
**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, 2018

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

(State or other jurisdiction of incorporation or organization)

10 Post Office Square, Suite 502 South, Boston, MA
(Address of principal executive offices)

90-0136863

(IRS Employer Identification No.)

02109
(Zip code)

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

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 May 1, 2018, the registrant had 11,941,939 shares of common stock, \$0.01 par value per share, outstanding.

	Page
<u>PART I — FINANCIAL INFORMATION</u>	
<u>Cautionary Note Regarding Forward-Looking Statements</u>	3
<u>Item 1. Financial Statements</u>	5
<u>Condensed Consolidated Balance Sheets (unaudited) at March 31, 2018 and December 31, 2017</u>	5
<u>Condensed Consolidated Statements of Operations (unaudited) for the Three Months Ended March 31, 2018 and 2017</u>	6
<u>Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the Three Months Ended March 31, 2018 and 2017</u>	7
<u>Condensed Consolidated Statements of Cash Flows (unaudited) for the Three Months Ended March 31, 2018 and 2017</u>	8
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	9
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	18
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	24
<u>Item 4. Controls and Procedures</u>	24
<u>PART II — OTHER INFORMATION</u>	
<u>Item 6. Exhibits</u>	26
<u>Signatures</u>	27

All brand names, trademarks or service marks appearing in this quarterly report are the property of their respective owners. The Registrant’s use or display of another party’s trademark, service mark, trade dress or product in this quarterly report is not intended to, and does not, imply a relationship with, or endorsement or sponsorship of, the Registrant by such other party.

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 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 planned Phase 3 clinical trial of A4250 in patients with progressive familial intrahepatic cholestasis, or PFIC), 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;
- 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, our planned Phase 3 clinical trial of A4250 in patients with PFIC or related extension study, or any other trials that will be required to obtain marketing approval for A4250 to treat patients with PFIC or any other pediatric cholestatic liver disease, for elobixibat to treat nonalcoholic steatohepatitis, or NASH, or for A3384 to treat bile acid malabsorption, or BAM;
- whether favorable findings from clinical trials of A4250 to date, including findings in indications other than PFIC, will be predictive of results from future clinical trials, including the trials comprising our planned Phase 3 PFIC program for A4250;
- 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 planned 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 A4250 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 planned Phase 3 PFIC program for A4250, and the outcomes of such trials;
- whether changes made in the process of finalizing the protocol for the planned double blind Phase 3 trial of A4250 in patients with PFIC result in a delay in its initiation;

- delays or other challenges in the recruitment of patients for the planned double blind Phase 3 trial of A4250;
- whether A4250 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 A4250, 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 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 A4250, 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 A4250, 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 performance of our third-party suppliers, manufacturers and contract research organizations and our ability to obtain alternative sources of raw materials; and
- our ability to attract and retain key personnel.

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, 2017, 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 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 and per share data)
(unaudited)

	<u>March 31, 2018</u>	<u>December 31, 2017</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 192,916	\$ 53,231
Prepaid expenses and other assets	661	1,054
Other receivables	1,438	726
Total current assets	<u>195,015</u>	<u>55,011</u>
Property and equipment, net	172	178
Goodwill	17,260	17,260
Other noncurrent assets	449	775
Total assets	<u>\$ 212,896</u>	<u>\$ 73,224</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Trade payables	\$ 2,248	\$ 1,350
Accrued expenses	4,497	6,105
Other liabilities	411	474
Total current liabilities	<u>7,156</u>	<u>7,929</u>
Liability related to sale of future royalties	45,533	—
Long-term liabilities	41	42
Total liabilities	<u>52,730</u>	<u>7,971</u>
Stockholders' Equity:		
Common stock, \$0.01 par value per share — 30,000,000 authorized at March 31, 2018 and December 31, 2017; 11,897,146 and 8,902,784 issued and outstanding at March 31, 2018 and December 31, 2017, respectively	119	89
Additional paid in capital	209,830	114,522
Accumulated other comprehensive income	2,195	1,001
Accumulated deficit	<u>(51,978)</u>	<u>(50,359)</u>
Total stockholders' equity	<u>160,166</u>	<u>65,253</u>
Total liabilities and stockholders' equity	<u>\$ 212,896</u>	<u>\$ 73,224</u>

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,	
	2018	2017
Revenue	\$ 11,202	\$ 1
Operating expenses:		
Research and development	6,151	2,812
General and administrative	4,128	3,212
Other expense, net	1,504	74
Total operating expenses	<u>11,783</u>	<u>6,098</u>
Operating loss	(581)	(6,097)
Interest income (expense), net	(1,016)	(249)
Non-operating income (expense), net	(22)	(325)
Net loss before income taxes	(1,619)	(6,671)
Income tax	—	—
Net loss	<u>\$ (1,619)</u>	<u>\$ (6,671)</u>
Net loss per share - basic and diluted	<u>\$ (0.15)</u>	<u>\$ (1.06)</u>
Weighted average shares outstanding - basic and diluted	<u>10,896,575</u>	<u>6,292,644</u>

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,	
	2018	2017
Net loss	\$ (1,619)	\$ (6,671)
Other comprehensive loss:		
Foreign currency translation adjustment	1,194	(479)
Total other comprehensive income (loss)	1,194	(479)
Total comprehensive loss	<u>\$ (425)</u>	<u>\$ (7,150)</u>

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,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$ (1,619)	\$ (6,671)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non cash interest expense on liability related to royalty monetization	1,007	—
Accretion of debt discount and amortization of issuance costs	—	171
Depreciation and amortization	53	5
Change in fair value of financial instruments	—	333
Stock-based compensation expense	1,188	1,405
Non cash loss on foreign currency remeasurement	1,200	—
Changes in operating assets and liabilities:		
Trade receivables	—	26
Prepaid expenses and other current assets	401	8
Other receivables	(738)	(300)
Other non current assets	332	(77)
Trade payables	924	334
Accrued expenses	(1,581)	(3,623)
Other liabilities and long-term liabilities	(69)	(140)
Net cash provided by (used in) operating activities	<u>1,098</u>	<u>(8,529)</u>
Cash flows from investing activities:		
Purchase of property, plant and equipment	(47)	(95)
Net cash used in investing activities	<u>(47)</u>	<u>(95)</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	94,150	—
Proceeds from royalty liability agreement	44,525	—
Payments of principal on borrowings	—	(789)
Net cash provided by (used in) financing activities	<u>138,675</u>	<u>(789)</u>
Effect of exchange rate changes on cash and cash equivalents	(41)	(375)
Net increase (decrease) in cash and cash equivalents	139,685	(9,788)
Cash and cash equivalents—beginning of period	53,231	29,931
Cash and cash equivalents—end of period	<u>\$ 192,916</u>	<u>\$ 20,143</u>
Supplemental disclosures of cash flow information:		
Cash paid for interest	\$ —	\$ 78

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. (Parent), together with its direct and indirect subsidiaries (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. A4250, the Company's Phase 3 lead product candidate, is in development initially for the treatment of patients with progressive familial intrahepatic cholestasis (PFIC), 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, 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 Parent's Annual Report on Form 10-K for the fiscal year ended December 31, 2017. In the opinion of management, all adjustments (including normal recurring accruals) 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, 2018 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.

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 Condensed Consolidated Financial Statements include the accounts of Parent and its direct or indirect wholly owned subsidiaries, Albireo Limited, Albireo AB, Elobix AB, Albireo, Inc., Albireo Security Corp. and Bidel UK Limited. All intercompany balances and transactions have been eliminated in consolidation.

Foreign currency translation

Functional and presentation 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). The functional currency for Parent, Albireo, Inc. and Albireo Security Corp. is the U.S. Dollar (USD), the functional currency for Albireo Limited, Elobix AB and Bidel UK Limited is the Euro, and the functional currency for Albireo AB is the Swedish Krona (SEK). The Company consolidates its financial statements in USD.

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 translation at period-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized within Other (income) expense, net in the Condensed Consolidated Statements of Operations as part of operating expenses.

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, 2018 and December 31, 2017;
- b. income and expenses for each statement of comprehensive income (loss) are translated at the average exchange rate for the applicable period;

- c. significant transactions use the closing exchange rate on the date of the transaction; and
- d. all resulting exchange differences arising from such translation 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, deferred tax assets and royalty monetization liability estimated at fair value. Actual results could materially differ from these estimates.

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.

Research and development expenses

Research and development costs are expensed as incurred and include primarily salaries, benefits and other staff-related costs; clinical trial and related clinical manufacturing costs; contract services and other outside costs.

The Company's nonclinical studies and clinical trials are performed by third-party contract research organizations (CROs). Some of these expenses are billed monthly for services performed, while others are billed based upon milestones achieved. For nonclinical studies, the significant factors used in estimating accruals include the percentage of work completed to date and contract milestones achieved. For clinical trial expenses, the significant factors used in estimating accruals include the number of patients enrolled and percentage of work completed to date or contract milestones achieved. The Company's estimates are highly dependent upon the timeliness and accuracy of the data provided by the respective CROs regarding the status of the contracted activity, with adjustments made when deemed necessary.

Revenue recognition

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 a non-exclusive license to its intellectual property, and is entitled to payments resulting from pharmaceutical ingredient or related procurement services. Revenue related to these payments is recorded on a net basis; in this instance, the Company acts as an agent, as it does not have discretion to change suppliers and does not perform any part of the services or manufacture of the subject pharmaceutical ingredients. The costs associated with these activities are netted against the related revenue in the condensed consolidated statements of operations.

As of March 31, 2018, the Company is eligible to receive additional regulatory-based milestone amounts of up to approximately €4.3 million (\$5.3 million based on the Euro to USD exchange rate as of March 31, 2018). The upfront cash payment and any payments for milestones and royalties are non-refundable, non-creditable and not subject to set-off. In December 2017, the Company executed a royalty interest acquisition agreement (RIAA) with HealthCare Royalty Partners III, L.P. (HCR) which is detailed below.

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 at will 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.

The Company assessed this arrangement in accordance with Accounting Standards Codification (ASC) Topic 606, *Revenue from Contracts with Customers* (ASC 606), and concluded that the contract counterparty, EA Pharma, is a customer. The Company identified the following material promises under the arrangement: (1) a sub-licensable and non-exclusive license to use the Company's intellectual property and collaboration compounds to conduct research activities and (2) the technology transfer of the Albireo intellectual property and compound. Participation on the joint development committee ("JDC") and joint commercialization committee ("JCC") was determined to be quantitatively and qualitatively immaterial and therefore is excluded from performance obligations. The license was determined to not be distinct from the technology transfer; as such, the Company determined that these promises should be combined into a single performance obligation.

Under the Agreement, in order to evaluate the appropriate transaction price, the Company determined that the upfront amount constituted the entirety of the consideration to be included in the transaction price as of the outset of the arrangement, which was allocated to the single performance obligation. At the outset of the arrangement, the transaction price included only the €10.0 million upfront consideration received, and was increased to include the \$8.0 million received in conjunction with the 2015 amendment. The potential milestone payments were excluded from the transaction price, as all milestone amounts were fully constrained. In April 2013, December 2015, and October 2016, the Company achieved various development milestone events, and recognized revenue related to these events; because the Company previously satisfied its performance obligation to deliver the license, the Company recorded these milestone payments as received. The Company will reevaluate the transaction price at the end of each reporting period and as other uncertain events are resolved or other changes in circumstances occur, and, if necessary, adjust its estimate of the transaction price.

In January 2018, the Japanese Ministry of Health Labour and Welfare (MHLW) approved a new drug application filed by EA Pharma for elobixibat for the treatment of chronic constipation, for which the Company received a milestone payment of \$11.2 million. Based on the regulatory approval, the Company determined that the milestone was no longer at risk of significant reversal. As such, because the single performance obligation had previously been satisfied, the Company recognized this amount in full in Q1 2018.

Revenue associated with the performance obligation was recognized as the performance obligation was satisfied, which occurred upon the transfer of the license and technology transfer in 2012. \$11.2 million was recognized as revenue in Q1 2018, and there was no deferred revenue or contract asset as of March 31, 2018.

Monetization of Future Royalties

In December 2017, the Company executed the RIAA with HCR pursuant to which it sold to HCR the right to receive all royalties and sales milestones 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 and sales milestones for elobixibat from EA Pharma under the Agreement. If EA Pharma does not successfully commercialize elobixibat in Japan, the Company may not receive any future payments under its RIAA or the Agreement. The Company is obligated to make royalty interest payments to HCR under the RIAA only to the extent it receives future 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) in the balance sheet at March 31, 2018. 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 during the period from the inception of the royalty transaction in December 2017 to March 31, 2018:

	<u>March 31, 2018</u>
	<u>(in thousands)</u>
Liability related to sale of future royalties—beginning balance	\$ —
Proceeds from sale of future royalties, net	44,525
Non cash interest expense on liability related to royalty monetization	1,007
Liability related to sale of future royalties—ending balance	<u>\$ 45,532</u>

As royalties are remitted to HCR, the balance of the royalty obligation will be effectively repaid over the life of the agreement. In order to determine the amortization 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 capped amount. 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. Since inception, the Company's estimate of its total interest expense resulted in a quarterly effective interest rate of approximately 3.95%. 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, biosimilar competition, 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, reduced non-cash royalty revenues and reduced non-cash interest expense over the life of the royalty obligation.

Loss contingencies

Loss contingencies are recorded as liabilities when it is probable that a liability has occurred and the amount of loss is reasonably estimable. Disclosure is required when there is a reasonable possibility that an ultimate loss will be material. Contingent liabilities are often resolved over long periods of time. Estimating probable losses requires analysis that often depends on judgments about potential actions by third parties, such as regulators.

Recently adopted accounting pronouncements

Effective January 1, 2018, the Company adopted ASC Topic 606, *Revenue from Contracts with Customers*, using the modified retrospective transition method. Under this method, results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with ASC 605. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five step analysis (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step analysis to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company enters into licensing agreements which are within the scope of ASC 606, under which it may exclusively license rights to research, develop, manufacture and commercialize its product candidates to third parties. The terms of these arrangements may include payment to the Company of one or more of the following: non-refundable, upfront license fees; reimbursement of certain costs; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products.

In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under each of its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must use significant judgment to determine: (a) the number of performance obligations based on the determination under step (ii) above and (b) the transaction price under step (iii) above. The Company uses judgment to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price as described further below. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied.

Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

Exclusive Licenses

If the license to the Company's intellectual property is determined to be distinct from the other promises or performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. In assessing whether a promise or performance obligation is distinct from the other promises, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can benefit from a promise for its intended purpose without the receipt of the remaining promise, whether the value of the promise is dependent on the unsatisfied promise, whether there are other vendors that could provide the remaining promise, and whether it is separately identifiable from the remaining promise. For licenses that are combined with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research and development and licensing agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

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). To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

Impact of Adoption

The most significant change relates to the Company's accounting for contingent milestone payments. Under ASC 605, the Company recognized revenue related to contingent milestone payments as the milestone was achieved, using the milestone method. Under ASC 606, the Company performs an assessment of the probability of milestone achievement at each reporting date, and determines whether the cumulative revenue related to the milestone is at risk of significant reversal.

As a result of adopting ASC 606 on January 1, 2018, the Company did not record any cumulative changes in the current period, as the performance obligation related to the Agreement with EA Pharma was fully satisfied in 2012. Additionally, there was no difference in the revenue recognized or costs recorded in the three months ended March 31, 2018 as what would have been recognized or recorded under ASC 605.

In September 2016, the FASB issued ASU 2016-15, "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments (a consensus of the Emerging Issues Task Force)," which changes how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The new standard is effective for fiscal years beginning after December 15, 2017 and for interim periods therein, with early adoption permitted. The Company has determined there is no impact of this standard as of the date of the adoption.

In May 2017, the FASB issued ASU 2017-09, “*Compensation – Stock Compensation (Topic 718), Scope of Modification Accounting*,” (ASC 718), which amends the scope of modification accounting for share-based payment arrangements and provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under ASC 718. The new standard is effective for fiscal years beginning after December 15, 2017 and for interim periods therein, with early adoption permitted. The Company has adopted this standard as of January 1, 2018 and determined there is minimal impact on the Company’s condensed consolidated financial statements.

Accounting pronouncements issued but not yet adopted

In February 2016, the FASB issued ASU 2016-02, “*Leases (Topic 842)*.” The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The Company is currently evaluating the impact this ASU will have on its consolidated financial statements and currently does not plan to early adopt this standard.

2. Commitments and contingencies

Operating lease commitments

Our Parent is a party to an Office Lease Agreement with SHIGO 10 PO Owner LLC for approximately 5,116 rentable square feet in the building located at 10 Post Office Square, Boston, Massachusetts, which serves as Parent’s executive offices. The initial term of the lease is 62 months beginning on March 1, 2017. Parent has the option to extend the lease one time for an additional 5-year period. Following an initial two-month rent abatement period, Parent is obligated to make monthly rent payments in an amount beginning at \$20,997 and escalating by approximately 2% annually for the term of the lease. In addition, Parent is responsible under the lease for specified costs and charges, including certain operating expenses, utilities, taxes and insurance.

Albireo AB is a party to a 36-month building lease for approximately 5,113 square feet of office space in Gothenburg, Sweden. The current quarterly payment under the lease is SEK 322,917 (\$38,795 based on the SEK to USD exchange rate as of March 31, 2018) and subject to change based on applicable taxes and otherwise to increase based on changes in the Swedish Consumer Price Index (CPI). The current term of the lease expires in November 2019, but renews automatically thereafter for consecutive three-year terms unless notice of nonrenewal is given by either party at least nine months prior to the end of the then-current term, subject to Albireo AB’s right to terminate the lease at any time upon six months’ notice.

As of March 31, 2018, future minimum commitments under facility operating leases were \$1,158,000.

Rent expense recognized under the Company’s operating leases was \$102,000 and \$92,000 for the three months ended March 31, 2018 and 2017, respectively.

Agreements with CROs

As of March 31, 2018, 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 \$18.8 million to CROs upon the completion of contracted work.

Other Commitments

In connection with the spin-off of Albireo Limited from AstraZeneca in 2008 and associated transfer agreements, the Company became party to an assignment agreement between AstraZeneca and a named inventor on a patent related to elobixibat. In connection with this agreement, upon the initial launch of a pharmaceutical product that constitutes an IBAT inhibitor in specified countries, the inventor is entitled to a one-time “launch fee” payment of SEK 4.0 million (\$481,000, based on the SEK to USD exchange rate as of March 31, 2018).

3. Net income (loss) per share

Basic net income (loss) per share, or Basic EPS, is calculated by dividing the net income (loss) by the weighted average number of shares of common stock outstanding. Diluted net income (loss) per share, or Diluted EPS, is calculated by dividing the net income (loss) by the weighted-average number of shares of common stock plus, in the case of dilutive net income per share, dilutive common stock equivalents 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,	
	2018	2017
Basic EPS:		
Numerator		
Net loss	\$ (1,619)	\$ (6,671)
Net loss	<u>\$ (1,619)</u>	<u>\$ (6,671)</u>
Denominator		
Weighted average number of shares	10,896,575	6,292,644
Number of shares used for basic EPS computation	<u>10,896,575</u>	<u>6,292,644</u>
Basic EPS	<u>\$ (0.15)</u>	<u>\$ (1.06)</u>
Diluted EPS:		
Numerator		
Net loss	\$ (1,619)	\$ (6,671)
Net loss	<u>\$ (1,619)</u>	<u>\$ (6,671)</u>
Denominator		
Weighted average number of shares	10,896,575	6,292,644
Number of shares used for diluted EPS computation	<u>10,896,575</u>	<u>6,292,644</u>
Diluted EPS	<u>\$ (0.15)</u>	<u>\$ (1.06)</u>

The following outstanding common stock equivalents were excluded from the computation of Diluted EPS for the three months ended March 31, 2018 and 2017 because including them would have been anti-dilutive:

	For the Three Months Ended March 31,	
	2018	2017
Warrants to purchase common stock	—	67,271
Options to purchase common stock	703,016	735,329

4. Income taxes

The Company did not record a tax provision or benefit for the three months ended March 31, 2018 or 2017. 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. The Company had approximately \$22.9 million in valuation allowances recorded against its deferred tax assets as of both March 31, 2018 and December 31, 2017.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 (SAB 118), which provides guidance on accounting for the tax effects of the Tax Cuts and Jobs Act (TCJA). SAB 118 provides a measurement period that should not extend beyond one year from the TCJA enactment date for companies to complete the accounting under ASC Topic 740, *Income Taxes*. Although no changes were made to provisional amounts during the three months ended March 31, 2018, the Company will continue to refine its estimates related to the new legislation as clarifying guidance and interpretations are issued and the Company's 2017 tax returns are completed.

5. Stock-based Compensation

The Company recognized stock-based compensation expense for employees of \$1.2 million and \$612,000 for the three months ended March 31, 2018 and 2017, respectively. The stock compensation amount for the three months ended March 31, 2017 does not include \$788,000 that was recorded in the three months ended June 30, 2017 attributable to a correction for fiscal year 2016 due to the use of an incorrect service period.

A summary of the outstanding stock options as of March 31, 2018 is as follows:

	Stock Options Outstanding			
	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding—December 31, 2017	1,035,361	\$ 17.78	8.71	\$ 11,896
Granted	80,000	\$ 32.57	—	\$ —
Expirations/forfeitures	(36,490)	\$ 45.77	—	\$ —
Exercises	—	\$ —	—	\$ —
Outstanding—March 31, 2018	<u>1,078,871</u>	\$ 17.58	8.15	\$ 17,354
Exercisable—March 31, 2018	<u>441,614</u>	\$ 14.14	7.07	\$ 9,560
Vested or expected to vest at—March 31, 2018	<u>1,059,449</u>	\$ 17.89	8.15	\$ 16,741

Aggregate intrinsic value represents the difference between the estimated fair value of the underlying common stock and the exercise price of outstanding, in-the-money options.

Options to purchase 19,422 shares of common stock are performance based and vest upon the date the Company files a drug approval application for its product candidate A4250 for any orphan indication, if such filing occurs prior to a specified date. This unvested performance-based option is excluded from the vested or expected to vest balance as of March 31, 2018.

As of March 31, 2018, the total unrecognized compensation expense related to unvested options was \$9.2 million, which the Company expects to recognize over a weighted average vesting period of 2.5 years.

In determining the estimated fair value of the stock-based awards, the Company uses the Black-Scholes option pricing model and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

The fair value of stock option awards granted during the three months ended March 31, 2018 was estimated with the following assumptions:

	Three Months Ended March 31, 2018
Price per share of common stock	\$32.57
Expected term (in years)	5.3-5.9
Risk-free interest rate	2.6
Expected volatility	85.2
Dividend rate	0%

6. Long-term debt

	March 31, 2017 (in thousands)
Long-term debt, including current portion:	
Loan Facility	\$ 2,488
Total debt	2,488
Less: current portion	(2,488)
Long-term debt	<u>\$ —</u>

Loan Facility

The Company (in particular, Albireo Limited) executed a loan agreement (Loan Facility) with Kreos Capital IV (UK) Limited (Kreos UK) in December 2014, at which time the Company borrowed €6.0 million (\$7.3 million). The Loan Facility had a term of 36 months with principal and interest payable monthly, with an annual interest rate of 11.5%. In addition, the Company was required to make an end-of-loan payment equal to 1.25% of the amounts lent by Kreos UK. The debt was paid in full during 2017.

7. Financings

At-the-Market Sales

In October 2017, the Company entered into an at-the-market offering program Sales Agreement with Cowen and Company, LLC (Cowen) relating to the sale of shares of the Company's common stock having an aggregate offering price of up to \$50.0 million from time to time through Cowen, acting as its agent. In February 2018, the Company sold an aggregate of 728,862 shares of common stock pursuant to the sales agreement and received proceeds, net of offering expenses, of approximately \$24.2 million.

January 2018 Underwritten Public Offering

On January 29, 2018, the Company completed an underwritten public offering of 2,265,500 shares of its common stock, at a price to public of \$33.00 per share. The Company received net proceeds from this offering of \$70.0 million, after deducting underwriting discounts, commission and offering expenses.

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, 2017, 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, 2017 or 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, 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 have completed a Phase 2 clinical trial of A4250 in children with chronic cholestasis and pruritus and we plan to initiate a Phase 3 clinical trial of A4250 in patients with PFIC in the spring of 2018. In addition to PFIC, we plan to consider conducting future clinical development of A4250 as a treatment for one or more other pediatric cholestatic liver diseases and disorders. Our most advanced product candidates in addition to A4250 include elobixibat, which is approved in Japan for the treatment of chronic constipation and which we are considering conducting a Phase 2 clinical trial of as a treatment for nonalcoholic steatohepatitis, or NASH, and A3384, which is a product candidate to treat bile acid malabsorption. We also have a preclinical program in NASH.

Since inception, we have incurred significant operating losses. As of March 31, 2018, we had an accumulated deficit of \$52.0 million. We expect to continue to incur significant expenses and increasing operating losses for at least the next few years 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, 2018, we had approximately \$192.9 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, milestone payments and payment for pharmaceutical ingredient or related procurement services that are made pursuant to license agreements or related supply agreements. 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, and payments for pharmaceutical ingredient or related procurement services. For these agreements, management applies judgment in the allocation of total agreement consideration to the performance obligations on a reliable basis that reasonably reflects the selling prices that might be expected to be achieved in stand-alone transactions. 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.

Our significant accounting policies are described in Note 1 to our audited consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and in Note 1 to our condensed consolidated financial statements included in this quarterly report. We believe that our accounting policies relating to revenue recognition and the adoption of ASC 606 (see Note 1 to our condensed consolidated financial statements included in this quarterly report), royalty monetization and related estimates (see Note 1 to our condensed consolidated financial statements included in this quarterly report), research and development expenses and stock-based compensation are the most critical to understanding and evaluating our reported financial results. We have identified these policies as critical because they are both important to the presentation of our financial condition and results of operations and require us to make judgments and estimates on matters that are inherently uncertain and may change in future periods. These policies are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Estimates” in our Annual Report on Form 10-K for the year ended December 31, 2017.

Results of Operations

Three Months Ended March 31, 2018 and March 31, 2017

Revenue

	<u>Three Months Ended March 31,</u>		<u>Change</u>
	<u>2018</u>	<u>2017</u>	<u>\$</u>
	<u>(in thousands)</u>		
Revenue	<u>\$ 11,202</u>	<u>\$ 1</u>	<u>\$ 11,201</u>

There was \$11.2 million in revenue for the three months ended March 31, 2018 compared with \$1,000 for the three months ended March 31, 2017, an increase of \$11.2 million. The higher revenue is due to a milestone payment received from EA Pharma due to the approval by the Japanese MHLW of the new drug application for elobixibat for the treatment of chronic constipation.

Research and development expenses

	<u>Three Months Ended March 31,</u>		<u>Change</u>
	<u>2018</u>	<u>2017</u>	<u>\$</u>
	(in thousands)		
Research and development expenses	<u>\$ 6,151</u>	<u>\$ 2,812</u>	<u>\$ 3,339</u>

Research and development expenses were \$6.2 million for the three months ended March 31, 2018 compared with \$2.8 million for the three months ended March 31, 2017, an increase of \$3.3 million. The higher research and development expenses for the 2018 period were principally due to an increase of \$1.8 million in costs associated with development of A4250, including costs incurred for manufacturing and clinical development activities in preparation for a planned Phase 3 clinical trial in patients with PFIC, an increase of \$1.0 million in personnel and related expenses as we continue to increase our headcount and an increase of \$315,000 in costs related to nonclinical development activities.

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, 2018 and 2017.

	<u>Three Months Ended March 31,</u>		<u>Change</u>
	<u>2018</u>	<u>2017</u>	<u>\$</u>
	(in thousands)		
Direct third-party project costs:			
A4250	\$ 3,390	\$ 1,598	\$ 1,792
Elobixibat	23	3	20
A3384	128	46	82
Preclinical	338	23	315
Total	<u>\$ 3,879</u>	<u>\$ 1,670</u>	<u>\$ 2,209</u>
Other project costs(1):			
Personnel costs	\$ 1,410	\$ 463	\$ 947
Other costs(2)	862	679	183
Total	<u>\$ 2,272</u>	<u>\$ 1,142</u>	<u>\$ 1,130</u>
Total research and development costs	<u>\$ 6,151</u>	<u>\$ 2,812</u>	<u>\$ 3,339</u>

(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

	<u>Three Months Ended March 31,</u>		<u>Change</u>
	<u>2018</u>	<u>2017</u>	<u>\$</u>
	(in thousands)		
General and administrative expenses	<u>\$ 4,128</u>	<u>\$ 3,212</u>	<u>\$ 916</u>

General and administrative expenses were \$4.1 million for the three months ended March 31, 2018 compared with \$3.2 million for the three months ended March 31, 2017, an increase of \$916,000. The higher general and administrative expenses for the 2018 period were principally due to increases of \$418,000 in salary and benefits, \$256,000 in stock-based compensation costs and \$236,000 in costs for accounting, legal and consulting services.

Other (income) expense, net

	<u>Three Months Ended March 31,</u>		<u>Change</u>
	<u>2018</u>	<u>2017</u>	<u>\$</u>
	(in thousands)		
Other (income) expense, net	\$ 1,504	\$ 74	\$ 1,430

Other (income) expense, net totaled \$1.5 million of expense for the three months ended March 31, 2018 compared with \$74,000 of expense for the three months ended March 31, 2017, a difference of \$1.4 million. The difference resulted from differences in currency exchange rates in the two periods.

Interest income (expense), net

	<u>Three Months Ended March 31,</u>		<u>Change</u>
	<u>2018</u>	<u>2017</u>	<u>\$</u>
	(in thousands)		
Interest income (expense), net	\$ (1,016)	\$ (249)	\$ (767)

Interest income (expense), net totaled \$1.0 million of expense for the three months ended March 31, 2018 compared with \$249,000 of expense for the three months ended March 31, 2017, a difference of \$767,000. The difference was principally attributable to \$1.0 million in non-cash interest expense recorded in connection with the sale of future royalties, partially offset by interest income for the 2018 period, compared to interest expense related to our prior loan facility for the 2017 period.

Non-operating income (expense), net

	<u>Three Months Ended March 31,</u>		<u>Change</u>
	<u>2018</u>	<u>2017</u>	<u>\$</u>
	(in thousands)		
Non-operating income (expense), net	\$ (22)	\$ (325)	\$ 303

Net non-operating expense was \$22,000 for the three months ended March 31, 2018 compared with net non-operating expense of \$325,000 for the three months ended March 31, 2017, a difference of \$303,000. The difference of net non-operating expense for the 2018 period primarily reflects the exercise of warrants by our lender in May 2017.

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 continue to incur additional costs associated with operating as a public company and anticipate 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 shares of common stock, preference shares 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. 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, 2018, our cash and cash equivalents were approximately \$192.9 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 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 €9.0 million (\$11.2 million based on the Euro to U.S. Dollar, or USD, exchange rate at January 31, 2018).

In January 2018, we completed an underwritten public offering of 2,265,500 shares of our common stock for net proceeds of approximately \$70.0 million under a universal shelf registration statement on Form S-3 with the SEC, which was declared effective on December 5, 2017 and pursuant to which we registered for sale up to \$125 million of any combination of our common stock, preferred stock, debt securities, warrants, rights, purchase contracts and/or units from time to time and at prices and on terms that we may determine. 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 and Company LLC, or Cowen, in October 2017. Under the sales agreement, we may offer and sell, from time to time at our discretion, shares of our common stock through Cowen as our sales agent. 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 of 1933, as amended. We are not obligated to make any sales of common stock under the sales agreement. As of March 31, 2018, approximately \$25.2 million of securities remain available for issuance under the shelf registration statement, including up to \$25.0 million of our common stock available for issuance under the at-the-market offering program sales agreement.

In October 2017, we entered into an asset purchase agreement pursuant to which we sold legacy intellectual property of our predecessor, Biodel, for \$4.5 million.

In May 2017, we completed an underwritten public offering of 2,530,000 shares of our common stock at a price to the public of \$20.50 per share. Our net proceeds from the offering, after underwriting discounts, commissions and offering expenses, were \$48.5 million.

In April 2012, we (Albireo AB) entered into a license agreement with EA Pharma for the development and commercialization of elobixibat in specified countries in Asia. Albireo AB subsequently transferred the agreement to its wholly owned subsidiary, Elobix AB, and the agreement was amended in January 2015, April 2016 and December 2017. As of May 1, 2018, we have received approximately \$45.4 million in upfront and milestone payments from EA Pharma under this agreement. We are eligible to receive additional amounts of up to €4.3 million under the amended agreement (\$5.3 million based on the Euro to USD exchange rate as of March 31, 2018) 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 ¥3.5 billion if specified sales milestones are achieved for elobixibat.

Cash Flows

Three Months Ended March 31, 2018 and March 31, 2017

	Three Months Ended March 31,	
	2018	2017
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ 1,098	(8,529)
Investing activities	(47)	(95)
Financing activities	138,675	(789)
Total	\$ 139,726	\$ (9,413)
Effect of exchange rate changes on cash and cash equivalents	(41)	(375)
Net increase in cash and cash equivalents	<u>139,685</u>	<u>(9,788)</u>

Operating activities

Net cash provided by operating activities for the three months ended March 31, 2018 was \$1.1 million compared to net cash used in operating activities of \$8.5 million for the corresponding 2017 period, a change of \$9.6 million. The change is due to the milestone payment from EA Pharma of \$11.2 million during the 2018 period.

Investing activities

Net cash used in investing activities was \$47,000 for the three months ended March 31, 2018 compared to \$95,000 for the corresponding 2017 period, a decrease of \$48,000. The decrease was due to greater property and equipment purchases in 2017 in connection with our move to our current offices in Boston.

Financing activities

Net cash provided by financing activities for the three months ended March 31, 2018 was \$138.7 million compared to net cash used in financing activities of \$789,000 for the corresponding 2017 period, a difference of \$139.5 million. The difference was principally due to our receipt of (i) \$94.2 million in aggregate net proceeds from our public offering in January 2018 and our sales through our at-the-market offering program sales agreement in February 2018 and (ii) \$44.5 million in net proceeds from HCR under our RIAA in February 2018.

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 at least into 2021. 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, timing of initiation, duration and any potential delays of, and the results of, our planned Phase 3 clinical trial of A4250;
- the scope, number, progress, duration, cost, results and timing of clinical trials and nonclinical studies of our current or potential 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 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 filed a universal shelf registration statement on Form S-3 with the SEC, which was declared effective on December 5, 2017 and pursuant to which we registered for sale up to \$125 million of any combination of our common stock, preferred stock, debt securities, warrants, rights, purchase contracts and/or units from time to time and at prices and on terms that we may determine. As of March 1, 2018, approximately \$25.2 million of securities remain available for issuance under this shelf registration statement, including up to \$25.0 million of our common stock available for issuance pursuant to the at-the-market offering program sales agreement that we entered into with Cowen in October 2017, as described above.

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

Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in foreign currency exchange rates and interest rates. We do not hold or issue financial instruments for trading purposes.

Foreign Currency Exchange Risk

The functional currency for Albireo Pharma, Inc., Albireo, Inc. and Albireo Security Corp. is the USD, the functional currency for Albireo Limited, Elobix AB and Bidel UK Limited is the Euro, and the functional currency for Albireo AB is the Swedish Krona, or SEK. The Company consolidates its financial statements in USD. Our transactions are denominated in USD, the Euro and SEK, and are exposed to the effects of these exchange rates. Our results of operations and cash flows are, therefore, subject to fluctuations due to changes in foreign currency exchange rates. Fluctuations in currency exchange rates could harm our business in the future. The effect of a 10% adverse change in exchange rates on foreign denominated cash, receivables and payables as of December 31, 2017 would not have been material.

To date, we have not entered into any material foreign currency hedging contracts although we may do so in the future.

Interest Rate Sensitivity

As of March 31, 2018, we had approximately \$192.9 million in cash and cash equivalents. Our surplus cash and cash equivalents are invested in interest-bearing accounts from time to time which earn interest based on the terms agreed for each account. We have not entered into investments for trading or speculative purposes. Due to the short-term nature of these investments, we believe that we do not have any material exposure to changes in the fair value of our investment portfolio as a result of changes in interest rates. Declines in interest rates, however, will reduce future investment income. If overall interest rates had decreased by 10% during the periods presented, our interest income would not have been materially affected.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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 and as a result of the material weaknesses discussed below, our disclosure controls and

procedures were not 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.

Material Weaknesses and Remediation of Material Weaknesses

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. We have identified material weaknesses in our internal control over financial reporting, as described below. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

As previously disclosed, management has identified material weaknesses that are pervasive in our internal control processes and involve the control environment, risk assessment, control activity and monitoring components of the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013 framework). Specifically, the material weaknesses relate to: an insufficiently staffed finance organization with the requisite knowledge of U.S. GAAP and SEC reporting or skills in and ability to focus on internal control over financial reporting matters; not fully designing, implementing and monitoring policies or financial reporting controls that identify and sufficiently mitigate risks of material misstatement to the financial statements; and insufficient design, implementation and monitoring of general information technology controls to support the effective operation of financial controls.

We became a public company via a share exchange transaction completed in November 2016. Prior to that, our parent company was a private entity domiciled in the United Kingdom. We have historically not had the people, processes and systems in place in order to have operating controls over our financial statement close process appropriate for a public company.

Management is committed to the planning and implementation of remediation efforts to address the material weaknesses, and significant progress has been made to date. These remediation efforts, summarized below, which have been implemented or are in process of implementation, are intended to both address the identified material weaknesses and to enhance our overall financial control environment. In particular, we:

- hired a full-time chief financial officer in July 2016;
- hired a controller in March 2017;
- hired an accounting manager in March 2017;
- hired a staff accountant in Sweden in September 2017;
- are in the process of implementing a new accounting information system for fiscal year 2018;
- are redesigning our accounting processes with the implementation of the new system;
- are developing and are in the process of implementing formal policies and documentation procedures related to financial reporting; and
- engaged additional external resources to support and supplement our existing internal resources.

When fully implemented and operational, we believe the measures described above will remediate the material weaknesses we have identified and strengthen our internal control over financial reporting. We expect that the material weaknesses will be remediated prior to the filing of our Annual Report on Form 10-K for the year ending December 31, 2018. The material weaknesses will not be considered remediated until the remediated controls operate for a sufficient period of time and management has concluded, through testing, that the controls are operating effectively. We are committed to continuing to improve our internal control processes and will continue to diligently and vigorously review our financial reporting controls and procedures. As we continue to evaluate and work to improve our internal control over financial reporting, our management may determine to take additional measures.

Changes in Internal Control over Financial Reporting

Other than as described above, there were no changes in our internal control over financial reporting identified in connection with the evaluation of such internal control that occurred during the three months ended March 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 6. Exhibits

<u>Exhibit No.</u>	<u>Description</u>	<u>Filed Herewith</u>	<u>Incorporated by Reference Herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File/ Req. Number</u>
31.1	<u>Certification of the Registrant’s Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>	X			
31.2	<u>Certification of the Registrant’s Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>	X			
32.1	<u>Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>	X			
101	The following materials from the Registrant’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets (unaudited) at March 31, 2018 and December 31, 2017, (ii) Condensed Consolidated Statements of Operations (unaudited) for the three months ended March 31, 2018 and 2017, (iii) Condensed Consolidated Statements of Comprehensive Income (Loss) (unaudited) for the three months ended March 31, 2018 and 2017, (iv) Condensed Consolidated Statements of Cash Flows (unaudited) for the three months ended March 31, 2018 and 2017, and (v) Notes to Condensed Consolidated Financial Statements (unaudited).	X			

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 10, 2018

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

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 10, 2018

/s/ Ronald H.W. Cooper

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

CERTIFICATIONS UNDER SECTION 302

I, Thomas A. Shea, 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 10, 2018

/s/ Thomas A. Shea

Thomas A. Shea

Chief Financial Officer, Treasurer and Secretary (principal financial officer and principal accounting officer)

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, 2018 (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 10, 2018

/s/ Ronald H.W. Cooper

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

Dated: May 10, 2018

/s/ Thomas A. Shea

Thomas A. Shea
Chief Financial Officer, Treasurer and Secretary
(principal financial officer and principal accounting officer)

