the second quarter of 2016, a decrease of $124,000. For the six months ended June 30, 2017, non-operating income, net totaled $260,000 compared with $620,000 for the corresponding 2016 period, a decrease of $360,000. The decrease for both 2017 periods primarily reflected a change in mark-to-market adjustments on warrants between the periods.

On August 15, 2017, Albireo filed Form 12b-25, Notification of Late Filing, with the Securities and Exchange Commission in respect of its Form 10-Q for the second quarter ended June 30, 2017. The delayed filing resulted from clerical errors which were discovered late in Albireo's financial closing process for the second quarter of 2017 and which related to the first quarter of 2017. Albireo corrected the errors in the second quarter. Albireo believes that the errors and corrections do not have a material impact on its financial statements for the three and six months ended June 30, 2017.

About Albireo
Albireo Pharma is a clinical-stage biopharmaceutical company focused through its operating subsidiary on the development of novel bile acid modulators to treat orphan pediatric liver diseases and other liver and gastrointestinal diseases and disorders. Albireo's clinical pipeline includes a Phase 3 product candidate, a second Phase 2 product candidate and a third product candidate for which an application for regulatory approval has been submitted in Japan. Albireo was spun out from AstraZeneca in 2008.

Albireo Pharma is located in Boston, Massachusetts, and its key operating subsidiary is located in Gothenburg, Sweden. For more information on Albireo, please visit www.albireopharma.com.

Forward-Looking Statements
This press release includes "forward-looking statements" *within the meaning of the Private Securities Litigation Reform Act of 1995*. Forward-looking statements include statements, other than statements of historical fact, regarding: the plans for, or progress or scope of, development of A4250, elobixibat or any other Albireo product candidate or program, including

regarding the planned Phase 3 clinical program for A4250 in patients with PFIC; the target indication(s) for development, the size, design, population, location, conduct, objective, duration or endpoints of any clinical trial, or the timing for initiation or completion of or reporting of results from any clinical trial, including the timing for initiation of the planned Phase 3 PFIC clinical program for A4250; EA Pharma's plans with regard to the development or commercialization of elobixibat; the competitive position of A4250, elobixibat or any other Albireo product candidate or program or the commercial opportunity in any target indication; any milestone or other payments that EA Pharma may make to Albireo; the period for which Albireo's cash resources will be sufficient to fund its operating requirements (runway); or Albireo's plans, expectations or future operations, financial position, revenues, costs or expenses. Albireo often uses words such as "anticipates," "believes," "plans," "expects," "projects," "future," "intends," "may," "will," "should," "could," "estimates," "predicts," "potential," "planned," "continue," "guidance," and similar expressions to identify forward-looking statements. Actual results, performance or experience may differ materially from those expressed or implied by any forward-looking statement as a result of various risks and uncertainties, including, but not limited to, risks and uncertainties relating to: whether favorable findings from clinical trials of A4250 to date, including findings in indications other than PFIC, will be predictive of results from future clinical trials of A4250, including the trials comprising the planned Phase 3 PFIC program; whether either or both of the FDA and EMA will determine that the primary endpoint and duration of the planned double blind Phase 3 trial in patients with PFIC is sufficient, even if such primary endpoint is met with statistical significance, to support approval of A4250 in the United States or the European Union, to treat PFIC, a symptom of PFIC or otherwise; the outcome and interpretation by regulatory authorities of the ongoing third-party study pooling and analyzing long-term PFIC patient data; whether Albireo's cash resources will be sufficient to advance A4250 through completion of the planned Phase 3 PFIC program; the timing for initiation or completion of, or for availability of data from, ongoing or future trials of A4250, including the trials comprising the planned Phase 3 PFIC program, and the outcomes of such trials; delays or other challenges in the initiation of, or recruitment of patients for, the planned double blind Phase 3 trial; whether Albireo receives additional feedback from regulatory authorities on the planned Phase 3 PFIC program for A4250 prior to initiation; the discretion that EA Pharma has in the development and potential commercialization of elobixibat in Japan; and the timing and success of acceptance and approval of the new drug application submitted by EA Pharma with the Japanese Pharmaceuticals and Medical Devices Agency for elobixibat for the treatment of chronic constipation in Japan. These and other risks and uncertainties that Albireo faces are described in greater detail under the heading "Risk Factors" in Albireo's most recent Annual Report on Form 10-K and in other filings that it makes with the Securities and Exchange Commission. As a result of risks and uncertainties that Albireo faces, the results or events indicated by any forward-looking statement may not occur. Albireo cautions you not to place undue reliance on any forward-looking statement. In addition, any forward-looking statement in this press release represents Albireo's views only as of the date of this press release and should not be relied upon as representing its views as of any subsequent date. Albireo disclaims any obligation to update any forward-looking statement, except as required by applicable law.

Source: Albireo Pharma, Inc.

Albireo Pharma, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)
(unaudited)

	June 30, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 62,598	$ 29,931
Trade receivables	—	26
Prepaid expenses and other assets	471	560
Other receivables	663	344
Total current assets	63,732	30,861
Property and equipment, net	155	21
Intangible assets	150	150
Goodwill	18,110	18,110
Other noncurrent assets	529	518
Total assets	$ 82,676	$ 49,660
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Trade payables	$ 1,329	$ 972
Accrued expenses	3,825	7,548
Long-term debt, current portion	1,928	3,075

Warrant liability	—	844
Other liabilities	298	269
Total current liabilities	7,380	12,708
Long-term liabilities	43	—
Total liabilities	7,423	12,708
Stockholders' Equity:		
Common stock, $0.01 par value per share — 30,000,000 authorized at June 30, 2017 and 200,000,000 authorized at December 31, 2016; 8,859,141 and 6,292,644 issued and outstanding at June 30, 2017 and December 31, 2016	90	63
Additional paid in capital	112,549	61,338
Accumulated other comprehensive income	1,406	1,496
Accumulated deficit	(38,792)	(25,945)
Total stockholders' equity	75,253	36,952
Total liabilities and stockholders' equity	$ 82,676	$ 49,660

Albireo Pharma, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenue	$ 1	$ 7,973	$ 2	$ 8,097
Operating expenses:				
Research and development	2,962	2,713	5,774	4,310
General and administrative	3,713	3,028	6,925	4,334
Other (income) expense, net	(65)	290	9	135
Total operating expenses	6,610	6,031	12,708	8,779
Operating income (loss)	(6,609)	1,942	(12,706)	(682)
Interest expense, net	(152)	(512)	(401)	(1,038)
Non-operating income, net	585	709	260	620
Net income (loss) before income taxes	(6,176)	2,139	(12,847)	(1,100)
Income tax	—	—	—	—
Net income (loss)	$ (6,176)	$ 2,139	$ (12,847)	$ (1,100)
Net income (loss) per share - basic	$ (0.86)	$ 7.42	$ (1.91)	$ (3.97)
Net income (loss) per share - diluted	$ (0.86)	$ 0.69	$ (1.91)	$ (3.97)
Weighted average shares outstanding - basic	7,172,265	288,427	6,734,885	277,120
Weighted average shares outstanding - diluted	7,172,265	3,101,115	6,734,885	277,120

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