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): **November 14, 2017**

ALBIREO PHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-33451**	**90-0136863**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

10 Post Office Square, Suite 502 South **Boston, Massachusetts**	**02109**
(Address of principal executive offices)	(Zip Code)

(857) 254-5555
Registrant's telephone number, including area code

Not applicable
(Former name or former address, if changed since last report)

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 14, 2017, Albireo Pharma, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2017. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibit is furnished with this report:

Exhibit Number	Description
99.1	Press release dated November 14, 2017

SIGNATURES

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 hereunto duly authorized.

ALBIREO PHARMA, INC.

Date: November 14, 2017

/s/ Thomas A. Shea
Thomas A. Shea
Chief Financial Officer

Exhibit 99.1

Albireo Reports Third Quarter 2017 Financial Results

— *Executing towards planned A4250 Phase 3 PFIC trial* —

— *Decision on potential approval of elobixibat in Japan expected in the first half of 2018* —

BOSTON — November 14, 2017 — 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 third quarter and nine months ended September 30, 2017 and provided a business update.

"In the third quarter, we took key steps toward our goal of bringing A4250 as a non-surgical treatment option to children suffering from progressive familial intrahepatic cholestasis (PFIC), a devastating and rare genetic liver disease for which there is no approved drug treatment," said Ron Cooper, President and Chief Executive Officer of Albireo. "In particular, as we are developing A4250 to treat a pediatric population, we were delighted that the European Medicines Agency's Paediatric Committee, which is responsible for activities on potential medicines for pediatric populations and supporting their EU development, agreed to our pediatric investigation plan (PIP) for A4250 in PFIC. Our planned Phase 3 clinical trial of A4250 in patients with PFIC is a key component of the agreed PIP, and we look forward to getting that study underway."

Albireo reported a net loss of $6.5 million for the third quarter of 2017 compared with a net loss of $4.0 million for the third quarter of 2016. For the nine months ended September 30, 2017, Albireo reported a net loss of $19.4 million compared with a net loss of $5.1 million for the corresponding 2016 period. As of September 30, 2017, cash and cash equivalents totaled $57.1 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, assuming receipt of a contingent milestone payment from licensee EA Pharma in 2018.

Recent Highlights and Corporate Update

A4250

- Continued to execute towards the planned initiation of a Phase 3 trial of A4250 in patients with PFIC. Albireo submitted the study protocol and is currently addressing refinements suggested by the FDA, with no change to the key study design details previously announced. Albireo now expects to initiate the Phase 3 trial by the spring of 2018.
- Final results from Albireo's Phase 2 clinical trial of A4250 in children with cholestatic liver disease and pruritus were presented in October 2017 in a poster, recognized as a Presidential Poster of Distinction, and Special Interest Groups session at the American Association for the Study of Liver Diseases (AASLD) The Liver Meeting® 2017 in Washington, D.C., and in a poster, again recognized as a Poster of Distinction, at the 2017 Annual Meeting of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition in Las Vegas. In the study, A4250 reduced serum bile acids (sBA) and improved pruritus in most patients, particularly patients with PFIC. A4250 exhibited a favorable overall tolerability profile in the study, with all patients completing the four-week treatment period and no reports of diarrhea associated with multiple dose therapy.

- The Paediatric Committee of the European Medicines Agency (EMA) agreed to Albireo's PIP for A4250 in PFIC. The agreement is an essential step for a potential EU marketing authorization application and provides an additional two years of market exclusivity for A4250 with completion of the plan.

- The EMA's Committee for Medicinal Products for Human Use (CHMP) reviewed A4250 data and confirmed PRIME eligibility for A4250 in the treatment of PFIC at the more advanced "proof of concept" stage, which triggers the early appointment of a CHMP rapporteur.

- Hosted a Key Opinion Leader (KOL) breakfast meeting focused on PFIC in New York City.

Elobixibat

- Continue to expect a decision from the Japanese Pharmaceuticals and Medical Devices Agency as to whether to approve elobixibat for the treatment of chronic constipation in Japan in the first half of 2018.

Corporate

- Roger Jeffs, former co-CEO of United Therapeutics Corporation, joined Albireo's board of directors, bringing significant orphan drug development and commercialization experience.

- Presented at multiple investor conferences, including the Rodman & Renshaw Global Investment Conference, Ladenburg Thalmann Healthcare Conference and Cantor Fitzgerald Global Healthcare Conference.

Financial Results for the Three and Nine Months ended September 30, 2017

Cash Position: Cash and cash equivalents totaled $57.1 million as of September 30, 2017.

Revenue: Revenue totaled $0 for the third quarter of 2017 compared with $28,000 for the third quarter of 2016. For the nine months ended September 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 the nine months ended September 30, 2017 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 $3.2 million for the third quarter of 2017 compared with $2.1 million for the third quarter of 2016, an increase of $1.2 million. For the nine months ended September 30, 2017, research and development expenses totaled $9.0 million compared with $6.4 million for the corresponding 2016 period, an increase of $2.6 million. The increase for both 2017 periods was driven primarily by increased costs associated with the development of A4250, including costs incurred for manufacturing and clinical development activities in preparation for a planned Phase 3 clinical trial in patients with PFIC.

G&A Expenses: General and administrative expenses totaled $3.7 million for the third quarter of 2017 compared with $1.3 million for the third quarter of 2016, an increase of $2.4 million. For the nine months

ended September 30, 2017, general and administrative expenses totaled $10.6 million compared with $5.7 million for the corresponding 2016 period, an increase of $5.0 million. The increase for both 2017 periods was principally attributable to increases in personnel expense, including stock-based compensation expense, costs associated with being a public company and costs for professional services.

Other (income) expense, net: Other (income) expense, net totaled $401,000 of income for the third quarter of 2017 compared with $58,000 of expense for the third quarter of 2016, a difference of $459,000. For the nine months ended September 30, 2017, other (income) expense, net totaled $392,000 of income compared with $193,000 of expense for the corresponding 2016 period, a difference of $585,000. The difference for both 2017 periods resulted from differences in currency exchange rates.

Interest income (expense), net: Net interest income (expense) totaled $23,000 of income for the third quarter of 2017 compared with $508,000 of expense for the third quarter of 2016, a difference of $531,000. For the nine months ended September 30, 2017, net interest expense totaled $378,000 compared with $1.5 million for the corresponding 2016 period, a decrease of $1.2 million. The difference 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, lower interest paid under an existing loan facility in accordance with the terms of the facility and an increase in interest income due to higher balances following the receipt of $48.5 million in net proceeds from an equity offering completed in May 2017.

Non-operating income (expense), net: Non-operating income (expense), net totaled $0 for the third quarter of 2017 compared with $84,000 of expense for the third quarter of 2016. For the nine months ended September 30, 2017, non-operating income (expense), net totaled $260,000 of income compared with $536,000 of income for the corresponding 2016 period, a decrease of $276,000. The change for both 2017 periods primarily reflected a change in mark-to-market adjustments on warrants between the periods and the exercise of the warrants by Albireo's lender in May 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 Phase 2 product candidate and a 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 changes made in the process of finalizing the protocol for the planned double blind Phase 3 trial of A4250 in patients with PFIC result in a delay in its 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.

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Albireo Pharma, Inc.

Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)

(unaudited)

	September 30, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 57,073	$ 29,931
Trade receivables	11	26
Prepaid expenses and other assets	326	560
Other receivables	730	344
Total current assets	58,140	30,861
Property and equipment, net	190	21
Intangible assets	1,000	150
Goodwill	17,260	18,110
Other noncurrent assets	503	518
Total assets	$ 77,093	$ 49,660
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Trade payables	$ 1,577	$ 972
Accrued expenses	4,568	7,548
Long-term debt, current portion	1,470	3,075
Warrant liability	—	844
Other liabilities	315	269
Total current liabilities	7,930	12,708
Long-term liabilities	43	—
Total liabilities	7,973	12,708
Stockholders' Equity:		
Common stock, $0.01 par value per share — 30,000,000 authorized at September 30, 2017 and 200,000,000 authorized at December 31, 2016; 8,882,785 and 6,292,644 issued and outstanding at September 30, 2017 and December 31, 2016, respectively	91	63
Additional paid in capital	113,515	61,338
Accumulated other comprehensive income	817	1,496
Accumulated deficit	(45,303)	(25,945)
Total stockholders' equity	69,120	36,952
Total liabilities and stockholders' equity	$ 77,093	$ 49,660

Albireo Pharma, Inc.

Condensed Consolidated Statements of Operations

(in thousands, except share and per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue	$ —	$ 28	$ 2	$ 8,125
Operating expenses:				
Research and development	3,226	2,062	9,000	6,372
General and administrative	3,709	1,346	10,634	5,680
Other (income) expense, net	(401)	58	(392)	193
Total operating expenses	6,534	3,466	19,242	12,245
Operating income loss	(6,534)	(3,438)	(19,240)	(4,120)
Interest income (expense), net	23	(508)	(378)	(1,546)
Non-operating income (expense), net	—	(84)	260	536
Net loss before income taxes	(6,511)	(4,030)	(19,358)	(5,130)
Income tax	—	—	—	—
Net loss	$ (6,511)	$ (4,030)	$ (19,358)	$ (5,130)
Net loss per share - basic	$ (0.73)	$ (13.32)	$ (2.60)	$ (17.96)
Net loss per share - diluted	$ (0.73)	$ (13.32)	$ (2.60)	$ (17.96)
Weighted average shares outstanding - basic	8,878,430	302,584	7,452,709	285,668
Weighted average shares outstanding - diluted	8,878,430	302,584	7,452,709	285,668

Source: Albireo Pharma, Inc.