UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____ .

Commission File Number 001-33451

Albireo Pharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**90-0136863**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**
10 Post Office Square, Suite 1000, Boston, MA	**02109**
(Address of principal executive offices)	**(Zip code)**

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

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

As of April 30, 2020, there were 14,979,540 shares of Common Stock, $0.01 par value per share, outstanding.

Albireo Pharma, Inc.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, which we refer to as the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act, that relate to future events or to our future operations or financial performance. Any forward-looking statement involves known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statement. Forward-looking statements include statements, other than statements of historical fact, about, among other things:

- the progress, number, scope, cost, duration or results of our development activities, nonclinical studies and clinical trials of odevixibat (formerly known as A4250), elobixibat, A3384 or any of our other product candidates or programs, such as the target indication(s) for development or approval, the size, design, population, conduct, cost, objective or endpoints of any clinical trial, or the timing for initiation or completion of or availability of results from any clinical trial (including our Phase 2 trial of elobixibat in patients with non-alcoholic fatty liver disease, or NAFLD, and non-alcoholic steatohepatitis, or NASH; PEDFIC 1, our Phase 3 clinical trial of odevixibat in patients with progressive familial intrahepatic cholestasis, or PFIC; or BOLD, our pivotal clinical trial of odevixibat in patients with biliary atresia) for submission or approval of any regulatory filing, or for meeting with regulatory authorities;

- the potential benefits that may be derived from any of our product candidates;

- the timing of and our ability to obtain and maintain regulatory approval of our existing product candidates, any product candidates that we may develop, and any related restrictions, limitations, or warnings in the label of any approved product candidates;

- any payment that HealthCare Royalty Partners III, L.P., or HCR, or EA Pharma Co., Ltd., or EA Pharma, may make to us or any other action or decision that EA Pharma may make concerning elobixibat or our business relationship;

- the potential impacts of the COVID-19 pandemic on our business;

- our future operations, financial position, revenues, costs, expenses, uses of cash, capital requirements, our need for additional financing or the period for which our existing cash resources will be sufficient to meet our operating requirements; or

- our strategies, prospects, plans, expectations, forecasts or objectives.

Words such as, but not limited to, “believe,” “expect,” “anticipate,” “estimate,” “forecast,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “targets,” “likely,” “will,” “would,” “could,” “should,” “continue,” “scheduled” and similar expressions or phrases, or the negative of those expressions or phrases, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Although we believe that we have a reasonable basis for each forward-looking statement contained in this report, we caution you that these statements are based on our estimates or projections of the future that are subject to known and unknown risks and uncertainties and other important factors that may cause our actual results, level of activity, performance, experience or achievements to differ materially from those expressed or implied by any forward-looking statement. Actual results, level of activity, performance, experience or achievements may differ materially from those expressed or implied by any forward-looking statement as a result of various important factors, including our critical accounting policies and risks and uncertainties relating, among other things, to:

- the design, size, duration and endpoints for, and results from, PEDFIC 1, our Phase 3 clinical trial of odevixibat in patients with PFIC or our related extension study, or any other trials that will be required to obtain marketing approval for odevixibat to treat patients with PFIC, biliary atresia or any other pediatric

cholestatic liver disease, for elobixibat to treat NASH, or for A3384 as a potential treatment for gastrointestinal diseases or disorders;

- whether favorable findings from clinical trials of odevixibat to date, including findings in indications other than PFIC, will be predictive of results from future clinical trials, including the trials comprising our Phase 3 PFIC program for odevixibat, pivotal trial of odevixibat in biliary atresia and planned pivotal trial of odevixibat in Alagille syndrome, or ALGS; whether either or both of the U.S. Food and Drug Administration, or FDA, and European Medicines Agency, or EMA, will determine that the primary endpoint and treatment duration of the double blind Phase 3 trial in patients with PFIC are sufficient, even if such 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 an ongoing third-party study pooling and analyzing long-term PFIC patient data;

- the timing for initiation or completion of, or for availability of data from, the trials comprising the Phase 3 PFIC program for odevixibat, and the outcomes of such trials;

- delays or other challenges in the recruitment of patients for the pivotal trial of odevixibat in biliary atresia and the planned pivotal trial of odevixibat in ALGS;

- whether odevixibat will meet the criteria to receive a rare pediatric disease priority review voucher from the FDA when applicable, whether a rare pediatric disease priority review voucher that we may receive in the future for odevixibat, if any, will be valuable to us, and, if necessary, whether the rare pediatric disease priority review voucher program will be renewed beyond 2020;

- the COVID-19 pandemic, which may negatively impact the conduct of, and the timing of initiation, enrollment, completion and reporting with respect to, our clinical trials; negatively impact the supply of drug product for our clinical and preclinical programs; and/or result in other adverse impacts on our business;

- the competitive environment and commercial opportunity for a potential treatment for PFIC and other orphan pediatric cholestatic liver diseases;

- the conduct and results of clinical trials and nonclinical studies and assessments of odevixibat, elobixibat, A3384 or any of our other product candidates and programs, including the performance of third parties engaged to execute them and difficulties or delays in patient enrollment and data analysis;

- the medical benefit that may be derived from odevixibat, elobixibat, A3384 or any of our other product candidates;

- the extent to which our agreements with HCR and EA Pharma for elobixibat generate nondilutive income for us;

- the timing and success of submission, acceptance and approval of regulatory filings and any related restrictions, limitations or warnings in the label of any approved product candidates;

- the significant control or influence that EA Pharma has over the commercialization of elobixibat in Japan and the development and commercialization of elobixibat in EA Pharma’s other licensed territories;

- whether we elect to seek and, if so, our ability to establish a license or other partnering transaction with a third party for elobixibat in the United States or Europe;

- whether findings from nonclinical studies and clinical trials of IBAT inhibitors will be predictive of future clinical success for a product candidate of ours in the treatment of NASH;
- the accuracy of our estimates regarding expenses, costs, future revenues, uses of cash and capital requirements;
- our ability to obtain additional financing on reasonable terms, or at all;
- our ability to establish additional licensing, collaboration or similar arrangements on favorable terms and our ability to attract collaborators with development, regulatory and commercialization expertise;
- the success of competing third-party products or product candidates;
- our ability to successfully commercialize any approved product candidates, including their rate and degree of market acceptance;
- our ability to expand and protect our intellectual property estate;
- regulatory developments in the United States and other countries;
- the effectiveness of our internal control over financial reporting;
- the performance of our third-party suppliers, manufacturers and contract research organizations and our ability to obtain alternative sources of raw materials;
- our ability to attract and retain key personnel; and
- our ability to comply with regulatory requirements relating to our business, and the costs of compliance with those requirements, including those on data privacy and security.

These and other risks and uncertainties are described in greater detail under the caption “Risk Factors” in Item 1A of Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, in Item 1A of Part II of this quarterly report, and in other filings that we make with the Securities and Exchange Commission, or SEC. As a result of the risks and uncertainties, the results or events indicated by the forward-looking statements may not occur. We caution you not to place undue reliance on any forward-looking statement.

In addition, any forward-looking statement in this quarterly report represents our views only as of the filing date of this quarterly report and should not be relied upon as representing our views as of any subsequent date. We anticipate that subsequent events and developments may cause our views to change. Although we may elect to update these forward-looking statements publicly at some point in the future, we specifically disclaim any obligation to do so, except as required by applicable law. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

Albireo Pharma, Inc.

Condensed Consolidated Balance Sheets

(in thousands, except share data)

(unaudited)

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 150,515	$ 131,843
Prepaid expenses and other current assets	7,818	9,956
Total current assets	158,333	141,799
Property and equipment, net	554	597
Goodwill	17,260	17,260
Other assets	5,962	5,413
Total assets	$ 182,109	$ 165,069
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,788	$ 4,785
Accrued expenses	7,561	13,486
Other current liabilities	798	653
Total current liabilities	15,147	18,924
Liability related to sale of future royalties	49,407	48,714
Other long-term liabilities	4,121	4,270
Total liabilities	68,675	71,908
Stockholders’ Equity:		
Common stock, $0.01 par value per share — 30,000,000 authorized at March 31, 2020 and December 31, 2019; 14,977,855 and 12,749,443 issued and outstanding at March 31, 2020 and December 31, 2019, respectively	149	127
Additional paid-in capital	291,221	245,769
Accumulated other comprehensive income	12,739	6,452
Accumulated deficit	(190,675)	(159,187)
Total stockholders’ equity	113,434	93,161
Total liabilities and stockholders’ equity	$ 182,109	$ 165,069

See accompanying notes to Condensed Consolidated Financial Statements.

Albireo Pharma, Inc.

Condensed Consolidated Statements of Operations

(in thousands, except share and per share data)

(unaudited)

	Three Months Ended March 31,	
	2020	2019
Revenue	$ 1,549	$ 570
Operating expenses:		
Research and development	16,130	8,329
General and administrative	8,153	5,293
Other operating expense, net	6,816	2,296
Total operating expenses	31,099	15,918
Operating loss	(29,550)	(15,348)
Interest expense, net	(1,938)	(1,309)
Net loss	$ (31,488)	$ (16,657)
Net loss per share attributable to holders of common stock:		
Net loss per common share - basic and diluted	$ (2.23)	$ (1.39)
Weighted-average shares outstanding:		
Weighted-average common shares used to compute basic and diluted net loss per common share	14,132,217	12,001,125

See accompanying notes to Condensed Consolidated Financial Statements.

Albireo Pharma, Inc.

Condensed Consolidated Statements of Comprehensive Loss

(in thousands)

(unaudited)

	Three Months Ended March 31,	
	2020	2019
Net loss	$ (31,488)	$ (16,657)
Other comprehensive income:		
Foreign currency translation adjustment	6,287	2,298
Total other comprehensive income	6,287	2,298
Total comprehensive loss	$ (25,201)	$ (14,359)

See accompanying notes to Condensed Consolidated Financial Statements.

Albireo Pharma, Inc.

Condensed Consolidated Statements of Stockholders' Equity

(in thousands, except share and per share data)

(unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance--December 31, 2019	12,749,443	$ 127	$ 245,769	$ 6,452	$ (159,187)	$ 93,161
Share based compensation expense	—	—	2,381	—		2,381
Exercise of options	37,662	—	94	—	—	94
Issuance of common stock, net of costs	2,190,750	22	42,977	—	—	42,999
Other comprehensive income	—	—	—	6,287	—	6,287
Net loss	—	—	—	—	(31,488)	(31,488)
Balance--March 31, 2020	14,977,855	$ 149	$ 291,221	$ 12,739	$ (190,675)	$ 113,434

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance--December 31, 2018	11,969,928	$ 120	$ 214,694	$ 4,293	$ (96,470)	$ 122,637
Share based compensation expense	—	—	1,823	—	—	1,823
Exercise of options	68,908	—	1,290	—	—	1,290
Other comprehensive income	—	—	—	2,298	—	2,298
Net loss	—	—	—	—	(16,657)	(16,657)
Balance--March 31, 2019	12,038,836	$ 120	$ 217,807	$ 6,591	$ (113,127)	$ 111,391

See accompanying notes to Condensed Consolidated Financial Statements.

Albireo Pharma, Inc.

Condensed Consolidated Statements of Cash Flows

(in thousands)

(unaudited)

	Three Months Ended March 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (31,488)	$ (16,657)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accretion of liability related to sale of future royalties	2,040	2,005
Depreciation and amortization	39	11
Stock-based compensation expense	2,381	1,823
Foreign currency adjustments	6,544	3,441
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,283	(326)
Other assets	135	(440)
Accounts payable	2,233	(1,262)
Accrued expenses	(6,987)	(1,619)
Other current and long-term liabilities	24	(499)
Net cash used in operating activities	(23,796)	(13,523)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	42,999	—
Proceeds from exercise of options	94	1,290
Net cash provided by financing activities	43,093	1,290
Effect of exchange rate changes on cash and cash equivalents	(625)	(1,313)
Net increase (decrease) in cash and cash equivalents	18,672	(13,546)
Cash and cash equivalents—beginning of period	131,843	163,885
Cash and cash equivalents—end of period	$ 150,515	$ 150,339
Supplemental disclosures of cash and non-cash activities:		
Right of use assets and lease obligations recorded upon amended lease agreements	$ —	$ 1,205
Lease liability	$ —	$ 1,190

See accompanying notes to Condensed Consolidated Financial Statements.

Albireo Pharma, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Summary of significant accounting policies and basis of presentation

Organization

Albireo Pharma, Inc. (the Company) is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel bile acid modulators to treat orphan pediatric liver diseases and other liver and gastrointestinal diseases and disorders. The Company's clinical pipeline includes a Phase 3 product candidate, a Phase 2 product candidate, and elobixibat, which is approved in Japan for the treatment of chronic constipation. Odevixibat, the Company's Phase 3 lead product candidate, is in development for multiple pediatric cholestatic liver diseases, with an ongoing Phase 3 trial for the treatment of patients with progressive familial intrahepatic cholestasis (PFIC), a pivotal trial initiated for the treatment of patients with biliary atresia, and another pivotal trial for the treatment of patients with Alagille syndrome (ALGS) planned to be initiated by the end of 2020. PFIC, biliary atresia and ALGS are each a rare, life-threatening genetic disorder affecting young children.

Basis of presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information, and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the audited consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019. The Company combined prepaid expenses and other assets with other receivables in the Condensed Consolidated Statements of Cash Flows. These combinations are reflected at March 31, 2020 and March 31, 2019 respectively, with a change in the prior period presentation being made to conform to the current period presentation. There was no change to previously reported net loss or total comprehensive loss in the prior period presented as a result. In the opinion of management, all adjustments (including normal recurring adjustments) considered necessary for fair presentation have been included in the Condensed Consolidated Financial Statements. The results of operations for the three months ended March 31, 2020 are not necessarily indicative of the results that may be expected for the full fiscal year, any other interim period or any future fiscal year. The condensed consolidated financial statements are prepared on a basis consistent with prior periods.

Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB).

Principles of consolidation

The accompanying Consolidated Financial Statements include the accounts of the Company and its direct or indirect wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Foreign currency translation

Functional currency

Items included in the financial statements of each entity comprising the Company are measured using the currency of the primary economic environment in which the entity operates (the functional currency).

Transactions and balances

Foreign currency transactions in each entity comprising the Company are remeasured into the functional currency of the entity using the exchange rates prevailing at the respective transaction dates. Foreign exchange gains and losses resulting from the settlement of such transactions and from the remeasurement at period-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized within other operating expense, net in the Condensed Consolidated Statements of Operations.

The results and financial position of the Company that have a functional currency different from the USD are translated into the presentation currency as follows:

a. assets and liabilities presented are translated at the closing exchange rate as of March 31, 2020 and December 31, 2019;

b. income and expenses for each statement of comprehensive loss are translated at the average exchange rate for the applicable period; and

c. significant transactions use the closing exchange rate on the date of the transaction.

All resulting exchange differences arising from such translations are recognized directly in other comprehensive income (loss) and presented as a separate component of equity.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts of assets, liabilities, revenues and expenses reported in the financial statements and accompanying notes. Management must apply significant judgment in this process. On an ongoing basis, the Company evaluates its estimates and assumptions, including but not limited to accruals, and the accretion of interest on the monetization liability. Actual results could materially differ from these estimates.

Revenue recognition

Milestone Payments

At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on a level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

In 2012, the Company entered into a license agreement (the Agreement) with EA Pharma Co., Ltd. (EA Pharma, formerly Ajinomoto Pharmaceuticals Co., Ltd.) to develop a select product candidate (elobixibat) for registration and subsequent commercialization in select markets. In conjunction with the Agreement, the Company granted EA Pharma an exclusive license to its intellectual property for development and commercialization activities in the designated field and territories. The Company has completed all of its performance obligations under the Agreement.

As of March 31, 2020, the Company is eligible to receive an additional regulatory-based milestone payment under the Agreement of $4.7 million if a specified regulatory event is achieved for elobixibat. The cash payments and any other payments for milestones and royalties from EA Pharma are non-refundable, non-creditable and not subject to set-off.

The Agreement will continue until the last royalty period for any product in the territory, which is defined as the period when there are no remaining patent rights or regulatory exclusivity in place for any products subject to royalties. EA Pharma may terminate the Agreement upon 180 days' prior written notice to the Company. Either party may terminate the Agreement for the other party's uncured material breach or insolvency and in certain other circumstances agreed to by the parties.

Monetization of Future Royalties

In December 2017, the Company entered into a royalty interest acquisition agreement (RIAA) with HealthCare Royalty Partners III, L.P. (HCR) pursuant to which it sold to HCR the right to receive all royalties from sales in Japan and sales milestones achieved from any covered territory potentially payable to the Company under the Agreement, up to a specified maximum "cap" amount of $78.8 million, based on the funds the Company received from HCR to date. The Company received $44.5 million from HCR, net of certain transaction expenses, under the RIAA and the Company is eligible to receive an additional $15.0 million under the RIAA if a specified sales milestone is achieved for elobixibat in Japan. If the cap amount is reached, the Company will again become eligible to receive royalties from Japanese sales and sales milestones from covered territories for elobixibat from EA Pharma under the Agreement. The Company is obligated to make royalty interest payments to HCR under the RIAA only to the extent it receives future Japanese royalties, sales milestones or other specified payments from EA Pharma. Although the Company sold its rights to receive royalties from the sales of elobixibat in Japan, as a result of its ongoing involvement in the cash flows related to these royalties, the Company will continue to account for these royalties as revenue. The Company recorded the $44.5 million as a liability related to sale of future royalties (royalty obligation). The royalty obligation will be amortized using the effective interest rate method, based on the Company's best estimate of the time it will take to reach the capped amount.

The following table shows the activity within the liability account for the period ended March 31, 2020:

	March 31, 2020 (in thousands)
Liability related to sale of future royalties—beginning balance	$ 55,144
Foreign currency translation loss	43
Accretion of interest expense on liability related to royalty monetization	2,040
Repayment of the liability	(6,271)
Liability related to sale of future royalties—ending balance	$ 50,956
Less current portion classified within accrued expenses	(1,549)
Net ending liability related to sale of future royalties	$ 49,407

The Company records estimated royalties due for the current period in accrued other until the payment is received from EA Pharma at which time the Company then remits payment to HCR. As royalties are remitted to HCR, the balance of the royalty obligation will be effectively repaid over the life of the RIAA. In order to determine the accretion of the royalty obligation, the Company is required to estimate the total amount of future royalty payments to be received and submitted to HCR, as noted above, based on the Company's best estimate of the time it will take to reach the cap amount and when milestones will be received. The sum of these amounts less the $44.5 million proceeds the Company

received will be recorded as interest expense over the life of the royalty obligation. At March 31, 2020, the Company's estimate of its total interest expense resulted in an annual effective interest rate of approximately 16.76%.

The Company periodically assesses the estimated royalty payments to HCR and to the extent such payments are greater or less than its initial estimates or the timing of such payments is materially different than its original estimates, the Company will prospectively adjust the accretion of interest on the royalty obligation. There are a number of factors that could materially affect the amount and the timing of royalty payments, most of which are not within the Company's control. Such factors include, but are not limited to, the rate of elobixibat prescriptions, the number of doses administered, the introduction of competing products, manufacturing or other delays, patent protection, adverse events that result in governmental health authority imposed restrictions on the use of the drug products, significant changes in foreign exchange rates as the royalties remitted to HCR are in U.S. dollars while sales of elobixibat are in Japanese yen, and sales never achieving forecasted numbers, which would result in reduced royalty payments and reduced non-cash interest expense over the life of the royalty obligation. To the extent future royalties result in an amount less than the liability, the Company is not obligated to fund any such shortfall.

Recently adopted accounting pronouncements

In August 2018, the FASB issued ASU 2018-15, *"Intangibles – Goodwill and Other – Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract."* (ASU 2018-15) This standard aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). The guidance also requires the entity to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement, which includes reasonably certain renewals. The guidance becomes effective for the Company for the fiscal year beginning after December 15, 2019 and early adoption is permitted. The Company adopted this guidance in the first quarter of 2020 on a prospective basis and there was no material impact on its consolidated financial statements.

2. Fair Value of financial instruments

When measuring the fair value of financial instruments, the Company evaluates valuation techniques such as the market approach, the income approach and the cost approach. A three-level valuation hierarchy, which prioritizes the inputs to valuation techniques that are used to measure fair value, is based upon whether such inputs are observable or unobservable.

Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity. The three-level hierarchy for the inputs to valuation techniques is briefly summarized as follows:

Level 1—Observable inputs such as quoted prices (unadjusted) for *identical* instruments in active markets;

Level 2—Observable inputs such as quoted prices for *similar* instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or model-derived valuations whose significant inputs are observable for substantially the full term of the assets or liabilities; and

Level 3—Unobservable inputs that reflect the reporting entity's estimate of assumptions that market participants would use in pricing the asset or liability.

3. Commitments and contingencies

Agreements with CROs

As of March 31, 2020, the Company had various agreements with CROs for the conduct of specified research and development activities. Based on the terms of the respective agreements, the Company may be required to make future payments of up to $46.1 million to CROs upon the completion of contracted work.

4. Net loss per share

Basic net loss per share, or Basic EPS, is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding.

The following table sets forth the computation of Basic EPS and Diluted EPS (in thousands, except for share and per share data):

	Three Months Ended March 31,	
	2020	2019
Basic and Diluted EPS:		
Numerator		
Net loss	$ (31,488)	$ (16,657)
Denominator		
Weighted average number of shares outstanding	14,132,217	12,001,125
Basic and Diluted EPS	$ (2.23)	$ (1.39)

The following outstanding common stock equivalents were excluded from the computation of Diluted EPS for the three months ended March 31, 2020 and 2019 because including them would have been anti-dilutive:

	Three Months Ended March 31,	
	2020	2019
Options to purchase common stock and RSUs	2,293,790	1,757,728

5. Income taxes

The Company did not record a tax provision or benefit for the three months ended March 31, 2020 or 2019. The Company has continued to maintain a full valuation allowance against its net deferred tax assets. The Company has had an overall net operating loss position since its inception.

6. Financings

2020 Underwritten Public Offering

On February 3, 2020, the Company completed an underwriting public offering of 2,190,750 shares of its common stock, which includes the exercise in full of the underwriters' option to purchase additional shares. The Company received net proceeds from this offering of approximately $43.0 million, after deducting underwriting discounts, commissions and offering expenses.

7. Stock-based Compensation

The Company granted 518,325 options at a weighted average price of $24.38.

The Company recorded the following stock-based compensation expense:

	Three Months Ended March 31,	
	2020	2019
	(in thousands)	
Employee awards:		
Research and development expense	$ 880	$ 708
General and administrative expense	1,501	1,115
Total stock-based compensation expense	$ 2,381	$ 1,823

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and the related notes included elsewhere in this quarterly report and our audited financial statements and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results, performance or experience could differ materially from what is indicated by any forward-looking statement due to various important factors, risks and uncertainties, including, but not limited to, those set forth under "Cautionary Note Regarding Forward-Looking Statements" included elsewhere in this quarterly report or under "Risk Factors" in Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2019, in Item 1A of Part II of this Quarterly Report on Form 10-Q, or in other filings that we make with the SEC.

Overview

We are a biopharmaceutical company focused on the development and commercialization of novel bile acid modulators to treat orphan pediatric liver diseases and other liver or gastrointestinal diseases and disorders. The initial target indication for our lead product candidate, odevixibat (formerly known as A4250), is progressive familial intrahepatic cholestasis, or PFIC, a rare, life-threatening genetic disorder affecting young children for which there is currently no approved drug treatment. We are also pursuing the development of odevixibat in biliary atresia and in Alagille syndrome, or ALGS, each of which is a rare, life threatening disease that affects the liver and for which there is no approved pharmacologic treatment option. We initiated a pivotal clinical trial of odevixibat in biliary atresia in the first half of 2020 and we plan to initiate a pivotal trial in ALGS by the end of 2020. Our most advanced product candidate in addition to odevixibat is elobixibat, which is approved in Japan for the treatment of chronic constipation and for which we have initiated a Phase 2 clinical trial as a treatment for nonalcoholic fatty liver disease, or NAFLD, and nonalcoholic steatohepatitis, or NASH. We expect topline results from the Phase 2 trial in mid-2020. We are also exploring additional clinical development of our product candidate A3384 based on an evaluation of its patent coverage and our overall portfolio. We also have a preclinical program in adult liver disease.

Odevixibat — our lead product candidate for PFIC. We completed a Phase 2 clinical trial of odevixibat in children with chronic cholestasis and pruritus, and in May 2018, we enrolled the first patient in our Phase 3 clinical trial for odevixibat, given once per day as an oral capsule or sprinkled over food, in patients ages 6 months to 18 years with PFIC types 1 and 2, with 45 global sites recruiting, which we refer to as PEDFIC 1. PEDFIC 1 is testing two doses of odevixibat, 40 µg/kg/day and 120 µg/kg/day, along with placebo, over a treatment period of 24 weeks. In PEDFIC 1, assessment of change in pruritus is the primary endpoint in the U.S. and a key secondary endpoint in the E.U., and serum bile acid (sBA) responder rate is the primary endpoint in the E.U. and a key secondary endpoint in the U.S. We are using the planned commercial formulation in PEDFIC 1, but any commercial product will include final trade dress. In the first quarter of 2019, we revised our statistical analysis methodology for PEDFIC 1, in line with guidance from the U.S. Food and Drug Administration, or FDA, which resulted in an improvement in the power of the study. We have completed enrollment in PEDFIC 1 (62 out of a planned 60 patients), and have collected data from more than three quarters of the patients who have completed the randomized controlled period of the trial. We expect topline data from PEDFIC 1 in mid-2020, with a potential approval and commercial launch in the second half of 2021. We also submitted a protocol amendment for PEDFIC 2, our long term, open label extension study, which includes an additional cohort of PFIC patients who are not eligible for PEDFIC 1. The first sites have been activated and first patients enrolled in the expanded PEDFIC 2 cohort. In June 2018, the FDA granted a rare pediatric disease designation to odevixibat for the treatment of PFIC, which affirms our eligibility to apply for a rare pediatric disease priority review voucher upon submission of a new drug application for odevixibat. In September 2018, the FDA granted fast track designation to odevixibat for the treatment of pruritus associated with PFIC.

The precise prevalence of PFIC is unknown, and we are not aware of any patient registries or other method of establishing with precision the actual number of patients with PFIC in any geography. PFIC has been estimated to affect between one in every 50,000 to 100,000 children born worldwide. Based on the published incidence, published regional populations, and estimated median life expectancies, we estimate the prevalence of PFIC across the spectrum of the

disease to be approximately 8,000 to 10,000 patients in the U.S. and E.U., but we are not able to estimate the prevalence of PFIC with precision. We currently have not modeled other regional opportunities in Asia, the Middle East and Latin America. We are aware there may be higher prevalence of disease in some countries such as Saudi Arabia and Turkey. We hold global rights to odevixibat unencumbered. Our current plan is to commercialize odevixibat ourselves in the U.S. and E.U., and we have begun the process of identifying potential partners for other regions. There are currently no drugs approved for the treatment of PFIC. First-line treatment for PFIC is typically off-label ursodeoxycholic acid, or UDCA, which is approved in the United States and elsewhere for the treatment of primary biliary cholangitis, or PBC. However, many PFIC patients do not respond well to UDCA, undergo partial external bile diversion, or PEBD, surgery and often require liver transplantation. PEBD surgery is a life-altering and undesirable procedure in which bile is drained outside the body to a stoma bag that must be worn by the patient 24 hours a day.

Other indications under development for Odevixibat. We are also pursuing the development of odevixibat in patients with biliary atresia, another rare, life-threatening disease that affects the liver and for which there is no approved pharmacologic treatment option. In December 2018, the European Commission granted orphan designation to odevixibat for the treatment of biliary atresia, and in January 2019, the FDA granted orphan drug designation to odevixibat for the treatment of biliary atresia. The FDA has cleared our investigational new drug application, or IND, for the BOLD clinical trial, a global pivotal trial in biliary atresia, which we initiated in the first half of 2020 and plan for full site activation in the first half of 2021.We believe biliary atresia is one of the most common rare pediatric liver diseases, and is the leading cause of liver transplants in children. Our double-blind, placebo controlled pivotal trial in biliary atresia is designed to enroll approximately 200 patients at 70 sites globally. Patients will receive either placebo or high-dose (120µg/kg) odevixibat once daily. The primary endpoint is survival with native liver after two years of treatment.

Biliary atresia is a partial or total blocking or absence of large bile ducts that causes cholestasis and resulting accumulation of bile that damages the liver. The estimated worldwide incidence of biliary atresia is between 4.5 and 8.5 for every 100,000 live births. We estimate the prevalence of biliary atresia to be approximately 15,000 to 20,000 patients in the U.S. and E.U., but we are not able to estimate the prevalence of biliary atresia with precision. There are currently no drugs approved for the treatment of biliary atresia. The current standard of care is a surgery known as the Kasai procedure, or hepatoportoenterostomy, in which the obstructed bile ducts are removed and a section of the small intestine is connected to the liver directly. However, only an estimated 25% of those initially undergoing the Kasai procedure will survive to their twenties without need for liver transplantation.

In addition, we have been evaluating a pivotal study design for odevixibat in ALGS and we plan to initiate the trial by the end of 2020. ALGS is a genetic condition associated with liver, heart, eye, kidney and skeletal abnormalities. In particular, ALGS patients have fewer than normal bile ducts inside the liver, which leads to cholestasis and the accumulation of bile and causes scarring in the liver. ALGS is estimated to affect between one in every 30,000 to 70,000 children born worldwide. We estimate the prevalence of ALGS to be approximately 3,000 to 5,000 patients in the U.S. and E.U., but we are not able to estimate the prevalence of ALGS with precision. There are currently no drugs approved for the treatment of ALGS. Current treatment for ALGS is generally in line with current treatments for PFIC as described above. In August 2012, the European Commission granted orphan designation to odevixibat for the treatment of ALGS. In October 2018, the FDA granted orphan drug designation to odevixibat for the treatment of ALGS.

We continue to evaluate potential clinical development in other indications, including primary sclerosing cholangitis, which refers to swelling (inflammation), scarring, and destruction of bile ducts inside and outside of the liver. The first symptoms are typically fatigue, itching and jaundice, and many patients with sclerosing cholangitis also suffer from inflammatory bowel disease. The estimated incidence of primary sclerosing cholangitis is 6.3 cases per 100,000 people. There are currently no drugs approved for the treatment of sclerosing cholangitis. First-line treatment is typically off-label UDCA, although UDCA has not been established to be safe and effective in patients with sclerosing cholangitis in well controlled clinical trials.

Elobixibat as a potential treatment for NASH. NASH is a common, serious and sometimes fatal chronic liver disease that resembles alcoholic liver disease but occurs in people who drink little or no alcohol. Based on multiple epidemiological studies published by third parties in 2014 and 2015, we estimate that NASH affects 2 to 3.5% of adults, representing over 9 million people in the United States and 10 million people in the E.U. There are currently no drugs approved for the treatment of NASH. Lifestyle changes, including modification of diet and exercise to reduce body

weight, as well as treatment of concomitant diabetes and dyslipidemia, are commonly accepted as the standard of care for NASH, but have not conclusively been shown to prevent disease progression. Based on findings on parameters relevant to NASH in clinical trials of elobixibat that we previously conducted in patients with chronic constipation and in patients with elevated cholesterol and findings on other parameters relevant to NASH from nonclinical studies that we previously conducted with elobixibat or a different IBAT inhibitor, we believe elobixibat has potential benefit in the treatment of NASH. We have completed enrollment in our Phase 2 clinical trial of elobixibat in NAFLD and NASH. We expect to have topline results from the Phase 2 trial in mid-2020, although it is possible the present crisis could cause some data to be lost to follow-up. In addition, we expect data from a second investigator-initiated study through our partner EA Pharma, which is being conducted in Japan with elobixibat 10mg and in combination with a bile acid sequestrant, later this year or in early 2021, which we expect will add to the overall pool of data for elobixibat in NAFLD/NASH.

Since inception, we have incurred significant operating losses. As of March 31, 2020, we had an accumulated deficit of $190.7 million. We expect to continue to incur significant expenses and increasing operating losses as we continue our development of, and seek marketing approvals for, our product candidates, prepare for and begin the commercialization of any approved products, and add infrastructure and personnel to support our product development efforts and operations as a public company in the United States.

As a clinical-stage company, our revenues, expenses and results of operations are likely to fluctuate significantly from quarter to quarter and year to year. We believe that period-to-period comparisons of our results of operations should not be relied upon as indicative of our future performance.

As of March 31, 2020, we had approximately $150.5 million in cash and cash equivalents.

Financial Operations Overview

The following discussion sets forth certain components of our consolidated statements of operations as well as factors that impact those items.

Revenue

We generate revenue primarily from the receipt of royalty revenue, upfront or license fees and milestone payments. License agreements with commercial partners generally include nonrefundable upfront fees and milestone payments, the receipt of which is dependent upon the achievement of specified development, regulatory or commercial milestone events, as well as royalties on product sales of licensed products, if and when such product sales occur. For additional information about our revenue recognition, refer to Note 1 to our condensed consolidated financial statements included in this quarterly report.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of personnel costs (including salaries, benefits and stock-based compensation) for employees in research and development functions, costs associated with nonclinical and clinical development services, including clinical trials and related manufacturing costs, third-party contract research organizations, or CROs, and related services and other outside costs, including fees for third-party professional services such as consultants. Our nonclinical studies and clinical studies are performed by CROs. We expect to continue to focus our research and development efforts on nonclinical studies and clinical trials of our product candidates. As a result, we expect our research and development expenses to continue to increase for the foreseeable future.

Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of external costs such as fees paid to CROs and others in connection with our nonclinical and clinical development activities and related manufacturing. We do not allocate employee costs or facility expenses, including depreciation or

other indirect costs, to specific product development programs because these costs are deployed across multiple product development programs and, as such, are not separately classified.

Successful development of our current and potential future product candidates is highly uncertain. Completion dates and costs for our programs can vary significantly by product candidate and are difficult to predict. As a result, we cannot estimate with any degree of certainty the costs we will incur in connection with development of any of our product candidates. We anticipate we will make determinations as to which programs and product candidates to pursue and how much funding to direct to each program and product candidate on an ongoing basis in response to the results of ongoing and future clinical trials, our ability to enter into licensing, collaboration and similar arrangements with respect to current or potential future product candidates, the success of research and development programs and our assessments of commercial potential.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs (including salaries, benefits and stock-based compensation) for our executive, finance and other administrative employees. In addition, general and administrative expenses include fees for third-party professional services, including consulting, information technology, legal and accounting services and other corporate expenses and allocated overhead.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles for interim financial information. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. We base our estimates and assumptions on historical experience and on various assumptions that we believe are reasonable under the circumstances, and we evaluate them on an ongoing basis. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of revenues and expenses that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates and judgments. In addition, our reported financial condition and results of operations could vary if new accounting standards are enacted that are applicable to our business.

Results of Operations

Three Months Ended March 31, 2020 and March 31, 2019

Result of Operations

	Three Months Ended March 31,		Change
	2020	2019	$
	(in thousands)		
Revenue	$ 1,549	$ 570	$ 979
Operating Expenses			
Research and development	16,130	8,329	7,801
General and Administrative	8,153	5,293	2,860
Other operating expense, net	6,816	2,296	4,520
Total operating expenses	31,099	15,918	15,181
Operating loss	(29,550)	(15,348)	(14,202)
Interest expense, net	(1,938)	(1,309)	(629)
Net loss	$ (31,488)	$ (16,657)	$ (14,831)

Revenue

	Three Months Ended March 31,		Change
	2020	2019	$
	(in thousands)		
Revenue	$ 1,549	$ 570	$ 979

There was $1.5 million in revenue for the three months ended March 31, 2020 compared with $0.6 million for the three months ended March 31, 2019, an increase of $0.9 million. The higher revenue is due to the estimated royalty revenue received from EA Pharma for elobixibat for the treatment of chronic constipation.

Research and development expenses

	Three Months Ended March 31,		Change
	2020	2019	$
	(in thousands)		
Research and development expenses	$ 16,130	$ 8,329	$ 7,801

Research and development expenses were $16.1 million for the three months ended March 31, 2020 compared with $8.3 million for the three months ended March 31, 2019, an increase of $7.8 million. The increased research and development expenses for the 2020 period were principally due to personnel expenses, and program expenses as we continue to increase our headcount, and program activities, respectively.

The following table summarizes our principal product development programs and the out-of-pocket third-party expenses incurred with respect to each clinical-stage product candidate and our preclinical programs for the three months ended March 31, 2020 and 2019.

	Three Months Ended March 31,		Change
	2020	2019	$
	(in thousands)		
Direct third-party project costs:			
Odevixibat	$ 8,689	$ 3,364	$ 5,325
Elobixibat	868	223	645
A3384	59	74	(15)
Preclinical	1,295	1,003	292
Total	$ 10,911	$ 4,664	$ 6,247
Other project costs[1]:			
Personnel costs	$ 3,963	$ 2,700	$ 1,263
Other costs[2]	1,256	965	291
Total	$ 5,219	$ 3,665	$ 1,554
Total research and development costs	$ 16,130	$ 8,329	$ 7,801

(1) Other project costs are leveraged across multiple programs.
(2) Other costs include facility, supply, consultant and overhead costs that support multiple programs.

General and administrative expenses

	Three Months Ended March 31,		Change
	2020	2019	$
	(in thousands)		
General and administrative expenses	$ 8,153	$ 5,293	$ 2,860

General and administrative expenses were $8.2 million for the three months ended March 31, 2020 compared with $5.3 million for the three months ended March 31, 2019, an increase of $2.9 million. The increase is attributable to personnel and related expenses as we continue to increase our headcount, and commercialization readiness activity.

Other operating expense, net

	Three Months Ended March 31,		Change
	2020	2019	$
	(in thousands)		
Other operating expense, net	$ 6,816	$ 2,296	$ 4,520

Other operating expense, net totaled $6.8 million for the three months ended March 31, 2020 compared with $2.3 million of other operating expense for the three months ended March 31, 2019. The difference primarily relates to changes in exchange rates in the two periods.

Interest expense, net

	Three Months Ended March 31,		Change
	2020	2019	$
	(in thousands)		
Interest expense, net	$ (1,938)	$ (1,309)	$ (629)

Interest expense, net totaled $1.9 million of expense for the three months ended March 31, 2020 compared with $1.3 million for the three months ended March 31, 2019. The difference was principally attributable to non-cash interest expense recorded in connection with the sale of future royalties, related to sales of elobixibat in Japan offset by interest income associated with our interest bearing cash and cash equivalents.

Liquidity and Capital Resources

Sources of Liquidity

We do not expect to generate significant revenue from product sales unless and until we or a potential future licensee or collaborator obtains marketing approval for, and commercializes, one or more of our current or potential future product candidates (other than elobixibat as a treatment for chronic constipation in Japan), which we do not expect to occur until at least 2021, if at all. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of and seek regulatory approvals for our product candidates. We are subject to all of the risks applicable to the development of new pharmaceutical products and may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may harm our business. We expect that we will need substantial additional funding to complete development of and potentially commercialize our product candidates.

Our operations have historically been financed primarily through issuances of equity or convertible debt, upfront fees paid upon entering into license agreements, payments received upon the achievement of specified milestone events under license agreements, grants and venture debt borrowings and the HCR royalty monetization transaction. Our primary uses of capital are, and we expect will continue to be, personnel-related costs, third party expenses associated with our research and development programs, including the conduct of clinical trials, and manufacturing-related costs for our product candidates.

As of March 31, 2020, our cash and cash equivalents were approximately $150.5 million.

During the first quarter of 2018, following the Japanese MHLW's approval of elobixibat for the treatment of chronic constipation in January 2018, we received a $44.5 million payment, net of certain transaction expenses, from HCR under our RIAA. Under the terms of the RIAA, we are eligible to receive an additional $15.0 million if a specified sales milestone is achieved for elobixibat in Japan. Additionally, this approval triggered a milestone payment to us from EA Pharma of $11.2 million. As of March 31, 2020, we have received approximately $49.9 million in upfront and milestone payments from EA Pharma under a license agreement for the development and commercialization of elobixibat in specified countries in Asia. We are eligible to receive additional amounts of up to $4.7 million under the amended agreement, if a specified regulatory event is achieved for elobixibat. In addition, subject to the terms of the RIAA with HCR, we may in the future also become eligible under the license agreement to receive up to $31.9 million, if specified sales milestones are achieved for elobixibat and stepped royalties at rates beginning in the high single digits on any future elobixibat product sales.

In January 2018, we completed an underwritten public offering of 2,265,500 shares of our common stock for net proceeds of approximately $69.9 million. Subsequently, in February 2018, we sold 728,862 shares of our common stock for net proceeds of approximately $24.2 million pursuant to an at-the-market offering program Sales Agreement that we entered into with Cowen in October 2017. This agreement terminated on March 6, 2019.

On March 6, 2019, we filed a new universal shelf registration on Form S-3 with the SEC, which was declared effective on April 30, 2019, pursuant to which we registered for sale up to $200.0 million of any combination of our common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that we may determine. As of March 31, 2020, $132.6 million of securities remained available for issuance under our universal shelf registration statement.

On March 6, 2019, we entered into a new sales agreement, with respect to an at-the-market offering program under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $50.0 million. Subsequently, in May 2019, we sold 637,367 shares of our common stock for net proceeds of approximately $20.8 million pursuant to the sales agreement.

In addition, on February 3, 2020, we completed an underwritten public offering of 2,190,750 shares of our common stock under our universal shelf registration statement for net proceeds of approximately $43.0 million.

Cash Flows

Three months ended March 31, 2020 and March 31, 2019

	Three Months Ended March 31,	
	2020	2019
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (23,796)	(13,523)
Financing activities	43,093	1,290
Total	$ 19,297	$ (12,233)
Effect of exchange rate changes on cash and cash equivalents	(625)	(1,313)
Net increase (decrease) in cash and cash equivalents	18,672	(13,546)

Operating activities

Cash used in operating activities of $23.8 million during the three months ended March 31, 2020 was primarily a result of our $31.5 million net loss from operations and a net decrease in assets and liabilities of $3.3 million. The net decrease in operating assets and liabilities during the three months ended March 31, 2020 was primarily driven by decreases in accrued expenses and prepaid expenses and other current assets, and an increase to accounts payable. This decrease was offset by non cash items, including $6.5 million of foreign currency adjustments, $2.4 million of stock- based compensation expense and $2.0 million of non-cash interest on liability related to sale of future royalties. Cash used in operating activities was $13.5 million during the three months ended March 31, 2019. The cash used in operating activities was primarily a result of our $16.7 million net loss from operations and a net decrease in changes in operating assets and liabilities of $4.1 million. The net decrease in operating assets and liabilities for the three months ended March 31, 2019 was primarily driven by a decrease in accrued expenses and accounts payable, and an increase in other assets and prepaid expenses and other current assets. The decrease was offset by non cash items, including $3.4 million in foreign currency adjustments, $2.0 million in non-cash interest on liability related to sales of future royalties, and $1.8 million in stock-based compensation expense.

Financing activities

Cash provided by financing activities of $43.1 million during the three months ended March 31, 2020 was primarily related to proceeds from the issuance of common stock, net of issuance costs of $43.0 million and proceeds from exercise of options of $0.1 million. Cash provided by financing activities of $1.3 million during the three months ended March 31, 2019 was primarily related to proceeds from exercise of options.

Funding Requirements

Cash used to fund operating expenses is affected by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. We believe that our existing cash and cash equivalents will be sufficient to meet our projected operating requirements into the second half of 2021, including for our Phase 3 clinical program for odevixibat in PFIC and our pivotal trial of odevixibat in biliary atresia, and to initiate our planned pivotal trial of odevixibat in ALGS. However, our operating plans may change as a result of many factors, including those described below, and we may need additional funds sooner than planned to meet operational needs and capital requirements. In addition, if the conditions for raising capital are favorable we may seek to raise additional funds at any time.

Our future funding requirements will depend on many factors, including the following:

- the costs, design, duration and any potential delays of the Phase 3 clinical trial of odevixibat in PFIC, the pivotal clinical trial of odevixibat in biliary atresia and planned pivotal trial of odevixibat in ALGS; the scope, number, progress, initiation, duration, cost, results and timing of clinical trials and nonclinical studies of our current or future product candidates;

- whether and to what extent milestone events are achieved under our license agreement with EA Pharma, our RIAA with HCR or any potential future licensee or collaborator;

- the outcomes and timing of regulatory reviews, approvals or other actions;

- our ability to obtain marketing approval for our product candidates;

- our ability to establish and maintain additional licensing, collaboration or similar arrangements on favorable terms and whether and to what extent we retain development or commercialization responsibilities under any new licensing, collaboration or similar arrangement;

- the success of any other business, product or technology that we acquire or in which we invest;

- our ability to maintain, expand and defend the scope of our intellectual property portfolio;
- our ability to manufacture any approved products on commercially reasonable terms;
- our ability to establish a sales and marketing organization or suitable third-party alternatives for any approved product;
- the number and characteristics of product candidates and programs that we pursue;
- the potential impacts of the COVID-19 pandemic on our business;
- the costs of acquiring, licensing or investing in businesses, product candidates and technologies;
- our need and ability to hire additional management and scientific and medical personnel;
- the costs to operate as a public company in the United States, including the need to implement additional financial and reporting systems and other internal systems and infrastructure for our business;
- market acceptance of our product candidates, to the extent any are approved for commercial sale; and
- the effect of competing technological and market developments.

We cannot determine precisely the completion dates and related costs of our development programs due to inherent uncertainties in outcomes of clinical trials and the regulatory approval process. We cannot be certain that we will be able to successfully complete our research and development programs or establish licensing, collaboration or similar arrangements for our product candidates. Our failure or the failure of any current or potential future licensee to complete research and development programs for our product candidates could have a material adverse effect on our financial position or results of operations.

We expect to continue to incur losses. Our ability to achieve and maintain profitability is dependent upon the successful development, regulatory approval and commercialization of our product candidates and achieving a level of revenues adequate to support our cost structure. We may never achieve profitability.

If the conditions for raising capital are favorable, we may seek to finance future cash needs through public or private equity or debt offerings or other financings. Additionally, if we need to raise additional capital to fund our operations, complete clinical trials, or potentially commercialize our product candidates, we may likewise seek to finance future cash needs through public or private equity or debt offerings or other financings. The necessary funding may not be available to us on acceptable terms or at all.

We have an effective universal shelf registration statement on Form S-3 with the SEC, pursuant to which we registered for sale up to $200 million of any combination of our common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that we may determine, including up to $50.0 million of our common stock available for issuance pursuant to an at-the-market offering program sales agreement that we entered into with Cowen and Company, LLC, or Cowen, in March 2019. In May 2019, we sold 637,367 shares of our common stock for net proceeds of approximately $20.8 million pursuant to the at-the-market offering program sales agreement. In addition, on February 3, 2020, we completed an underwritten public offering of 2,190,750 shares of our common stock under our universal shelf registration statement for net proceeds of approximately $43.0 million. As of March 31, 2020, approximately $132.6 million of securities remain available for issuance under the shelf registration statement, including up to $28.6 million of our common stock that we may offer and sell, from time to time at our discretion, through Cowen as sales agent under the at-the-market offering program sales agreement. Under the sales agreement, Cowen may sell the shares by any method permitted by law deemed to be an “at the market” offering as defined in Rule 415 of the Securities Act. The sale of additional equity or convertible debt securities may result in significant dilution to our stockholders, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. The incurrence of additional debt financing would result in debt service obligations and

the instruments governing such debt may provide for operating and financing covenants that would restrict our operations. We may also seek to finance future cash needs through potential future licensing, collaboration or similar arrangements. These arrangements may not be available on acceptable terms or at all, and we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our development programs or obtain funds through third-party arrangements that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not required for smaller reporting companies.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of March 31, 2020, our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Form 10-Q, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

Other than as described above, there were no changes in our internal controls over financial reporting identified in connection with the evaluation of such internal controls that occurred during the three months ended March 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any material legal proceedings.

Item 1A. Risk Factors

Except as set forth below, there have been no material changes to the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the Securities and Exchange Commission, or SEC, on March 2, 2020.

The outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, could adversely impact our business, including our preclinical studies and clinical trials.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. In December 2019, a novel strain of coronavirus, SARS-CoV-2, which causes coronavirus disease 2019 (COVID-19), surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries, including the United States. In response to the spread of COVID-19, we have closed our executive offices with our administrative employees continuing their work outside of our offices, restricted on-site staff to only those required to execute their job responsibilities and limited the number of staff in any given research and development laboratory.

As a result of the COVID-19 outbreak, or similar pandemics, we have and may in the future experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays or disruptions in preclinical studies or clinical trials due to unforeseen circumstances at contract research organizations and vendors along their supply chain;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19, being forced to quarantine, or not being willing to travel to clinical trial sites;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the U.S. Food and Drug Administration and comparable foreign regulatory agencies, which may impact approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems; and
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, continued reliance on working from home or mass transit disruptions.

These and other factors arising from the COVID-19 pandemic could worsen in countries that are already afflicted with COVID-19, could continue to spread to additional countries, or could return to countries where the pandemic has been partially contained, each of which could further adversely impact our ability to conduct clinical trials and our business generally, and could have a material adverse impact on our operations and financial condition and results.

In addition, the trading prices for our common stock and the securities of other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak may impact our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

Item 5. Other Information

On May 4, 2020, we entered into that certain Second Amendment to Lease (the "Second Amendment") with NS Boston III PO Owner LLC (the "Landlord"), successor in interest to POSIG Investors LLC, the successor in interest to the SHIGO 10 PO Owner LLC, affecting that certain Office Lease Agreement dated February 7, 2017 (the "Original Lease"), as previously amended by that certain First Amendment to Lease dated March 28, 2019 (the "First Amendment", and together with the Original Lease and Second Amendment, collectively the "Lease"), pursuant to which approximately 3,490 rentable square feet of space (the "Expansion Space") was added to our existing Premises under the Lease. The Expansion Space is in the building located at 10 Post Office Square, Boston, Massachusetts and will expand the Company's executive offices.

The Term of the Lease with respect to the Expansion Space commences on July 1, 2020 and expires on June 30, 2021. We have the option to extend the Term of the Lease with respect to the Expansion Space so that it is coterminous with our existing premises (i.e., until October 31, 2026) by notice to Landlord given no later than December 31, 2020.

We will be obligated to make monthly Base Rent payments with respect to the Expansion Space in the amount of $18,032 per month commencing on July 1, 2020 and continuing until June 30, 2021. In the event we exercise our option to extend the Term of the Lease with respect to the Expansion Space, after a two-month Base Rent abatement period, we will be obligated to make monthly Base Rent payments in an amount beginning at $18,392 per month and increasing by approximately 2% annually for the remaining Term of the Lease. In addition, we are responsible under the Lease for specified costs and charges pertaining to the Expansion Space, including certain construction management fees and alteration costs, operating expenses, utilities, taxes and insurance.

Item 6. Exhibits

Exhibit No.	Description	Filed Herewith	Incorporated by Reference Herein from Form or Schedule	Filing Date	SEC File/ Req. Number
10.1*	Nonemployee Director Compensation Policy.	X			
10.2	Second amendment to Lease dated as of May 4, 2020, by and between NS Boston III PO Owner LLC and the Registrant.	X			
31.1	Certification of the Registrant's Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of the Registrant's Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets (unaudited) at March 31, 2020 and December 31, 2019, (ii) Condensed Consolidated Statements of Operations (unaudited) for the three months ended March 31, 2020 and 2019, (iii) Condensed Consolidated Statements of Comprehensive Income (Loss) (unaudited) for the three months ended March 31, 2020 and 2019, (iv) Condensed Consolidated Statement of Stockholders' Equity (unaudited) for the three months ended March 31, 2020 and 2019, (v) Condensed Consolidated Statements of Cash Flows (unaudited) for the three months ended March 31, 2020 and 2019, and (vi) Notes to Condensed Consolidated Financial Statements (unaudited).	X			

* Management contract or compensatory plan or arrangement

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 thereunto duly authorized.

ALBIREO PHARMA, INC.

Dated: May 7, 2020

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

ALBIREO PHARMA, INC.

NONEMPLOYEE DIRECTOR COMPENSATION POLICY

(Adopted January 23, 2017, Last modified March 6, 2020)

The Board of Directors of Albireo Pharma, Inc. (the "Company") has approved the following Nonemployee Director Compensation Policy (this "Policy") to provide an inducement to obtain and retain the services of qualified persons to serve as members of the Company's Board of Directors. The Policy establishes compensation to be paid to nonemployee directors of the Company.

Applicable Persons

This Policy shall apply to each director of the Company who is not an employee of, or compensated consultant to, the Company or any Affiliate (each, an "Outside Director"). "Affiliate" shall mean an entity which is a direct or indirect parent or subsidiary of the Company, as determined pursuant to Section 424 of the Internal Revenue Code of 1986, as amended.

Compensation

A. Equity Grants

1. Annual Stock Option Grants

Each Outside Director shall be granted, automatically and without any action on the part of the Board of Directors, under the Company's 2018 Equity Incentive Plan or a successor plan (the "Equity Plan"), a nonqualified stock option to purchase 8,000 shares of the Company's common stock, par value $0.01 per share ("Common Stock"), each year on the fifth (5^{th}) business day after the Company's annual meeting of stockholders (the "Annual Stock Options"); provided, however, that if there has been no annual meeting of stockholders held by the first business day of the third fiscal quarter, each Outside Director shall be granted, automatically and without any action on the part of the Board of Directors, such Annual Stock Option on the first business day of the third fiscal quarter of such year.

2. Initial Stock Option Grants for Newly Appointed or Elected Directors

Each new Outside Director shall be granted, automatically and without any action on the part of the Board of Directors, under the Equity Plan, a nonqualified stock option to purchase 16,000 shares of Common Stock on the date that the Outside Director is first appointed or elected to the Board of Directors (the "Initial Stock Options" and, together with the Annual Stock Options, the "Outside Director Stock Options").

3. Terms of Outside Director Stock Options

Unless otherwise specified by the Board of Directors or the Compensation Committee at the time of grant, each Outside Director Stock Option shall: (i) vest, in the case of (A) an Annual Stock Option, on the earlier of (a) one year from the date of the grant or (b) the day prior to the annual meeting for the next fiscal year that begins following the date of grant, subject to the Outside Director's continued service on the Board of Directors on the vesting date, and (B) an Initial Stock Option, in equal annual installments over three years from the date of grant; provided that each Initial Stock Option shall in any case be fully vested on the day prior to the annual meeting for the third fiscal year that begins following the date of grant, subject to the Outside Director's continued service on the Board of Directors on the applicable

vesting dates; (ii) terminate 10 years from the date of grant, (iii) become fully vested immediately prior to a Change of Control (as defined in the Equity Plan, as amended from time to time), and (iv) be granted under the Company's standard form of agreement unless on or prior to the date of grant the Board of Directors or the Compensation Committee shall determine that other terms or conditions shall be applicable.

B. Cash Fees

1. Annual Cash Fees

The following annual cash fees shall be paid to the Outside Directors serving on the Board of Directors and the Audit Committee, Compensation Committee and Nominating and Governance Committee, as applicable.

Board of Directors or Committee of Board of Directors	Annual Retainer Amount for Chair	Annual Retainer Amount for Other Members
Board of Directors	$ 65,000	$ 40,000
Audit Committee	$ 15,000	$ 7,500
Compensation Committee	$ 15,000	$ 7,500
Nominating and Governance Committee	$ 7,500	$ 3,750

2. Payment Terms for All Cash Fees

Cash fees payable to Outside Directors shall be paid quarterly in arrears as soon as practicable following the last business day of each fiscal quarter.

Following an Outside Director's first election or appointment to the Board of Directors, such Outside Director shall receive his or her cash compensation prorated during the first fiscal quarter in which he or she was initially appointed or elected for the number of days during which he or she provides service. If an Outside Director dies, resigns or is removed during any quarter, he or she shall be entitled to a cash payment on a prorated basis through his or her last day of service that shall be paid as soon as practicable following the last business day of the fiscal quarter.

Expenses

Upon presentation of documentation of such expenses reasonably satisfactory to the Company, each Outside Director shall be reimbursed for his or her reasonable out-of-pocket business expenses incurred in connection with attending meetings of the Board of Directors and Committees thereof or in connection with other business related to the Board of Directors. Each Outside Director shall abide by the Company's travel and other expense policies applicable to Company personnel.

Amendments

The Compensation Committee or the Board of Directors shall review this Policy from time to time to assess whether any amendments in the type and amount of compensation provided herein should be adjusted in order to fulfill the objectives of this Policy.

SECOND AMENDMENT TO LEASE

THIS SECOND AMENDMENT TO LEASE (this "Second Amendment"), dated as of May 4, 2020, is entered into by and between NS Boston III PO Owner LLC, a Delaware limited liability company ("Landlord") and Albireo Pharma, Inc., a Delaware corporation ("Tenant").

W I T N E S S E T H

WHEREAS, Landlord and Tenant are the current parties to that certain Office Lease Agreement dated as of February 7, 2017 by and between SHIGO 10 PO Owner LLC, a Delaware limited liability company, as landlord, and Tenant, as tenant (the "Original Lease"), as amended by that certain First Amendment to Lease dated as of March 28, 2019 by and between POSIG Investors, LLC, a Delaware limited liability company, as landlord, and Tenant, as tenant (the "First Amendment");

WHEREAS, the Original Lease, as amended by the First Amendment, shall be known as the "Lease";

WHEREAS, the Lease relates to the premises (hereafter, the "Existing Premises") measuring approximately 14,734 rentable square feet located on the tenth (10th) floor of the South Tower of the building known and numbered as 10 Post Office Square, Boston, Massachusetts (the "Building"); and

WHEREAS, Landlord and Tenant wish to modify and amend the Lease subject to the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the covenants herein reserved and contained, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree as follows:

1. Term. The term (the "Term") of the Lease is presently due to expire on October 31, 2026 (the "Expiration Date").

2. Addition of Expansion Premises. Effective as of July 1, 2020 (the "Expansion Premises Commencement Date"), the Lease shall be amended to provide that the premises demised to Tenant under the Lease shall include the premises measuring approximately 3,490 rentable square feet located on the tenth (10th) floor of the South Tower of the Building, as shown on Exhibit A attached hereto and made a part hereof (the "Expansion Premises"). Thereafter, all references to the "Premises" in the Lease shall be deemed to include both the Existing Premises and the Expansion Premises, and contain a total of 18,224 rentable square feet; provided, however, that unless Tenant exercises the Expansion Premises Extension Option (as hereinafter defined) in accordance with Section 11 below, the Term of the Lease with respect to the Expansion Premises only shall expire on June 30, 2021 (the "Expansion Premises Expiration Date").

3. Condition of Expansion Premises. Tenant shall accept the Expansion Premises in "AS IS, WHERE IS, WITH ALL FAULTS" condition, without any obligation on the part of Landlord to prepare the Expansion Premises for Tenant's occupancy thereof, and without any representations or warranties by Landlord as to the condition of the Expansion Premises or the suitability thereof for Tenant's use.

4. Alterations to Expansion Premises.

4.1 Tenant's Expansion Premises Alterations. Tenant acknowledges and agrees that any alterations, additions, improvements or other changes required to prepare the Expansion Premises for Tenant's occupancy thereof ("Tenant's Expansion Premises Alterations" or "Alterations") shall be controlled by Section 12 (Alterations, Additions and Improvements to the Premises) of the Original Lease and, subject to the provision of the Expansion Premises TI Allowance (as hereinafter defined), made at Tenant's sole cost and expense.

4.2 Amount of Expansion Premises TI Allowance. In the event Tenant exercises the Expansion Premises Extension Option in accordance with Section 11 below, Landlord shall provide tenant with a tenant improvement allowance of $52,350.00 (i.e., $15.00 per rentable square foot of the

Expansion Premises based on 3,490 rentable square feet) (the "Expansion Premises TI Allowance") to be used by Tenant toward the hard and soft costs of performing Tenant's Expansion Premises Alterations, subject to Section 4.5(1) below.

4.3 Requisitions. The Expansion Premises TI Allowance shall be (1) available to Tenant as of the date of the Extension Notice (as defined in Section 11.1 below) for Tenant's exercise of its Expansion Premises Extension Option and (2) payable by Landlord to Tenant in installments, as provided below, according to reasonable construction disbursement procedures and as Tenant's Expansion Premises Alterations progress. In any case, prior to payment of any such installment, Tenant shall deliver to Landlord a written requisition ("Requisition"), which Requisition shall be given no more frequently than once every thirty (30) days and which shall include, without limitation, (a) invoices from Tenant's contractors, approved by Tenant, and such other documentation as Landlord may reasonably request, showing in reasonable detail the cost of the items in question or improvements installed in the Expansion Premises for which reimbursement is requested, accompanied by certifications from Tenant's contractors that the amount of the Requisition in question is true and correct and does not exceed the cost of the items or improvements covered by such Requisition; (b) proof of payment by Tenant to Tenant's contractors (in the form of a cancelled check or other evidence reasonably satisfactory to Landlord) showing that the amount of the Requisition in question has been paid for in full; (c) copies of partial lien waivers or final lien waivers (in the case of a final installment), or such other form(s) as Landlord may reasonably require so that no mechanic's or materialman's liens shall attach to the Expansion Premises or the Building as a result of Tenant's Expansion Premises Alterations or, if attached, evidence reasonably satisfactory to Landlord that they have been satisfied of record or that they are being contested in good faith by Tenant with Tenant posting any bond or indemnity as required under applicable laws pending the resolution of such challenge; (d) certification from Tenant's architect that Tenant's Expansion Premises Alterations have been completed in accordance with Tenant's plans (if applicable and in the case of a final installment), (e) "as built" plans for Tenant's Expansion Premises Alterations (if applicable and in the case of a final installment), and (f) a "certificate of occupancy" and/or "occupancy permit" from the City of Boston (or the applicable governmental authority) for the Expansion Premises with Tenant's Expansion Premises Alterations completed (if applicable and in the case of a final installment).

4.4 Payments. Provided that Tenant shall not be in an Event of Default at the time of any Requisition, Landlord shall pay each Requisition within thirty (30) days after receiving all the materials enumerated in Section 4.3 above. All Requisitions shall incorporate a retainage equal to the greater of (1) the retainage set forth in the construction contract or (2) five percent (5%) of the amount due under the construction contract. Any retainage amounts withheld from any Requisitions shall be paid by Landlord to Tenant at the same time Landlord disburses payment for the final Requisition.

4.5 Restrictions on Expansion Premises TI Allowance. Notwithstanding anything to the contrary contained herein:

(1) In no event shall Tenant be entitled to apply any amount of the Expansion Premises TI Allowance towards (a) Tenant's furniture, fixtures and equipment, or (b) Tenant's rental obligation hereunder.

(2) Landlord shall have no obligation to pay the Expansion Premises TI Allowance after March 31, 2022 (the "Expansion Premises Outside Requisition Date").

(3) Tenant acknowledges and agrees that, prior to payment of any Requisition hereunder, Landlord shall have the right to examine and inspect Tenant's Expansion Premises Alterations to confirm that the improvements reflected on the Requisition have been performed in accordance with the terms, covenants and conditions of this Second Amendment; provided, however, that no such examination or inspection shall constitute an approval or warranty or give rise to any liability of Landlord with respect thereto.

4.6 Construction Management Fee; Out-of-Pocket Expenses. In consideration of Landlord's costs associated with the general coordination and oversight of Tenant's Expansion Premises Alterations,

Tenant shall pay to Landlord a construction management fee equal to two and one-half percent (2.5%) of the total project cost of Tenant's Expansion Premises Alterations, which construction mmanagement fee shall be deducted from the Expansion Premises TI Allowance. In addition, Tenant agrees to reimburse Landlord for any third-party out-of-pocket expenses reasonably incurred by Landlord in connection with the review of the plans, drawings and specifications for Tenant's Expansion Premises Alterations within thirty (30) days after receipt of Landlord's invoice therefor.

4.7 Notices Relating to Tenant's Expansion Premises Alterations. Notwithstanding the notice provisions contained in the Lease, as amended hereby, Landlord and Tenant acknowledge and agree that any written notices relating to Tenant's Expansion Premises Alterations may be sent via email as follows:

If to Landlord, then to Landlord's construction representative: Kevin Kiley, kkiley@synergy-inv.com.

If to Tenant, then to Tenant's construction representative: Janice Conlon, janice.conlon@albireopharma.com.

4.8 Removal of Tenant's Expansion Premises Alterations. Landlord reserves the right to require that Tenant remove Tenant's Expansion Premises Alterations upon the expiration or earlier termination of the Lease; provided, however, that Landlord shall notify Tenant in writing at the same time Landlord consents to the plans, drawings and specifications for Tenant's Expansion Premises Alterations (assuming consent is provided) whether or not Tenant's Expansion Premises Alterations will be required to be removed by Tenant at the end of the Term. If Tenant fails to remove Tenant's Expansion Premises Alterations (if so required), such failure shall be an Event of Default hereunder, and Landlord shall have all rights and remedies available under the Lease, at law or in equity. Tenant acknowledges and agrees that Tenant's Expansion Premises Alterations shall be the property of Tenant during the Term. Any Tenant's Expansion Premises Alterations not removed by Tenant shall, at Landlord's option, become the property of Landlord (without payment by Landlord) at the expiration or earlier termination of the Lease.

5. Signage for Expansion Premises. On or before the Expansion Premises Commencement Date, Landlord shall (1) update the alphabetical directory board or other directory device located within the main lobby of the Building to reflect the addition of the Expansion Premises, and (2) provide and maintain, in the elevator lobby of the floor on which the Expansion Premises are located, an alphabetical directory board or other directory device listing all tenants on the floor, including a single directory listing for Tenant. In addition, Tenant shall have the option to install identification signage using Tenant's corporate name and/or logo at the entrance of the Expansion Premises, subject to Landlord's prior written consent, which shall not be unreasonably withheld, conditioned or delayed.

6. Base Rent for Expansion Premises. Effective as of the Expansion Premises Commencement Date, Tenant shall pay Base Rent for the Expansion Premises as set forth in the schedule below and otherwise in accordance with the terms of the Lease.

Period	Annual Base Rent (Based on 12 months)	Monthly Base Rent	Per RSF
July 1, 2020 – June 30, 2021	$ 216,380.00	$ 18,031.67	$ 62.00

7. Additional Rent for Expansion Premises – Tenant's Share of Tax Increases. Effective as of the Expansion Premises Commencement Date, Tenant's Share of Tax Increases with respect to the Expansion Premises only

shall be 1.34%, which is a fraction, the numerator of which shall mean the rentable square footage of the Expansion Premises, and the denominator of which shall mean the rentable square footage of the South Tower of the Building, which is agreed to be 260,546 rentable square feet. Effective as of the Expansion Premises Commencement Date, with respect to the Expansion Premises only, Tenant shall pay Tenant's Share of Tax Increases over a Base Tax Year of fiscal year 2021 (i.e., July 1, 2020 – June 30, 2021).

8. Additional Rent for Expansion Premises – Tenant's Share of Expense Increases. Effective as of the Expansion Premises Commencement Date, Tenant's Share of Expense Increases with respect to the Expansion Premises only shall be 1.34%, which is a fraction, the numerator of which shall mean the rentable square footage of the Expansion Premises, and the denominator of which shall mean the rentable square footage of the South Tower of the Building, which is agreed to be 260,546 rentable square feet. Effective as of the Expansion Premises Commencement Date, with respect to the Expansion Premises only, Tenant shall pay Tenant's Share of Expense Increases over a Base Expense Year of calendar year 2020 (i.e., January 1, 2020 – December 31, 2020).

9. Electricity for Expansion Premises. Landlord shall deliver the Expansion Premises with electricity separately metered. Effective as of the Expansion Premises Commencement Date, Tenant shall pay for all electricity used by Tenant in the Expansion Premises based on the utility provider's reading of one or more direct meters, and payable by Tenant to the utility provider upon demand. Tenant's use of electrical services shall not exceed in voltage, rated capacity, or overall load that which is standard for the Building.

10. Security Deposit. Landlord and Tenant acknowledge and agree that the terms and conditions relating to the Security Deposit required under the Lease are set forth in Section 26 of the Original Lease, as modified by Section 11 of the First Amendment. Landlord and Tenant further acknowledge and agree that if Tenant exercises its Expansion Premises Extension Option, then effective as of the date of the Extension Notice for such Expansion Premises Extension Option, Section 11.2 of the First Amendment shall be amended and restated in its entirety as follows:

> 11.2 Notwithstanding the foregoing, provided that (1) Tenant shall not be in an Event of Default beyond any applicable notice and cure period on any Reduction Date (as hereinafter defined), and (2) Tenant shall have a Tangible Net Worth (as hereinafter defined) on each Reduction Date at least equal to the Tangible Net Worth reflected on Tenant's Q42018 financial statements (as evidenced by Tenant's then current financial statements), then at the written request of Tenant, the Security Deposit shall be reduced to (a) $456,753.33 at the end of Month 40 of the Term (as extended by this First Amendment) (the "First Reduction Date"), (b) $380,627.66 at the end of Month 52 of the Term (the "Second Reduction Date"), and (c) $304,501.99 at the end of Month 64 of the Term (the "Third Reduction Date"), and Landlord shall return the applicable portion of the Security Deposit to Tenant within thirty (30) days after receipt of Tenant's written request therefor. As used herein, the First Reduction Date, Second Reduction Date, and Third Reduction Date shall each be known as a "Reduction Date." Tenant acknowledges and agrees that in the event (i) Tenant shall be in an Event of Default beyond any applicable notice and cure period on any Reduction Date, or (ii) Tenant shall not have a Tangible Net Worth on each Reduction Date at least equal to the Tangible Net Worth reflected on Tenant's Q42018 financial statements, the Security Deposit then in effect shall remain in place (without reduction) for the balance of the Term of the Lease. As used herein, "Tangible Net Worth" shall mean total assets minus intangible assets (including goodwill, patents, trademarks and copyrights) and total liabilities, all as calculated in accordance with generally accepted accounting principles consistently applied.

11. Extension Option – Expansion Premises.

> 11.1 Expansion Premises Extension Option. Provided that (1) Tenant shall not be in an Event of Default either at the time of the Expansion Premises Extension Notice (as hereinafter defined) or at the

commencement of the Expansion Premises Extension Term (as hereinafter defined), and (2) Tenant has not assigned the Lease or sublet the Expansion Premises (or any portion thereof) except with respect to a Permitted Transfer in accordance with Section 18.7 of the Original Lease, Tenant shall have one (1) option (the "Expansion Premises Extension Option") to extend the Term of the Lease with respect to the Expansion Premises for the period commencing on July 1, 2021 and ending on October 31, 2026 (the "Expansion Premises Extension Term"), so that the Term for the entire Premises shall expire on the Expiration Date. Tenant must exercise the Expansion Premises Extension Option by providing written notice of election to Landlord (the "Extension Notice") no later than December 31, 2020. In the event Tenant properly exercises the Expansion Premises Extension Option as described herein, (a) the Base Rent with respect to the Expansion Premises for the Expansion Premises Extension Term shall be as set forth in the table below, (b) Tenant's Share of Tax Increases with respect to the Expansion Premises for the Expansion Premises Extension Term shall be as set forth in Section 7 above, (c) Tenant's Share of Expense Increases with respect to the Expansion Premises for the Expansion Premises Extension Term shall be as set forth in Section 8 above, and (d) the Expansion Premises Extension Term shall be effective without the requirement of any further act, lease or amendment by either party. All other terms of the Lease shall apply during the Expansion Premises Extension Term.

Period	Annual Base Rent (Based on 12 months)	Monthly Base Rent
July 1, 2021 – August 31, 2021	$ 0.00	$ 0.00
September 1, 2021 – June 30, 2022	$ 220,707.60	$ 18,392.30
July 1, 2022 – June 30, 2023	$ 225,121.75	$ 18,760.15
July 1, 2023 – June 30, 2024	$ 229,624.19	$ 19,135.35
July 1, 2024 – June 30, 2025	$ 234,216.67	$ 19,518.06
July 1, 2025 – June 30, 2026	$ 238,901.00	$ 19,908.42
July 1, 2026 – October 31, 2026	$ 243,679.02	$ 20,306.59

If Tenant shall fail to send the Expansion Premises Extension Notice within the time period herein provided, the Expansion Premises Extension Option shall cease to exist and terminate, and Tenant shall have no further opportunity to exercise the Expansion Premises Extension Option.

11.2 No Transfer. Except with respect to a Permitted Transfer in accordance with Section 18.7 of the Original Lease, Tenant may not assign or otherwise transfer its interest or rights under Section 11, and any such purported transfer or attempted transfer shall be null and void, without effect, and shall terminate Tenant's rights under Section 11.

12. Extension Option – Entire Premises. Landlord and Tenant acknowledge and agree that the Extension Option set forth in Section 52 (Extension Option) of the Original Lease shall remain in full force and effect; provided,

however, that Tenant shall be required to give Landlord a minimum of twelve (12) months prior written notice in order to exercise such Extension Option.

13. No Other Options. Tenant acknowledges and agrees that (1) except with respect to (a) the Expansion Premises Extension Option set forth in Section 11 of this Second Amendment and (b) the Extension Option set forth in Section 52 (Extension Option) of the Original Lease, as amended by Section 12 of this Second Amendment, Tenant has no options or rights to extend the Term of the Lease, (2) Tenant has no options, rights of first offer, rights of first refusal, or other rights to expand the rentable square feet comprising the Premises or lease any other space in the Building, and (3) Tenant has no options to terminate the Lease or contract the rentable square feet comprising the Premises.

14. Brokers. Except for Jones Lang LaSalle (representing Landlord) and CBRE/New England (representing Tenant), each party represents and warrants to the other that they have not made any agreement or taken any action which may cause anyone to become entitled to a commission as a result of the transactions contemplated by this Second Amendment, and each will indemnify and defend the other from any and all claims, actual or threatened, for compensation by any such third person by reason of such party's breach of their representation or warranty contained in this Second Amendment. Landlord will pay any commission due to the Broker(s) hereunder pursuant to its separate agreement with the Broker(s) hereunder subject to execution and delivery of this Second Amendment by Landlord and Tenant. The provisions of this Section 14 shall survive the expiration or earlier termination of the Lease.

15. Landlord's Notice Address. Effective as of the date of this Second Amendment, the Lease is hereby amended to provide that any notices to Landlord under the Lease shall be submitted to Landlord at the below address (or at such other address as Landlord may hereafter designate by notice to Tenant as required hereby).

NS Boston III PO Owner LLC
c/o Synergy Investments
10 Post Office Square, 14th Floor
Boston, MA 02109
Attention: VP, Leasing

with a copy to:

Rubin and Rudman LLP
53 State Street
Boston, MA 02109
Attention: Paul L. Baccari, Esq.

and a copy to:

legalnotices@synergy-inv.com

16. Landlord's Rent Payment Address. Effective as of the date of this Second Amendment, the Lease is hereby amended to provide that any Rent payments under the Lease shall be made payable to "NS Boston III PO Owner LLC" and submitted to Landlord at the below address (or at such other address as Landlord may hereafter designate by notice to Tenant as required hereby).

NS Boston III PO Owner LLC
c/o Synergy Investments
10 Post Office Square, 14th Floor
Boston, MA 02109
Attention: Accounting Department

17. Representations and Warranties. Tenant represents, warrants and covenants to Landlord that (1) the Lease is in full force and effect, and (2) to the best of Tenant's knowledge, Landlord is not in default under the Lease,

and no facts or circumstances exist which, with the passage of time or the giving of notice or both, would constitute a Landlord default under the Lease.

18. Authority. Tenant represents, warrants and covenants to Landlord that (1) Tenant is duly formed, has legal existence, is in good standing, and is qualified to do business in the state in which the Building is located, (2) Tenant has full right, power and authority to enter into this Second Amendment and has taken all corporate or partnership action, as the case may be, necessary to carry out the transaction contemplated herein, so that when executed, this Second Amendment constitutes a valid and binding obligation enforceable in accordance with its terms, and (3) the person or persons executing this Second Amendment on behalf of Tenant are duly authorized to do so.

19. References; Ratification. The Lease shall be modified such that each reference to the Lease contained therein shall be deemed to refer to the Lease as amended by this Second Amendment. Except as specifically modified or amended herein, the Lease remains unchanged and in full force and effect and is hereby ratified and confirmed in every respect.

20. Conflicts. In the event of a conflict between this Second Amendment and the Lease, this Second Amendment shall control.

21. Capitalized Terms. Capitalized terms used in this Second Amendment but not defined in this Second Amendment have the meanings ascribed to them in the Lease.

22. When Binding; Counterparts. This Second Amendment shall be binding upon the parties hereto only upon valid execution and delivery hereof by both Landlord and Tenant. Upon execution and delivery hereof by Landlord and Tenant, the agreements of the parties hereto shall be binding upon and inure to the benefit of their respective successors and assigns. This Second Amendment may be signed in counterpart originals, which taken together shall constitute one and the same instrument. Delivery of a copy of a signed counterpart original transmitted by facsimile or as a PDF or similar attachment to an email shall constitute a good and valid execution and delivery of this Second Amendment.

23. Exhibits. Additional terms to this Second Amendment, if any, are set forth in the attached Exhibits, which are incorporated herein by reference as follows:

Exhibit A – Plan of Expansion Premises

[SIGNATURES FOLLOW ON NEXT PAGE]

IN WITNESS WHEREOF, Landlord and Tenant have caused this Second Amendment to be executed as of the date set forth above.

LANDLORD:

NS BOSTON III PO OWNER LLC,
a Delaware limited liability company

By: Synergy Financial LLC,
a Massachusetts limited liability company,
Property Manager and Authorized Agent

By: /s/ David Greaney
David Greaney, Manager
Hereunto duly authorized

TENANT:

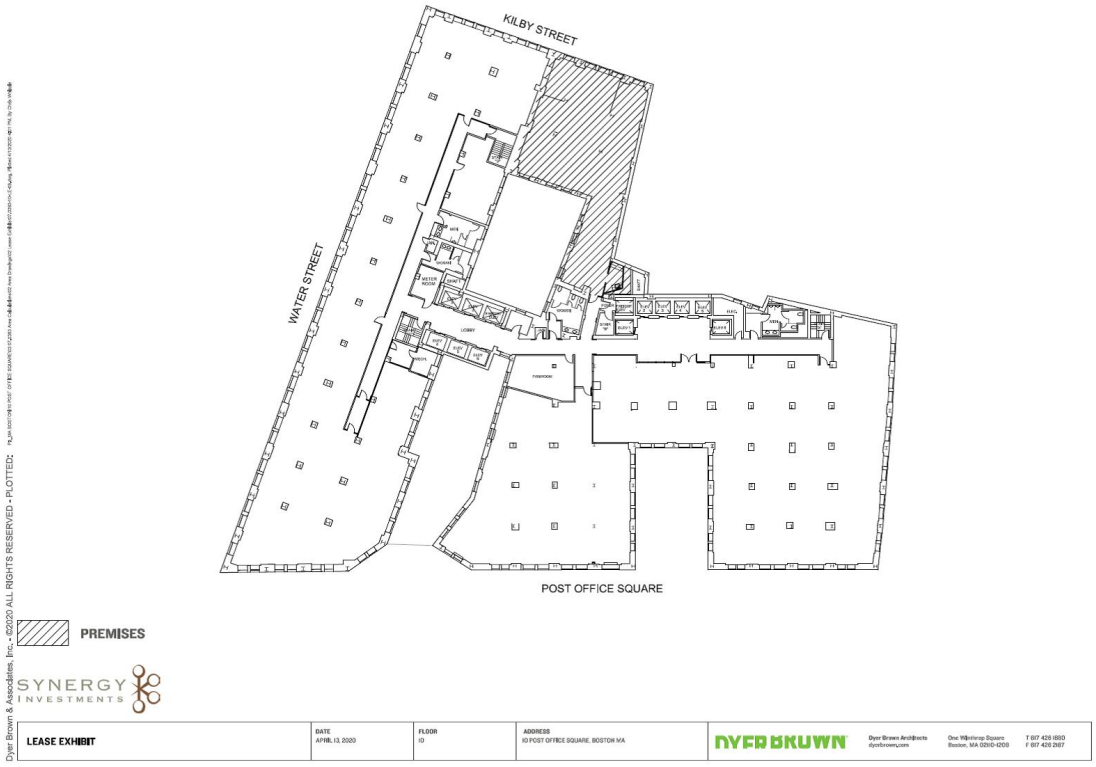
ALBIREO PHARMA, INC.,
a Delaware corporation

By: /s/ Simon Harford
Name: Simon Harford
Title: Chief Financial Officer
Hereunto duly authorized

[COUNTERPART SIGNATURE PAGE TO SECOND AMENDMENT]

EXHIBIT A

PLAN OF EXPANSION PREMISES



2386126_2

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

I, Ronald H.W. Cooper, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Albireo Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2020

/s/ Ronald H.W. Cooper
Ronald H.W. Cooper
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Simon N.R. Harford, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Albireo Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2020

/s/ Simon Harford
Simon N.R. Harford
Chief Financial Officer and Treasurer (principal financial officer and principal accounting officer)

Exhibit 32.1

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Albireo Pharma, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Quarterly Report for the quarter ended March 31, 2020 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 7, 2020

/s/ Ronald H.W. Cooper
Ronald H.W. Cooper
President and Chief Executive Officer
(principal executive officer)

Dated: May 7, 2020

/s/ Simon Harford
Simon N.R. Harford
Chief Financial Officer and Treasurer
(principal financial officer and principal accounting officer)