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): **August 6, 2020**

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 1000 **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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock	ALBO	The Nasdaq Capital Market

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 August 6, 2020, Albireo Pharma, Inc. issued a press release announcing its financial results for the second quarter ended June 30, 2020 and providing a business update. 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 August 6, 2020

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: August 6, 2020

/s/ Ronald H.W. Cooper
Ronald H.W. Cooper
President and Chief Executive Officer

Exhibit 99.1

Albireo Reports Q2 2020 Financial Results and Provides Business Update

— Completed last patient visits in Phase 3 PFIC and Phase 2 NASH Trials —
— Enrolled first biliary atresia patients in second odevixibat pivotal study —
— Completed two financing transactions to secure cash into beginning of 2022 —
— Management to host conference call and webcast today at 10:00 a.m. ET —

BOSTON, MA — August 6, 2020 — Albireo Pharma, Inc. (Nasdaq: ALBO), a clinical-stage orphan pediatric liver disease company developing novel bile acid modulators, today provided a business update and reported financial results for the second quarter ended June 30, 2020.

"We are approaching arguably the most important moment in the history of our company having achieved last patient visits in our odevixibat Phase 3 program in PFIC and elobixibat Phase 2 program in NASH," said Ron Cooper, President and Chief Executive Officer of Albireo. "We eagerly await the topline data in those two trials, while continuing to enroll patients in our precedent setting odevixibat biliary atresia pivotal program (BOLD) and gearing up to initiate a third odevixibat pivotal trial in Alagille syndrome by end of year. With a strong financial foundation and cash runway into the beginning of 2022, we have enabled our continued growth past the planned approval and commercial launch of odevixibat for PFIC, supported additional odevixibat pivotal trials, and advanced development of both elobixibat in NASH and the exciting preclinical programs rounding out our pipeline."

Recent Highlights

Odevixibat

- Achieved last patient visit in the PEDFIC 1 Phase 3 trial with odevixibat in progressive familial intrahepatic cholestasis (PFIC). Expect topline data to include 62 out of a planned 60 enrolled patients, with no patients lost to follow-up due to COVID-19. Company continues to anticipate topline data in the coming weeks aligned to our mid-2020 guidance, with regulatory approval, issuance of a rare pediatric disease priority review voucher and launch anticipated in H2 2021.

- Enrolled first patients in Company's Phase 3 BOLD study in biliary atresia, a rare pediatric liver disease that is the leading cause of liver transplants among children, and for which there is no approved pharmacological treatment. BOLD is a double-blind, randomized, placebo-controlled trial designed to evaluate the efficacy and safety of odevixibat in children who have biliary atresia and have undergone a Kasai procedure before age three months. The U.S. Food and Drug Administration (FDA) and European Commission have granted orphan designations for odevixibat in the treatment of biliary atresia.

- Preparing to initiate clinical trial in Alagille syndrome by the end of 2020, following agreement on the protocol design by U.S. and European regulatory authorities. Topline data expected to be available between the announcement of PFIC and biliary atresia topline results. The FDA and European Commission have granted orphan designations for odevixibat in the treatment of Alagille syndrome.

- Launched Expanded Access Program (EAP) for eligible patients with PFIC in the U.S., Canada, Australia and Europe.

- Agreed to financial support of a genetic testing program for all types of PFIC and Alagille syndrome at no cost to qualified patients in the U.S. The program builds on Albireo's commitment to support patients in their journey to diagnosis and treatment of rare pediatric cholestatic liver diseases.

Elobixibat

- Achieved last patient visit in the Phase 2 trial in nonalcoholic steatohepatitis (NASH) and nonalcoholic fatty liver disease (NAFLD) designed as a proof of concept to demonstrate a combination of positive trends in liver markers, CV risk factors and favorable GI tolerability. Data will be available for 43 out of 47 patients, as 4 patients were lost to follow-up primarily due COVID-19. Company anticipates topline data in the coming weeks ahead of the odevixibat PEDFIC 1 data.

- Company continues to anticipate topline data by the end of the year or early next year in a second Phase 2 study of elobixibat in 100 patients with NASH and NAFLD, conducted through partner EA Pharma in Japan.

Early Stage Pipeline

- Progressed preclinical development and expect to complete IND-enabling studies in lead preclinical candidate this year.

Corporate

- Announced two financing transactions: restructured royalty monetization agreement with HealthCare Royalty Partners III, L.P. to receive an additional $15 million in non-dilutive capital for elobixibat in the treatment of chronic constipation in Japan, and an agreement with Hercules Capital, Inc. on a debt facility to provide up to $80 million of new capital with initial draw down of $10 million, resulting in net cash of $24.3 million and extending the cash runway into the beginning of 2022.

- Hosted a Key Opinion Leader call with Chad Gwaltney, Ph.D., who discussed key considerations for the design and implementation of clinical outcome assessments, including patient-reported and observer-reported outcomes in PEDFIC 1 & 2. Dr. Gwaltney provided further background on the PRUCISION measurement tools used in the Phase 3 trials, which were developed rigorously with patients, caregivers, and expert clinicians, as well as in close consultation with the FDA.

- Presented at the Jefferies virtual investor conference.

Second Quarter 2020 Financial Results

- Revenue was $1.9 million for the second quarter of 2020, compared with $1.3 million for the second quarter of 2019. The higher revenue was due to the estimated royalty revenue received from EA Pharma for elobixibat for the treatment of chronic constipation. The royalty revenue is passed on to HealthCare Royalty Partners.

- R&D expenses were $18.4 million for the second quarter of 2020, compared with $11.0 million for the second quarter of 2019. The higher expenses were primarily due to program expenses for odevixibat, as well as personnel costs, as the Company continues to develop additional indications for its lead asset.

- G&A expenses were $8.5 million for the second quarter of 2020, compared with $5.5 million for the second quarter of 2019. The increase was attributable to personnel and related expenses, as the Company continues to increase its headcount and commercialization readiness expenses.

- Net loss for the second quarter of 2020 was $20.6 million, or $(1.38) per share, compared with $16.6 million, or $(1.35) per share for the second quarter of 2019.

- Company had cash and cash equivalents at June 30, 2020 of $152.0 million. During the second quarter of 2020, an additional $24.3 million of net cash was received from recently completed non-dilutive financings. As a result, cash and cash equivalents are anticipated to be sufficient into the beginning of 2022.

Conference Call

As previously announced, Albireo will host a conference call and webcast today, August 6, 2020, at 10:00 a.m. ET. To access the live conference call by phone, dial 877-407-0792 (domestic) or 201-689-8263 (international), and provide the access code 13706144. A live audio webcast will be accessible from the Media & Investors page of Albireo's website, http://ir.albireopharma.com/. To ensure a timely connection to the webcast, it is recommended that participants register at least 15 minutes prior to the scheduled start time. An archived version of the webcast will be available for replay on the Events & Presentations section of the Media & Investors page of Albireo's website for 3 months following the event.

About Albireo

Albireo Pharma is a clinical-stage biopharmaceutical company focused on the development of novel bile acid modulators to treat orphan pediatric liver diseases, and other liver and gastrointestinal diseases and disorders. Albireo's lead product candidate, odevixibat, is being developed to treat rare pediatric cholestatic liver diseases and is in Phase 3 development in progressive familial intrahepatic cholestasis (PFIC) and biliary atresia, with a third Phase 3 trial being planned in Alagille syndrome. Albireo's clinical pipeline also includes two Phase 2 product candidates. Elobixibat is in Phase 2 development in NAFLD and NASH. Approved in Japan for the treatment of chronic constipation, elobixibat is the first ileal bile acid transporter (IBAT) inhibitor approved anywhere in the world.

Albireo was spun out from AstraZeneca in 2008. Albireo Pharma is located in Boston, Mass., and its key operating subsidiary is located in Gothenburg, Sweden. The *Boston Business Journal* named Albireo one of the 2020 Best Places to Work in Massachusetts for the second consecutive year. 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, among other things: the plans for, or progress, scope, cost, initiation, duration, enrollment, results or timing for availability of results of, development of odevixibat, elobixibat or any other Albireo product candidate or program, including regarding expectations regarding the impact of COVID-19 on our business and our ability to adapt our approach as appropriate; the Phase 3 clinical program for odevixibat in patients with PFIC, the potential availability of odevixibat through the EAP, whether the FDA continues to allow odevixibat to be administered through the EAP, the pivotal trial for odevixibat in biliary atresia (BOLD), the planned pivotal trial for odevixibat in Alagille syndrome, and the Phase 2 clinical trial for elobixibat in NAFLD/NASH; the target indication(s) for development or approval, the size, design, population, location, conduct, cost, objective, enrollment, duration or endpoints of any clinical trial, or the timing for initiation or completion of or availability or reporting of results from any clinical trial, including the Phase 3 PFIC trial for odevixibat, and the long-term open-label extension study, the pivotal trial for odevixibat in biliary atresia, the planned pivotal trial for odevixibat in Alagille syndrome, or the Phase 2 trial for elobixibat in NAFLD/NASH; the potential approval and commercialization of odevixibat; discussions with the FDA or EMA regarding our programs; the potential benefits or competitive position of odevixibat, elobixibat, or any other Albireo product candidate or program or the commercial opportunity in any target indication; the potential benefits of an orphan drug designation; 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, uncertainties and other factors, including, but not limited to: negative impacts of the COVID-19 pandemic, including on manufacturing, supply, conduct or initiation of clinical trials, or other aspects of our business; whether favorable findings from clinical trials of odevixibat to date, including findings in indications other than PFIC, will be predictive of results from the trials comprising the Phase 3 PFIC program or any other clinical trials of odevixibat; whether either or both of the FDA and EMA will determine that the primary endpoint for their respective evaluations and treatment duration of the double-blind Phase 3 trial in patients with PFIC are sufficient, even if the primary endpoint is met with statistical significance, to support approval of odevixibat in the United States or the European Union, to treat PFIC, a symptom of PFIC, a specific PFIC subtype(s) or otherwise; the outcome and interpretation by regulatory authorities of the ongoing third-party study pooling and analyzing of long-term PFIC patient data; the timing for initiation or completion of, or for availability of data from, clinical trials of odevixibat, including the trials comprising the Phase 3 PFIC program, the pivotal program in biliary atresia or the planned pivotal program in Alagille syndrome, and the outcomes of such trials; Albireo’s ability to obtain coverage, pricing or reimbursement for approved products in the United States or European Union; delays or other challenges in the recruitment of patients for, or the conduct of, the double-blind Phase 3 trial or other pivotal trials; and Albireo’s critical accounting policies. 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 or in subsequent 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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Source: Albireo Pharma, Inc.

Albireo Pharma, Inc.

Condensed Consolidated Balance Sheets

(in thousands, except share data)

(unaudited)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 152,020	$ 131,843
Prepaid expenses and other current assets	7,967	9,956
Total current assets	159,987	141,799
Property and equipment, net	597	597
Goodwill	17,260	17,260
Other assets	6,161	5,413
Total assets	$ 184,005	$ 165,069
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,734	$ 4,785
Accrued expenses	11,752	13,486
Other current liabilities	732	653
Total current liabilities	17,218	18,924
Liability related to sale of future royalties	64,351	48,714
Note payable, net of discount	9,400	—
Other long-term liabilities	3,916	4,270
Total liabilities	94,885	71,908
Stockholders' Equity:		
Common stock, $0.01 par value per share — 30,000,000 authorized at June 30, 2020 and December 31, 2019; 14,989,021 and 12,749,443 issued and outstanding at June 30, 2020 and December 31, 2019, respectively	149	127
Additional paid-in capital	294,075	245,769
Accumulated other comprehensive income	6,174	6,452
Accumulated deficit	(211,278)	(159,187)
Total stockholders' equity	89,120	93,161
Total liabilities and stockholders' equity	$ 184,005	$ 165,069

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,	
	2020	**2019**	**2020**	**2019**
Revenue	$ 1,912	$ 1,250	$ 3,461	$ 1,820
Operating expenses:				
Research and development	18,397	11,034	34,527	19,363
General and administrative	8,474	5,485	16,627	10,778
Other operating (income) expense, net	(6,744)	8	72	2,304
Total operating expenses	20,127	16,527	51,226	32,445
Operating loss	(18,215)	(15,277)	(47,765)	(30,625)
Interest expense, net	(2,388)	(1,351)	(4,326)	(2,660)
Net loss	$ (20,603)	$ (16,628)	$ (52,091)	$ (33,285)
Net loss per share attributable to holders of common stock:				
Net loss per common share - basic and diluted	$ (1.38)	$ (1.35)	$ (3.58)	$ (2.73)
Weighted-average shares outstanding:				
Weighted-average common shares used to compute basic and diluted net loss per common share	14,981,756	12,355,969	14,556,986	12,178,376