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): **February 25, 2021**

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** (Address of principal executive offices)		**02109** (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))

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 February 25, 2021, Albireo Pharma, Inc. issued a press release announcing its financial results for the fourth quarter and year ended December 31, 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 February 25, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: February 25, 2021

/s/ Ronald H.W. Cooper

Name: Ronald H.W. Cooper
Title President and Chief Executive Officer

Exhibit 99.1

Albireo Reports Q4 and Year-End 2020 Financial Results and Business Update

– NDA and MAA for odevixibat accepted, on track for anticipated H2 21 launch –

– Announces odevixibat co-promotion agreement with Travere, a leading rare disease company –

– ASSERT global pivotal Phase 3 trial in Alagille syndrome initiated and enrolling –

– BOLD global pivotal Phase 3 study in biliary atresia initiated and enrolling –

– Pipeline expansion with two new lead compounds in adult cholestatic and viral liver diseases –

- Company to host a conference call and webcast today at 10:00 a.m. ET –

BOSTON, MA — Feb. 25, 2020 — Albireo Pharma, Inc. (Nasdaq: ALBO), a clinical-stage rare pediatric liver disease company developing novel bile acid modulators, today provided a business update and reported financial results for the fourth quarter and year ended December 31, 2020.

"2020 was a tremendous year as we delivered on several key milestones, including announcement of positive results from our pivotal PEDFIC 1 Phase 3 study in PFIC patients, completion of regulatory filings in the U.S. and EU in record time, and initiation of two additional pivotal Phase 3 studies in Alagille syndrome and biliary atresia," said Ron Cooper, President and Chief Executive Officer of Albireo. "We anticipate 2021 to be a similar year of significant accomplishments with the planned approval and commercialization of odevixibat in the U.S. and EU, issuance of our priority review voucher, enrollment advancing in our Phase 3 trials and fully characterizing our two new bile acid modulators with novel MOAs."

Recent and Upcoming Highlights

Odevixibat

- The Company filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) and a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) seeking approval of odevixibat for the treatment of patients with progressive familial intrahepatic cholestasis (PFIC) in the fourth quarter with follow-on announcement January 25, 2021 of the acceptance from both U.S. and EU regulatory agencies.

- The FDA granted Priority Review and set a Prescription Drug User Fee Act (PDUFA) goal date of July 20, 2021. Odevixibat previously received Fast Track, Rare Pediatric Disease and Orphan Drug Designations in the U.S.

- In Europe, odevixibat is the only ileal bile acid transport inhibitor (IBATi) granted accelerated assessment by the EMA, and has been granted Orphan Designation as well as access to the PRIority MEdicines (PRIME) scheme for the treatment of PFIC. The EMA's Pediatric Committee has agreed to Albireo's odevixibat Pediatric Investigation Plans.

- With U.S. and EU regulatory filings for odevixibat in PFIC completed, the Company anticipates potential regulatory approvals and issuance of a rare pediatric disease Priority Review Voucher, and continues to advance launch plans for the second half of 2021 with focus on global market access, distribution and patient support.

- The Company entered into a limited co-promotion agreement in the US with Travere Therapeutics. Travere is a leading rare disease company and marketer of Cholbam® (cholic acid) capsules, which are used by pediatric hepatologists who are the main call point for odevixibat. The co-promotion agreement is set for two years with optionality for extending the relationship. Albireo will book all revenue and will pay Travere certain fees to compensate its sales representatives for their efforts in selling odevixibat.

- Completed first ex-U.S. commercial distributorship with Medison Pharma, Ltd. ("Medison") for odevixibat in Israel. Medison is a leading international commercial partner for highly innovative therapies. Under the agreement, Medison will be responsible for approval and commercialization in Israel in close alignment and with oversight from Albireo.

- BOLD, the first and only pivotal Phase 3 trial of an IBAT inhibitor in biliary atresia was initiated, with 42 sites activated and global enrollment continuing despite COVID-19 challenges.

- Initiated and enrolling the ASSERT Study, a global Phase 3 pivotal trial of odevixibat in patients with Alagille Syndrome (ALGS).

Early-Stage Pipeline

- The Company is exploring multiple approaches for modulating bile acids to significantly change the bile acid transporter approach in adult liver and viral diseases through new mechanisms of action. The planned primary focus is on primary sclerosing cholangitis (PSC) and primary biliary cholangitis (PBC) as well as viral liver diseases such as hepatitis B and D.

- Unveiled novel bile acid modulator approaches and lead candidate A3907, a systemic oral apical sodium-dependent bile acid transporter (ASBT) inhibitor for adult liver diseases, having completed IND-enabling studies with plans for Phase 1 study initiation by end of the first quarter and topline results by the end of the year.

- Selected new development candidate A2342, an oral systemic sodium-taurocholate co-transporting peptide (NTCP) inhibitor for viral disease.

Corporate

- The Company hosted a Commercial Day on February 11, 2021 with presentations on corporate ambition and outlook, the larger market opportunity in rare pediatric and adult liver disease and global commercialization and launch plans for odevixibat following anticipated approval for progressive familial intrahepatic cholestasis (PFIC) patients.

- Recently appointed key leadership positions: Kevin Springman as the President of the Americas is in place, and Steve Arnold as the President of International starting in March. These leaders are finalizing specialized U.S. and international teams to have in place starting in the second half of 2021. Springman has had a successful track record in sales, marketing and market access roles at Sobi and before that at AstraZeneca. Arnold has extensive experience building and leading international teams, most recently at Intercept, and prior to that at UCB and Gilead.

Fourth Quarter 2020 Financial Results

- Revenues were $2.7 million for the fourth quarter of 2020, compared to $6.4 million for the fourth quarter of 2019. The decrease in revenue primarily relates to a sales-based milestone achieved in 2019 offset by higher sales-based royalties earned in 2020. The royalty revenue is passed on to HealthCare Royalty Partners.

- R&D expenses were $20.1 million for the fourth quarter of 2020, compared to $14.2 million for the fourth quarter of 2019. The higher expenses were principally due to personnel expenses as we continue to increase our headcount and program activities. The increase in program activities related primarily to odevixibat for regulatory submissions in PFIC, and the initiation of clinical trials for additional indications for biliary atresia and ALGS.

- G&A expenses were $14.2 million for the fourth quarter of 2020, compared to $6.2 million for the fourth quarter of 2019. The increase is attributable to personnel and related expenses as the Company continues to increase headcount and commercialization readiness activities.

- Net loss for the fourth quarter of 2020 was $24.8 million, or $(1.30) per share, compared to $7.5 million, or $(0.57) per share for the fourth quarter of 2019.

Financial Results for the Year Ended December 31, 2020

- Revenues were $8.3 million for the year ended December 31, 2020, compared to $9.6 million for the year ended December 31, 2019. The year-over-year decrease in revenue primarily relates to a sales-based milestone achieved in 2019 offset by higher sales-based royalties earned in 2020.

- R&D expenses were $76.8 million for 2020, compared to $45.6 million for the same period in 2019. The higher research and development expenses for the 2020 period were principally due to personnel expenses as we continue to increase our headcount and program activities. The increase in program activities related primarily to odevixibat for regulatory submissions in PFIC, the initiation of clinical trials for additional indications for biliary atresia and ALGS, and preclinical programs.

- G&A expenses were $42.4 million for the year ended December 31, 2020 compared with $23.0 million for the year ended December 31, 2019. The increase is attributable to personnel and related expenses as the Company continues to increase headcount and commercialization readiness activities.

- Net loss for the year ended December 31, 2020 was $107.6 million, or $(6.73) per share, compared to $62.7 million, or $(5.04) per share for the year ended December 31, 2019.

- The Company had cash and cash equivalents at December 31, 2020, of $251.3 million, which compares to $131.8 million at December 31, 2019. The Company has sufficient capital resources to fund the planned launch and development programs. Cash runway into 2023 and plans to monetize a Priority Review Voucher, if received upon approval. The 2021 operating cash burn is anticipated to be in the range of $120-$130 million. 2021 revenue from odevixibat is anticipated to be in the low single digit US $ millions.

Conference Call

Albireo will host a conference call and webcast today, February 25 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 13715566. Live audio webcast will be accessible from the Media & Investors page of Albireo's website 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 Odevixibat

Odevixibat is an investigational product candidate being developed to treat rare pediatric cholestatic liver diseases, including PFIC, biliary atresia and ALGS. A potent, once-daily, non-systemic ileal bile acid transport inhibitor (IBATi), odevixibat acts locally in the small intestine. Odevixibat does not require refrigeration and can be taken as a capsule for older children, or opened and sprinkled onto food, which are factors of key importance for adherence in a pediatric patient population. The FDA has granted Priority Review and set a PDUFA goal date of July 20, 2021. In Europe, the EMA validated MAA. Odevixibat is the only IBATi granted accelerated assessment by the EMA.

Odevixibat also been granted Orphan Designation, as well as access to the PRIority MEdicines (PRIME) scheme for the treatment of PFIC. The EMA's Pediatric Committee has agreed to Albireo's odevixibat Pediatric Investigation Plans for PFIC and biliary atresia. In addition to PFIC, odevixibat has Orphan Drug Designations for the treatment of Alagille syndrome, biliary atresia and primary biliary cholangitis. With FDA and EMA regulatory submissions complete, odevixibat has the potential to become the first approved drug treatment for patients with PFIC in the U.S and Europe. The Company anticipates potential regulatory approvals, issuance of a rare pediatric disease priority review voucher and launch in the second half of 2021.

The MAA and NDA filings are supported by results from PEDFIC 1 and PEDFIC 2 Phase 3 studies. PEDFIC 1 was the first and largest, global, pivotal Phase 3 study conducted in PFIC, which evaluated the efficacy and tolerability of odevixibat in reducing pruritus and serum bile acids in a randomized, double-blind, placebo-controlled trial. In the PEDFIC 1 study, odevixibat met both primary endpoints and was well tolerated with very low incidence of diarrhea/frequent bowel movements (9.5% of odevixibat treated patients vs. 5.0% of placebo patients). ir.albireopharma.com/news-releases/news-release-details/albireo-phase-3-trial-meets-both-primary-endpoints-odevixibat. PEDFIC 2 is a long-term, open-label Phase 3 extension study. The Company also provides an Expanded Access Program (EAP) for eligible patients with PFIC in the U.S., Europe, Canada and Australia. Odevixibat is also currently being evaluated in the BOLD Phase 3 trial in patients with biliary atresia, and the global Phase 3 ASSERT trial for ALGS.

About Albireo

Albireo Pharma is a clinical-stage biopharmaceutical company focused on the development of novel bile acid modulators to treat rare pediatric and adult liver diseases. Albireo's lead product candidate, odevixibat, is being developed to treat rare pediatric cholestatic liver diseases with Phase 3 pivotal trials in PFIC, Alagille syndrome and biliary atresia. The Company completed IND-enabling studies for new preclinical candidate A3907 and plans to advance development in adult liver disease. Albireo was spun out from AstraZeneca in 2008 and is headquartered in Boston, Massachusetts, with its key operating subsidiary 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 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 or any other Albireo product candidate or program; including expectations regarding the impact of the COVID-19 pandemic on our business and our ability to adapt our plans and activities as appropriate; the pivotal trial for odevixibat in biliary atresia (BOLD), and the pivotal trial for odevixibat in Alagille syndrome (ASSERT); 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 long-term open-label extension study for odevixibat in PFIC, the pivotal trial for odevixibat in biliary atresia, the pivotal trial for odevixibat in Alagille syndrome; the potential approval and commercialization of odevixibat; the potential for odevixibat to become the first approved drug for PFIC patients; discussions with the FDA or EMA regarding our programs; the potential benefits or competitive position of odevixibat or any other Albireo product candidate or program or the commercial opportunity in any target indication; the potential effects of odevixibat of the treatment of PFIC patients and its potential to improve the current standard of care; the potential benefits of an orphan drug designation; the potential issuance of a rare pediatric disease priority review voucher; 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," or the negative of these terms or other 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: whether the NDA for odevixibat for the treatment of pruritus in patients with PFIC will be approved by the FDA and whether the MAA for odevixibat in PFIC will be approved by the EMA; whether the FDA or EMA will complete their respective reviews within the target timelines, including the FDA's PDUFA goal date, as a potential result of the impact of the COVID-19 pandemic or otherwise; the risk that the NDA will not be approved despite the FDA's acceptance of the NDA for review; whether the FDA will require additional information, whether we will be able to provide in a timely manner any additional information that the FDA requests, and whether such additional information will be satisfactory to the FDA; other potential 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 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 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 pivotal program in biliary atresia or the 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, company's clinical 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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Albireo Pharma, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)
(unaudited)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 251,272	$ 131,843
Prepaid expenses and other current assets	10,593	9,956
Total current assets	261,865	141,799
Property and equipment, net	478	597
Goodwill	17,260	17,260
Other assets	6,004	5,413
Total assets	$ 285,607	$ 165,069
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,283	$ 4,785
Accrued expenses	19,051	13,486
Other current liabilities	948	653
Total current liabilities	25,282	18,924
Liability related to sale of future royalties	65,894	48,714
Note payable, net of discount	9,621	—
Other long-term liabilities	3,579	4,270
Total liabilities	104,376	71,908
Stockholders' Equity:		
Preferred stock, $0.01 par value per share — 50,000,000 authorized at December 31, 2020 and December 31, 2019; 0 and 0 issued and outstanding at December 31, 2020 and December 31, 2019, respectively	—	—
Common stock, $0.01 par value per share — 30,000,000 authorized at December 31, 2020 and December 31, 2019; 19,107,040 and 12,749,443 issued and outstanding at December 31, 2020 and December 31, 2019, respectively	191	127
Additional paid-in capital	456,472	245,769
Accumulated other comprehensive (loss) income	(8,612)	6,452
Accumulated deficit	(266,820)	(159,187)
Total stockholders' equity	181,231	93,161
Total liabilities and stockholders' equity	$ 285,607	$ 165,069

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

	Three Months Ended December 31,		Year Ended December 31,	
	2020	**2019**	**2020**	**2019**
Revenue	$ 2,716	$ 6,431	$ 8,308	$ 9,636
Operating expenses:				
Research and development	20,050	14,216	76,777	45,575
General and administrative	14,158	6,175	42,448	22,963
Other operating (income) expense, net	(10,090)	(4,109)	(14,646)	2,210
Total operating expenses	24,118	16,282	104,579	70,748
Operating loss	(21,402)	(9,851)	(96,271)	(61,112)
Interest expense, net	(3,397)	(1,362)	(11,362)	(5,296)
Other non-operating income	—	3,691	—	3,691
Net loss	$ (24,799)	$ (7,522)	$ (107,633)	$ (62,717)
Net loss per common share - basic and diluted	$ (1.30)	$ (0.57)	$ (6.73)	$ (5.04)
Weighted-average common shares used to compute basic and diluted net loss per common share	19,082,963	12,698,492	15,983,058	12,437,742