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 June 30, 2017

OR

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

For the transition period from _____ to _____.

Commission File Number 001-33451

Albireo Pharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**90-0136863**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**
10 Post Office Square, Suite 502 South, Boston, MA	**02109**
(Address of principal executive offices)	**(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	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☒
		Emerging growth company	☐

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

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

As of August 1, 2017, the registrant had 8,882,452 shares of common stock, $0.01 par value per share, outstanding.

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, 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 (including a new drug application in Japan for elobixibat), 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 EA Pharma Co., Ltd. (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 or our need for additional financing; and
- our strategies, prospects, plans, expectations 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 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 or achievements expressed or implied by any forward-looking statement to differ. These risks, uncertainties and other factors include, among other things, our critical accounting policies and:

- the clinical trial design, size, duration and endpoints for our planned Phase 3 clinical trial of A4250 in patients with PFIC, or that will be required to obtain marketing approval for A4250 to treat patients with PFIC or any other pediatric cholestatic liver disease 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 duration of the planned double blind Phase 3 trial in patients with PFIC is sufficient, even if such primary endpoint is met with statistical significance, to support approval of A4250 in the United States or the European Union, to treat PFIC, a symptom of PFIC or otherwise;
- the outcome and interpretation by regulatory authorities of the ongoing third-party study pooling and analyzing long-term PFIC patient data;
- 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 we receive additional feedback from regulatory authorities on our planned Phase 3 PFIC program for A4250 prior to initiation;
- delays or other challenges in the initiation of, or recruitment of patients for, the planned double blind Phase 3 trial of A4250;

- whether our current cash resources will be sufficient to fund our planned Phase 3 clinical program for A4250 in patients with PFIC to completion;
- whether A4250 will meet the criteria to receive a pediatric priority review voucher from the FDA when applicable, and, if necessary, whether the pediatric 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 agreement with EA Pharma for elobixibat generates nondilutive income for us;
- the timing and success of submission, acceptance and approval of regulatory filings, including in particular the new drug application submitted by EA Pharma in Japan for elobixibat for the treatment of chronic constipation, 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 development and commercialization of elobixibat in Japan and 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 future product candidate of ours in the treatment of nonalcoholic steatohepatitis, or NASH;
- the accuracy of our estimates regarding expenses, 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, 2016, in Exhibit 99.3 to our Current Report on Form 8-K filed May 23, 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)

	June 30, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 62,598	$ 29,931
Trade receivables	—	26
Prepaid expenses and other assets	471	560
Other receivables	663	344
Total current assets	63,732	30,861
Property and equipment, net	155	21
Intangible assets	150	150
Goodwill	18,110	18,110
Other noncurrent assets	529	518
Total assets	$ 82,676	$ 49,660
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Trade payables	$ 1,329	$ 972
Accrued expenses	3,825	7,548
Long-term debt, current portion	1,928	3,075
Warrant liability	—	844
Other liabilities	298	269
Total current liabilities	7,380	12,708
Long-term liabilities	43	—
Total liabilities	7,423	12,708
Stockholders' Equity:		
Common stock, $0.01 par value per share — 30,000,000 authorized at June 30, 2017 and 200,000,000 authorized at December 31, 2016; 8,859,141 and 6,292,644 issued and outstanding at June 30, 2017 and December 31, 2016, respectively	90	63
Additional paid in capital	112,549	61,338
Accumulated other comprehensive income	1,406	1,496
Accumulated deficit	(38,792)	(25,945)
Total stockholders' equity	75,253	36,952
Total liabilities and stockholders' equity	$ 82,676	$ 49,660

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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenue	$ 1	$ 7,973	$ 2	$ 8,097
Operating expenses:				
Research and development	2,962	2,713	5,774	4,310
General and administrative	3,713	3,028	6,925	4,334
Other (income) expense, net	(65)	290	9	135
Total operating expenses	6,610	6,031	12,708	8,779
Operating income (loss)	(6,609)	1,942	(12,706)	(682)
Interest expense, net	(152)	(512)	(401)	(1,038)
Non-operating income, net	585	709	260	620
Net income (loss) before income taxes	(6,176)	2,139	(12,847)	(1,100)
Income tax	—	—	—	—
Net income (loss)	$ (6,176)	$ 2,139	$ (12,847)	$ (1,100)
Net income (loss) per share - basic	$ (0.86)	$ 7.42	$ (1.91)	$ (3.97)
Net income (loss) per share - diluted	$ (0.86)	$ 0.69	$ (1.91)	$ (3.97)
Weighted average shares outstanding - basic	7,171,610	288,427	6,734,555	277,120
Weighted average shares outstanding - diluted	7,171,610	3,101,115	6,734,555	277,120

See accompanying notes to Condensed Consolidated Financial Statements.

Albireo Pharma, Inc.

Condensed Consolidated Statements of Comprehensive Income (Loss)

(in thousands)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net income (loss)	$ (6,176)	$ 2,139	$ (12,847)	$ (1,100)
Other comprehensive income (loss):				
Foreign currency translation adjustment	389	380	(90)	41
Total other comprehensive income (loss)	389	380	(90)	41
Total comprehensive income (loss)	$ (5,787)	$ 2,519	$ (12,937)	$ (1,059)

See accompanying notes to Condensed Consolidated Financial Statements.

Albireo Pharma, Inc.

Condensed Consolidated Statements of Cash Flows

(in thousands)

(unaudited)

	Six Months Ended June 30,	
	2017	**2016**
Cash flows from operating activities:		
Net loss	$ (12,847)	$ (1,100)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accretion of debt discount and amortization of issuance costs	301	557
Depreciation and amortization	13	7
Change in fair value of financial instruments	(251)	(620)
Stock-based compensation expense	2,051	55
Changes in operating assets and liabilities:		
Trade receivables	27	1,248
Prepaid expenses and other current assets	94	298
Other receivables	(292)	(130)
Other noncurrent assets	(12)	—
Trade payables	280	(815)
Taxes payable	—	—
Accrued expenses	(3,864)	2,115
Other liabilities and long-term liabilities	29	(23)
Other noncurrent liabilities	43	
Net cash provided by (used in) operating activities	(14,428)	1,592
Cash flows from investing activities:		
Purchase of property, plant and equipment	(146)	(3)
Net cash used in investing activities	(146)	(3)
Cash flows from financing activities:		
Proceeds from issuance of Ordinary A shares	—	35
Proceeds from issuance of warrants, net of issuance costs	—	39
Proceeds from issuance of common stock, net of issuance costs	48,508	—
Exercise of stock options	62	
Payments of principal on borrowings	(1,648)	(709)
Net cash provided by (used in) financing activities	46,922	(635)
Effect of exchange rate changes on cash and cash equivalents	319	176
Net increase in cash and cash equivalents	32,667	1,130
Cash and cash equivalents—beginning of period	29,931	5,120
Cash and cash equivalents—end of period	$ 62,598	$ 6,250
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 136	$ 283
Shares issued upon cashless exercise of Kreos warrants	617	—

See accompanying notes to Condensed Consolidated Financial Statements.

1. Summary of significant accounting policies and basis of presentation

Organization and Share Exchange

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 one Phase 3 product candidate, one Phase 2 product candidate and a third product candidate for which an application for regulatory approval has been filed in Japan. A4250, the Company's 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.

Prior to November 3, 2016, Parent's name was Biodel Inc. (Biodel). On that date, Biodel effected a 1-for-30 reverse stock split of its common stock (Reverse Stock Split) and completed a share exchange transaction with Albireo Limited, a limited company domiciled in London, United Kingdom, in accordance with the terms of an Amended and Restated Share Exchange Agreement, dated as of July 13, 2016, by and among Biodel, Albireo Limited and the shareholders and noteholders of Albireo Limited (the Agreement). Pursuant to the Agreement, each holder of shares or notes convertible into shares of Albireo Limited received newly issued shares of Biodel common stock and Albireo Limited became a wholly owned subsidiary of Biodel (the Transaction). Following completion of the Transaction, the business of Albireo Limited became the business of Parent and Parent changed its name to Albireo Pharma, Inc.

For accounting purposes, the Transaction was treated as a "reverse acquisition" and Albireo Limited was considered the accounting acquirer. Accordingly, with respect to periods prior to completion of the Transaction, the accompanying Condensed Consolidated Financial Statements reflect the historical results of Albireo Limited and its direct and indirect subsidiaries and do not include the historical results of Biodel prior to completion of the Transaction. All share and per share information for periods prior to completion of the Transaction has been retroactively adjusted to reflect the exchange of shares in the Transaction based on an exchange ratio of 0.06999 and, where applicable, the Reverse Stock Split.

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, 2016. 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 and six months ended June 30, 2017 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). Any reference in these Condensed Consolidated Financial Statements to common stock or options or warrants to purchase shares of common stock of the Company means the common stock or options or warrants to purchase shares of common stock of Parent. Any reference in these Condensed Consolidated Financial Statements to common stock means, for periods prior to November 3, 2016, Ordinary shares of Albireo Limited.

The Company has reclassified certain amounts in the Condensed Consolidated Balance Sheet as of December 31, 2016 from Advances from licensees and from Warrant liability to Other liabilities to conform to the current year presentation.

Error corrections

In fiscal 2016, the Company under recognized stock-based compensation expense by $788,000. The understatement of stock-based compensation expense was attributable to the use of an incorrect service period, and related period of expense recognition, for certain stock option awards. This understatement was identified during the first quarter of 2017 and the Company attempted to correct the prior period error at that time. In seeking to correct the prior period understatement in the first quarter of 2017, the Company made clerical errors that resulted in the failure to recognize the additional $788,000 of stock-based compensation expense as intended, the

incorrect recognition of $788,000 of other comprehensive loss related to foreign currency translation adjustment, the understatement of cash used in operating activities by $788,000 and the incorrect reporting of the effect of foreign exchange changes on cash and cash equivalents as a decrease of $375,000 rather than as an increase of $413,000.

In the preparation of its unaudited interim financial statements for the second quarter of 2017, the Company detected the clerical errors made in the first quarter of 2017 and corrected the accounting. As a result, there is $788,000 of additional stock-based compensation expense included in general and administrative expenses for the three and six month periods ended June 30, 2017, as well as an additional $788,000 of other comprehensive income for the three months ended June 30, 2017. The Company determined that the errors and subsequent corrections recorded for the second quarter ended June 30, 2017 are not material to its financial statements for any prior period and does not expect the corrections to be material to its financial statements for the year ending December 31, 2017.

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 and, for periods following completion of the Transaction, Biodel 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 and Albireo, Inc. is the U.S. Dollar (USD), the functional currency for Albireo Limited, Elobix AB and Biodel 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.

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

a. assets and liabilities presented are translated at the closing exchange rate as of June 30, 2017 and December 31, 2016;

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 warrant liability estimated at fair value. Actual results could materially differ from these estimates.

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

Revenue is generated from the receipt of upfront or license fees, milestone payments and payments for pharmaceutical ingredient or related procurement services that are made pursuant to out-licensing or related supply agreements.

Where an out-licensing arrangement of the Company involves the provision of multiple elements that may contain different remuneration arrangements such as upfront payments, milestone payments or product sales, the arrangement is assessed to determine whether separate delivery of the individual elements of such arrangement comprises more than one unit of accounting. The delivered elements are separated if (a) they have value to the licensee on a stand-alone basis, (b) there is objective and reliable evidence of the fair value of the undelivered element(s) and (c) if the arrangement includes a general right of return relative to the delivered element(s), delivery or performance of the undelivered element(s) is considered probable and is substantially in the control of the Company. Allocation of revenue to the different elements that require separate accounting is based on the separate selling prices determined for each component, and total consideration is then allocated pro rata across the components of the arrangement. If separate selling prices are not available, the Company will use its best estimate of such selling prices, consistent with the overall pricing strategy and relevant market factors.

The Company has determined that each element of its out-licensing agreements is a separate and distinct unit of accounting, and, as such, the fair value of each element has been subscribed and recognized as follows:

- Nonrefundable upfront payments received from the Company's out-licensing agreements relating to technical expertise and intellectual property are recognized in income if all rights relating to the intellectual property and all obligations resulting from them have been relinquished under the contract terms and the Company has no continuing material obligation to perform under the agreement. However, if rights to the intellectual property continue to exist or obligations resulting from them have yet to be fulfilled, the payments received would be deferred until all rights and obligations have been fulfilled.
- Nonrefundable payments that are linked to the achievement of significant and substantive development or regulatory milestones in the research and development process are recognized as revenue upon the achievement of the specified milestone.
- Revenue and costs associated with procurement services associated with pharmaceutical ingredients are recognized net in revenue when title and risk of loss of the pharmaceutical ingredients have passed to the licensee as the Company is not the primary obligor, and revenue and costs associated with related procurement services are recognized net in revenue when the Company is contractually bound.

As of June 30, 2017, the Company had a license agreement with EA Pharma Co., Ltd. (EA Pharma, formerly Ajinomoto Pharmaceuticals Co., Ltd.), entered into in 2012, to develop a select product candidate (elobixibat) for registration and subsequent commercialization in select markets. The Company satisfied its material performance obligations under the agreement in 2012, upon the delivery of technical expertise and intellectual property rights to EA Pharma.

Payments resulting from pharmaceutical ingredient or related procurement services are recognized as revenue as the activities are performed and are presented on a net basis. Revenue is recorded on a net basis because 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.

For certain contingent payments under research and development arrangements, the Company recognizes revenue using the milestone method. Under the milestone method, a payment that is contingent upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is an event: (i) that can be achieved based in whole or in part on either the Company's performance or on the occurrence of a specific outcome resulting from the Company's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to the Company. The determination that a milestone is substantive requires estimation and judgment and is made at the inception of the arrangement. Milestones are considered substantive when the consideration earned from the achievement of the milestone is: (A) commensurate with either the Company's performance to achieve the milestone or the enhancement of value of the item delivered as a result of a specific outcome resulting from the Company's

performance to achieve the milestone, (B) related solely to past performance and (C) reasonable relative to all deliverables and payment terms in the arrangement. In making the determination as to whether a milestone is substantive or not, management of the Company considers all facts and circumstances relevant to the arrangement, including factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the milestone, the level of effort and investment required to achieve the milestone and whether any portion of the milestone consideration is related to future performance or deliverables. The Company has evaluated each milestone specified under its license agreement with EA Pharma and determined the milestone to be substantive.

Under the terms of the license agreement with EA Pharma, the Company was eligible as of June 30, 2017 to receive up to approximately (a) €13.3 million ($15.2 million based on the Euro to USD exchange rate as of June 30, 2017) if specified regulatory events are achieved for elobixibat in Japan and (b) ¥3.5 billion ($31.1 million based on the Japanese Yen to USD exchange rate as of June 30, 2017) if specified sales milestones are achieved for elobixibat in EA Pharma's licensed territory following regulatory approval in any country in EA Pharma's licensed territory. The likelihood that the Company will achieve any particular milestone event with respect to elobixibat in any particular period, or at all, is uncertain, and the Company may not earn any future milestone payment with respect to elobixibat in any particular period, or ever. In addition, the Company is eligible to receive stepped royalties beginning in the high single digits on any future elobixibat product sales. The Company will recognize royalty revenue in the period of sale of elobixibat, based on the underlying contract terms, provided that the reported sales are reliably measurable and the Company has no remaining performance obligations, assuming all other revenue recognition criteria are met.

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

In March 2016, the FASB issued ASU No. 2016-09, "*Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*," which changes the accounting for stock-based payment transactions, including income tax consequences, classification of awards as either equity or liabilities, and classification in the statement of cash flows. The new standard is effective for fiscal years beginning after December 15, 2016 and for interim periods therein. The Company adopted this standard on a prospective basis as of January 1, 2017, which had no impact on deferred tax balances, the consolidated statement of cash flows or otherwise on the Company's consolidated financial statements.

Accounting pronouncements issued but not yet adopted

In May 2014, the FASB issued ASU No. 2014-09, "*Revenue from Contracts with Customers: (Topic 606)*." This ASU affects any entity that either enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets unless those contracts are within the scope of other standards (e.g., insurance contracts or lease contracts). This ASU will supersede the revenue recognition requirements in ASC Topic 605, "*Revenue Recognition*," and most industry-specific guidance. In addition, the existing requirements for the recognition of a gain or loss on the transfer of nonfinancial assets that are not in a contract with a customer (e.g., assets within the scope of ASC Topic 360, "*Property, Plant, and Equipment*," and intangible assets within the scope of ASC Topic 350, "*Intangibles-Goodwill and Other*") are amended to be consistent with the guidance on recognition and measurement (including the constraint on revenue) in this ASU. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In July 2015, the FASB deferred the effective date of ASU 2014-09. This ASU will be effective for the Company on January 1, 2018 (for the Company's 2018 fiscal year). The Company plans to adopt this standard effective January 1, 2018 using the modified retrospective approach, whereby the cumulative effect of applying the standard would be recognized at the date of initial application within retained earnings. The Company currently has one contract that generates revenue and will be impacted by the adoption of the new guidance. The Company is currently evaluating the impact this ASU will have on its consolidated financial statements.

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.

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 is currently evaluating the impact this ASU will have on its consolidated financial statements.

2. Fair value of financial instruments

In measuring fair value, 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.

The following tables present the fair values for the Company's financial instruments as well as the input levels used to determine these fair values as of June 30, 2017 and December 31, 2016. The Company values its current assets, which include trade and other receivables, and liabilities, which include trade payables, at historical cost, which approximates fair value. The estimated fair value of the Loan Facility (see Note 7) was $1.9 million as of June 30, 2017. The Company used the income approach to value the Loan Facility.

		Total Carrying Value on the Condensed Consolidated Balance Sheet		Fair Value Measurements	
	Fair Value Level	June 30, 2017	December 31, 2016	June 30, 2017	December 31, 2016
			(in thousands)		
Financial Instruments Recorded at Fair Value on a Recurring Basis					
Current liabilities:					
Warrant liability	3	$ —	$ 844	$ —	$ 844

On December 17, 2014, the Company (in particular, Albireo Limited) executed a convertible loan instrument, which provided 1,251,000 €1.00 ($1.12) unsecured convertible loan notes (2014 Convertible Loans), denominated in Euros, and was subsequently amended on October 1, 2015. On October 1, 2015, the Company executed a convertible loan instrument which provided 5,000,000 $1.00 unsecured convertible loan notes (the 2015 Convertible Loans), denominated in USD. The valuation methods used to value the 2014 Convertible Loans, the 2015 Convertible Loans and their respective associated derivative liabilities were the income approach and the Monte Carlo simulation analysis. The fair value of the 2014 Convertible Loans increased by $25,000 and $17,000 for the three and six months ended June 30, 2016, respectively. The fair value of the 2015 Convertible Loans increased by $222,000 and $127,000 for the three and six months ended June 30, 2016, respectively. Immediately prior to completion of the Transaction on November 3, 2016, the conversion rights for the 2014 Convertible Loans and the 2015 Convertible Loans were exercised.

There were no transfers from one Level to another Level during the periods reported.

Warrants

In connection with the Loan Facility, the Company issued to Kreos Capital IV (Expert Fund) Limited (Kreos Capital) detachable warrants with a right to acquire shares at €720,000 (the Warrants). The Company recognized the Warrants at fair value at the time of execution of the Loan Facility and remeasured their fair value on a recurring basis thereafter. In connection with the Transaction, the Warrants were replaced with warrants to purchase 67,271 shares of the Company's common stock at an exercise price of $11.78 per share (the Replacement Kreos Warrants). The exchange was accounted for as a modification whereby the fair value of the Replacement Kreos Warrants was compared to the fair value of the Warrants immediately before the terms were modified, measured based on the market price of the common stock of the Company and other pertinent factors on the date of the modification.

On May 10, 2017, Kreos Capital notified the Company of its intent to exercise the Replacement Kreos Warrants on a "cashless" basis. In conjunction with the exercise, the Company remeasured the fair value of the Replacement Kreos Warrants to be $618,000 immediately prior to the exercise. The number of shares of the Company's common stock issued in the cashless exercise, 29,831 shares, was determined by a formula specified in the warrant document. The existing liability of the fair value at date of exercise was reclassified to Additional paid in capital.

The fair value of the Replacement Kreos Warrants decreased by $584,000 and $226,000 for the three and six months ended June 30, 2017, respectively. The fair value of the Warrants decreased by $956,000 and $765,000 for the three and six months ended June 30, 2016, respectively.

See Note 7 for a further description of the Loan Facility, Warrants and Replacement Kreos Warrants.

3. Commitments and contingencies

Operating lease commitments

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 318,197 ($35,907 based on the SEK to USD exchange rate as of June 30, 2017) 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 June 30, 2017, future minimum commitments under facility operating leases were $1,339,000.

Rent expense recognized under the Company's operating leases was $185,000 and $54,000 for the six months ended June 30, 2017 and 2016, respectively.

Agreements with CROs

As of June 30, 2017, the Company had various agreements with CROs for the conduct of specified research and development activities and, based on the terms of the respective agreements, may be required to make future payments of up to $6.0 million 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 ($473,000, based on the SEK to USD exchange rate as of June 30, 2017).

4. 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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Basic EPS:				
Numerator				
Net income (loss)	$ (6,176)	$ 2,139	$ (12,847)	$ (1,100)
Net income (loss)	$ (6,176)	$ 2,139	$ (12,847)	$ (1,100)
Denominator				
Weighted average number of shares	7,171,610	288,427	6,734,555	277,120
Number of shares used for Basic EPS computation	7,171,610	288,427	6,734,555	277,120
Basic EPS	$ (0.86)	$ 7.42	$ (1.91)	$ (3.97)
Diluted EPS:				
Numerator				
Net income (loss)	$ (6,176)	$ 2,139	$ (12,847)	$ (1,100)
Net income (loss)	$ (6,176)	$ 2,139	$ (12,847)	$ (1,100)
Denominator				
Weighted average number of shares	7,171,610	288,427	6,734,555	277,120
Conversion of convertible preferred shares	—	2,754,386	—	—
Weighted average effect of dilutive securities:				
Warrants to purchase common stock	—	58,302	—	—
Number of shares used for Diluted EPS computation	7,171,610	3,101,115	6,734,555	277,120
Diluted EPS	$ (0.86)	$ 0.69	$ (1.91)	$ (3.97)

As described in Note 1, “Organization and Share Exchange,” the share and per share information as of and for the period ended June 30, 2016 has been retroactively adjusted to reflect the exchange of shares in the Transaction based on an exchange ratio of 0.06999 and does not include the historical results of Biodel.

The following outstanding common stock equivalents were excluded from the computation of Diluted EPS for the three months ended June 30, 2017 and 2016 and the six months ended June 30, 2017 and 2016 because including them would have been anti-dilutive:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2017	2016	2017	2016
Convertible preference shares (on an as-converted basis)	—	—	—	2,754,386
Warrants to purchase convertible preference shares (on an as-converted basis)	—	56,637	—	53,549
Options to purchase common stock	767,662	151,370	767,662	76,517

5. Income taxes

The Company did not record a tax provision or benefit for either the three or six months ended June 30, 2017 or June 30, 2016. 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 $53.3 million in valuation allowances recorded against its deferred tax assets as of both June 30, 2017 and December 31, 2016.

The Company’s 2015 federal tax return, in respect of its predecessor (Biodel), is under examination.

6. Stock-based Compensation

On November 3, 2016, the Albireo Pharma, Inc. 2016 Equity Incentive Plan (the 2016 Equity Plan) was approved by the Company's stockholders. The 2016 Equity Plan replaced Biodel's 2010 Stock Incentive Plan, as amended (the 2010 Plan), in connection with completion of the Transaction. The 2016 Equity Plan authorized the issuance of up to 635,000 shares, plus up to 249,059 shares issued if awards outstanding under the 2010 Plan were cancelled, forfeited or expired on or after the Transaction. All stock options outstanding under the 2010 Plan remain in full force and effect pursuant to their terms and the terms of the 2010 Plan. The 2016 Equity Plan is structured to comply with the requirements imposed by Section 162 (m) of the Internal Revenue Code of 1986, as amended, and related regulations.

Prior to completion of the Transaction, Albireo Limited adopted a share option plan on March 18, 2016, providing for the grant of share options to employees, consultants, officers and directors of Albireo Limited or its subsidiaries (the Pre-Transaction Plan). The Pre-Transaction Plan was amended by Albireo Limited on April 18, 2016. Pursuant to the terms of the Pre-Transaction Plan and prior to completion of the Transaction, Albireo Limited issued or granted options to purchase 246,666 Ordinary A shares. These options were classified as a liability on the basis that they were granted in a currency other than the functional currency of the employing entity of the recipients and were subject to revaluation until exercised or forfeited. The options were replaced with options to purchase shares of the Company's common stock in conjunction with the Transaction. The replacement was accounted for as a modification whereby the fair value of the replacement awards was compared to the fair value of the original award immediately before the terms were modified, measured based on the market price of the common stock of Biodel and other pertinent factors on the date of the modification. The options were then classified as equity awards with the liability reclassified to Additional paid in capital.

The Company's employment agreements with certain of its executives provide that, upon a change of control as defined, all of the then outstanding unvested options and any other rights to purchase Company shares will become fully vested and exercisable and any vesting-like restrictions will lapse in full, unless earlier vesting is provided for in the applicable program under which such option or other right to purchase Company shares was granted or under applicable law. The Transaction was not a change of control under the employment agreements.

The Company recognized stock-based compensation expense for employees of $1,439,000 and $55,000 for the three months ended June 30, 2017 and 2016, respectively, and $2,051,000 and $55,000 for the six months ended June 30, 2017 and 2016, respectively.

A summary of the outstanding stock options as of June 30, 2017 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, 2016	694,869	$ 26.71	7.35	$ 6,435
Granted	249,900	$ 19.21	—	$ —
Expirations	(48,680)	$ 175.10	—	$ —
Exercises	(6,666)	$ 9.00	—	$ —
Outstanding—June 30, 2017	889,423	$ 16.62	8.59	$ 9,951
Exercisable—June 30, 2017	277,292	$ 21.55	7.00	$ 6,325
Vested or expected to vest at—June 30, 2017	870,001	$ 16.96	8.59	$ 9,570

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 June 30, 2017.

As of June 30, 2017, the total unrecognized compensation expense related to unvested options was $7.4 million, which the Company expects to recognize over a weighted average vesting period of 2.4 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 and six months ended June 30, 2017, was estimated with the following assumptions:

	Three Months Ended June 30, 2017	Six Months Ended June 30, 2017
Price per share of common stock	$17.05-$23.82	$17.05-$23.82
Expected term (in years)	5.2-6.7	5.2-6.7
Risk-free interest rate	1.9-2.1%	1.9-2.1%
Expected volatility	69.5-76.7	69.5-78.4
Dividend rate	0%	0%

7. Long-term debt

	June 30, 2017	December 31, 2016
	(in thousands)	
Long-term debt, including current portion:		
Loan Facility	$ 1,928	$ 3,075
Total debt	1,928	3,075
Less: current portion	(1,928)	(3,075)
Long-term debt	$ —	$ —

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 has a term of 36 months with principal and interest payable monthly, with an annual interest rate of 11.5%. In addition, the Company is required to make an end-of-loan payment equal to 1.25% of the amounts lent by Kreos UK. The principal amount outstanding as of June 30, 2017 was $1.4 million (€1.3 million). The outstanding amount is due and payable in average monthly installments of €253,000 ($289,000, based on the Euro to USD exchange rate as of June 30, 2017) and an end of loan payment of €670,000 ($765,000, based on the Euro to USD exchange rate as of June 30, 2017) due and payable on December 1, 2017.

The Company is accreting the debt discount of $114,000 remaining as of June 30, 2017 over the remaining six months of the loan term. Interest expense included $130,000 and $239,000 of discount accretion for the three months ended June 30, 2017 and 2016, respectively, and $301,000 and $472,000 of discount accretion for the six months ended June 30, 2017 and 2016, respectively.

The Company has the option to redeem all outstanding amounts. Upon the occurrence of a sale or a change of control, the Company shall redeem the principal, accrued interest and other fees, and remaining interest payments calculated until the end of the term, discounted by 5%.

Parent's subsidiary, Albireo Limited, has pledged its shares in its subsidiary, Albireo AB, and has granted a debenture (incorporating fixed and floating charges) over its assets by way of security for the obligations it owes under the Loan Facility.

The Loan Facility is guaranteed by Parent and two of Parent's indirect subsidiaries, Elobix AB and Albireo AB, as the principal obligors that have severally agreed to indemnify and keep indemnified Kreos UK in full and on demand from and against all and any losses, costs, claims, liabilities, damages, demands and expenses suffered or incurred by Kreos UK arising out of, or in connection with, any failure of the Company to perform or discharge any of its obligations or liabilities.

In addition, Parent, Elobix AB and Albireo AB have agreed to pledge the following:

- Parent shares in Albireo Limited
- Albireo AB shares in Elobix AB
- Albireo AB bank accounts
- Albireo AB A4250 patents

- Elobix elobixibat patents
- Elobix bank accounts

Although the bank accounts of Albireo AB and Elobix AB were pledged, Albireo AB and Elobix AB are not restricted from using the cash for working capital requirements.

The Company also pledged its present and future rights to fees, royalties and other payments due and payable any time under its license agreement with EA Pharma to Kreos UK in support of the Loan Facility.

On February 4, 2016, the Company (in particular, Albireo Limited) entered a Deed of Variation related to the Loan Facility. Under the terms of the Deed of Variation, the timing of principal payments was changed such that €512,000 ($585,000, based on the Euro to USD exchange rate as of June 30, 2017) of the payments was deferred to become payable at the end of the loan term. The total principal due under the Loan Facility remained unchanged. In addition, there were no changes to the maturity date or the stated interest rate. The Company accounted for the amendment to the Loan Facility prospectively in accordance with ASC 470-50, *Modifications and Extinguishments*, as there were no concessions granted to the Company by the lender and the difference in cash flows between the original and amended loans did not change by more than 10% per lender. As a result of the modification, the transaction costs incurred in connection with the amendment were expensed when incurred and the effective interest rate calculation was updated, resulting in an effective interest rate of 39.3%.

8. Derivatives

The following disclosures summarize the fair value of derivative instruments not designated as hedging instruments in the Condensed Consolidated Balance Sheet as of June 30, 2017 and the effects of changes in fair value related to those derivative instruments on the Condensed Consolidated Statements of Operations for the six months ended June 30, 2017 (in thousands):

Derivative Instruments Not Designated as Hedging Instruments	Balance Sheet Location	June 30, 2017	December 31, 2016
Warrants liability	Current liabilities	—	844

Effect of Derivative Instruments Not Designated as Hedging Instruments	Location of Gains (Losses) Recognized	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016
Derivative liabilities	Non-operating expense, net	$ —	$ (145)
Warrants liability	Non-operating income, net	251	765

Effect of Derivative Instruments Not Designated as Hedging Instruments	Location of Gains (Losses) Recognized	Three Months Ended June 30, 2017	Three Months Ended June 30, 2016
Derivative liabilities	Non-operating expense, net	$ —	$ (247)
Warrants liability	Non-operating income, net	609	956

The derivative liabilities related to the conversion feature embedded in the 2014 Convertible Loans and 2015 Convertible Loans have been separately recognized at their respective fair values. The Company determined that embedded features met the definition of a derivative and were required to be recorded at fair value at issuance and remeasured for each reporting period thereafter. Immediately prior to completion of the Transaction on November 3, 2016, the conversion rights for the 2014 Convertible Loans and the 2015 Convertible Loans were exercised.

9. Financings

May 2017 Underwritten Public Offering

On May 30, 2017, the Company completed an underwritten public offering of 2,530,000 shares of its common stock, which included the full exercise of the underwriter's option to purchase 330,000 shares to cover overallotments, at a price to the public of $20.50 per share. The Company received net proceeds from this offering of $48.5 million, after deducting underwriting discounts, commissions 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, 2016, 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, 2016 or other filings that we make with the SEC.

Overview

Prior to November 3, 2016, we were a specialty biopharmaceutical company known as Biodel Inc. that historically had been focused on the development and commercialization of innovative treatments for diabetes. On November 3, 2016, we completed a share exchange transaction, or the Transaction, pursuant to an Amended and Restated Share Exchange Agreement dated July 13, 2016 that we entered into with Albireo Limited and the shareholders and noteholders of Albireo Limited. Upon the completion of the Transaction, we changed our name to "Albireo Pharma, Inc.," the business of Albireo Limited became our business and we became a biopharmaceutical company focused on the development and commercialization of novel bile acid modulators to treat orphan pediatric liver diseases and gastrointestinal disorders where improper flow or absorption of bile causes serious medical conditions for which there is high unmet need. 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 in children with chronic cholestasis and we plan to initiate a Phase 3 clinical trial in patients with PFIC by the end of 2017. In addition to PFIC, we plan to consider conducting future clinical development of A4250 as a treatment for other pediatric cholestatic liver diseases and disorders. Our clinical-stage product candidates in addition to A4250 include elobixibat, for which our licensee has submitted a new drug application for approval in Japan to treat chronic constipation, and A3384, which is in development to treat bile acid malabsorption. We also have a preclinical program in nonalcoholic steatohepatitis, or NASH.

For accounting purposes, the Transaction was treated as a "reverse acquisition" and Albireo Limited was considered the accounting acquirer. Accordingly, with respect to periods prior to completion of the Transaction, this discussion and analysis reflects the historical results of Albireo Limited and its direct and indirect subsidiaries and does not include the historical results of Biodel prior to completion of the Transaction.

Biodel was incorporated in December 2003 and commenced active operations in January 2004. Albireo Limited's business began when Albireo Limited was spun out of AstraZeneca AB in 2008.

Since inception, we have incurred significant operating losses. As of June 30, 2017, we had an accumulated deficit of $38.8 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. Accordingly, 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 June 30, 2017, we had $62.6 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 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 separately identifiable components on a reliable basis that reasonably reflects the selling prices that might be expected to be achieved in stand-alone transactions.

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, 2016 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, research and development expenses, stock-based compensation and fair value of financial instruments 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, 2016.

Results of Operations

Three Months Ended June 30, 2017 and June 30, 2016

Revenue

	Three Months Ended June 30,		Change
	2017	2016	$
	(in thousands)		
Revenue	$ 1	$ 7,973	$ (7,972)

Revenue was $1,000 for the three months ended June 30, 2017 compared with $8.0 million for the three months ended June 30, 2016, a decrease of $8.0 million. The decrease for the 2017 period was attributable to a nonrefundable one-time payment of $8.0 million received from EA Pharma in April 2016 in connection with a renegotiated payment stream linked to know-how and intellectual property that we delivered upon inception of the license agreement in 2012. The renegotiated payment stream was implemented via an amendment to the license agreement that did not change the contingent nature of the remaining deliverables or the parties' respective obligations under the agreement.

Research and development expenses

	Three Months Ended June 30,		Change
	2017	2016	$
	(in thousands)		
Research and development expenses	$ 2,962	$ 2,713	$ 249

Research and development expenses were $3.0 million for the three months ended June 30, 2017 compared with $2.7 million for the three months ended June 30, 2016, an increase of $249,000. The increase in research and development expenses was principally due to increases for the 2017 period in costs related to A4250, mainly in connection with preparatory activities in the 2017 period for a planned Phase 3 clinical trial in patients with PFIC and nonclinical carcinogenicity studies, and nonclinical development activities associated with A3384 and our preclinical NASH program, partially offset by reductions for the 2017 period in other project costs attributable to patent expenses.

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 June 30, 2017 and 2016.

	Three Months Ended June 30,		Change
	2017	2016	$
	(in thousands)		
Direct third-party project costs:			
A4250	$ 1,872	$ 1,413	$ 459
Elobixibat	(7)	11	(18)
A3384	62	—	62
Preclinical	61	4	57
Total	$ 1,988	$ 1,428	$ 560
Other project costs(1):			
Personnel costs	$ 482	$ 513	$ (31)
Other costs(2)	492	772	(280)
Total	$ 974	$ 1,285	$ (311)
Total research and development costs	$ 2,962	$ 2,713	$ 249

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

General and administrative expenses

	Three Months Ended June 30,		Change
	2017	2016	$
	(in thousands)		
General and administrative expenses	$ 3,713	$ 3,028	$ 685

General and administrative expenses were $3.7 million for the three months ended June 30, 2017 compared with $3.0 million for the three months ended June 30, 2016, an increase of $685,000. The higher general and administrative expenses for the 2017 period were principally due to increases of $1.3 million in stock-based compensation, which includes $788,000 attributable to the correction of an understatement of stock-based compensation expensed for the year ended December 31, 2016 due to the use of incorrect service periods in determining the expense, $618,000 in salary and benefits resulting from new hires made in the second half of 2016 and $487,000 in costs associated with being a public company and being incorporated in Delaware, offset by lower accounting and legal fees of $1.7 million as a result of the completion of the Transaction in November 2016. We expect that we will incur increased accounting, audit, legal, regulatory, compliance, and investor and public relations expenses associated with operating as a public company in future periods.

Other (income) expense, net

	Three Months Ended June 30,		Change
	2017	2016	$
	(in thousands)		
Other (income) expense, net	$ (65)	$ 290	$ (355)

Other (income) expense, net totaled $65,000 of income for the three months ended June 30, 2017 compared with $290,000 of expense for the three months ended June 30, 2016, a difference of $355,000. The difference resulted from differences in currency exchange rates in the two periods.

Interest expense, net

	Three Months Ended June 30,		Change
	2017	2016	$
	(in thousands)		
Interest expense, net	$ (152)	$ (512)	$ 360

Interest expense, net totaled $152,000 for the three months ended June 30, 2017 compared with $512,000 for 2016, a decrease of $360,000. The lower net interest expense for the 2017 period was attributable to the conversion of convertible loan notes issued in 2014 and 2015 into equity in connection with the completion of the Transaction in November 2016 and a reduction in the amount of interest paid under our loan facility in accordance with its terms.

Non-operating income, net

	Three Months Ended June 30,		Change
	2017	2016	$
	(in thousands)		
Non-operating income, net	$ 585	$ 709	$ (124)

Non-operating income, net was $585,000 for the three months ended June 30, 2017 compared with $709,000 for the three months ended June 30, 2016, a decrease of $124,000. The lower net non-operating income for the 2017 period primarily reflected a change in the mark-to-market adjustments on warrants between the periods.

Six Months Ended June 30, 2017 and June 30, 2016

Revenue

	Six Months Ended June 30,		Change
	2017	2016	$
		(in thousands)	
Revenue	$ 2	$ 8,097	$ (8,095)

Revenue was $2,000 for the six months ended June 30, 2017 compared with $8.1 million for the six months ended June 30, 2016, a decrease of $8.1 million. The decrease for the 2017 period was attributable to a nonrefundable one-time payment of $8.0 million received from EA Pharma in April 2016 in connection with a renegotiated payment stream under our license agreement with EA Pharma.

Research and development expenses

	Six Months Ended June 30,		Change
	2017	2016	$
		(in thousands)	
Research and development expenses	$ 5,774	$ 4,310	$ 1,464

Research and development expenses were $5.8 million for the six months ended June 30, 2017 compared with $4.3 million for the six months ended June 30, 2016, an increase of $1.5 million. The higher research and development expenses for the 2017 period were principally due to an increase of $1.4 million in costs related to A4250, mainly in connection with preparatory activities for a planned Phase 3 clinical trial in patients with PFIC, the conduct of a clinical study to assess absorption, distribution, metabolism and excretion and nonclinical carcinogenicity studies, as well as nonclinical development activities associated with A3384 and other project costs attributable to research and development consulting services.

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 six months ended June 30, 2017 and 2016.

	Six Months Ended June 30,		Change
	2017	2016	$
		(in thousands)	
Direct third-party project costs:			
A4250	$ 3,485	$ 2,070	$ 1,415
Elobixibat	(4)	81	(85)
A3384	108	4	104
Preclinical	84	144	(60)
Total	$ 3,673	$ 2,299	$ 1374
Other project costs(1):			
Personnel costs	$ 944	$ 998	$ (54)
Other costs(2)	1,157	1,013	144
Total	$ 2,101	$ 2,011	$ 90
Total research and development costs	$ 5,774	$ 4,310	$ 1,464

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

General and administrative expenses

	Six Months Ended June 30,		Change
	2017	2016	$
		(in thousands)	
General and administrative expenses	$ 6,925	$ 4,334	$ 2,591

General and administrative expenses were $6.9 million for the six months ended June 30, 2017 compared with $4.3 million for the six months ended June 30, 2016, an increase of $2.6 million. The higher general and administrative expenses for the 2017 period

were principally attributable to increases of $1.9 million in stock-based compensation expense, which included $788,000 attributable to the correction of an understatement of stock-based compensation expense for the year ended December 31, 2016 due to the use of incorrect service periods in determining the expense, $1.3 million in salary and benefits resulting from new hires made in the second half of 2016 and $901,000 in costs associated with being a public company and being incorporated in Delaware, partially offset by lower legal and accounting fees of $1.4 million as a result of the completion of the Transaction in November 2016.

Other (income) expense, net

	Six Months Ended June 30,		Change
	2017	2016	$
		(in thousands)	
Other (income) expense, net	$ 9	$ 135	$ (126)

Other (income) expense, net totaled $9,000 of expense for the six months ended June 30, 2017 compared with $135,000 of expense for the six months ended June 30, 2016, a difference of $126,000. The difference resulted from changes in currency exchange rates between the two periods.

Interest expense, net

	Six Months Ended June 30,		Change
	2017	2016	$
		(in thousands)	
Interest expense, net	$ (401)	$ (1,038)	$ 637

Interest expense, net totaled $401,000 for the six months ended June 30, 2017 compared with $1.0 million for the six months ended June 30, 2016, a decrease of $637,000. The lower net interest expense was attributable to the conversion of convertible loan notes issued in 2014 and 2015 into equity in connection with the completion of the Transaction in November 2016 and a reduction in the amount of interest paid under our loan facility in accordance with its terms.

Non-operating income, net

	Six Months Ended June 30,		Change
	2017	2016	$
		(in thousands)	
Non-operating income, net	$ 260	$ 620	$ (360)

Non-operating income, net was $260,000 for the six months ended June 30, 2017 compared with $620,000 for the six months ended June 30, 2016, a decrease of $360,000. The lower net non-operating income primarily reflected a change in the mark-to-market adjustments on warrants between the periods.

Liquidity and Capital Resources

Sources of Liquidity

We do not expect to generate revenue from product sales unless and until we or a licensee obtains regulatory approval of and commercializes our current or any potential future product candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of and seek regulatory approvals for our product candidates. We are subject to all of the risks applicable to the development of new pharmaceutical products and may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may harm our business. We expect that we will need substantial additional funding to complete development of and potentially commercialize our product candidates.

Our operations have historically been financed primarily through issuances of 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.

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 approximately $48.5 million.

In November 2016, we completed the Transaction and, immediately prior to the Transaction, an associated equity financing of $10.0 million. In the Transaction, we acquired cash of approximately $20 million, net of Biodel's commitments, that Biodel had on hand on the closing date.

In December 2014, we (Albireo Limited) entered into a loan facility agreement with Kreos Capital IV (UK) Limited, or Kreos UK, enabling us to borrow up to €6.0 million ($7.3 million). The loan facility has a term of 36 months, with principal and interest payable monthly after an initial six-month interest-only period, at an annual rate of 11.5%. In addition, we are required to make an end-of-loan payment equal to 1.25% of the amounts lent by Kreos UK. On the date of the agreement, we borrowed the full €6.0 million ($7.3 million). In February 2016, we amended the loan facility to reduce principal repayments for a period of six months. As of June 30, 2017, the outstanding balance due on the loan facility, including interest and the end-of-loan payment, was €1.8 million ($2.1 million based on the Euro to USD exchange rate as of June 30, 2017).

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 and April 2016. As of June 30, 2017, we have received approximately $34.7 million in upfront and milestone payments from EA Pharma under this agreement. We are eligible to receive additional payments of up to €13.3 million under the amended agreement ($15.2 million based on the Euro to USD exchange rate as of June 30, 2017) if specified regulatory events are achieved for elobixibat and up to ¥3.5 billion ($31.1 million based on the Japanese Yen to USD exchange rate as of June 30, 2017) if specified sales milestones are achieved for elobixibat. We are also eligible for stepped royalties at rates beginning in the high single digits on any future elobixibat product sales.

As of June 30, 2017, our cash and cash equivalents were $62.6 million.

Cash Flows

Six Months Ended June 30, 2017 and June 30, 2016

	Six Months Ended June 30,	
	2017	2016
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (14,428)	1,592
Investing activities	(146)	(3)
Financing activities	46,922	(635)
Total	$ 32,348	$ 954
Effect of exchange rate changes on cash and cash equivalents	319	176
Net increase in cash and cash equivalents	32,667	1,130

Operating activities

Net cash used in operating activities for the six months ended June 30, 2017 was $14.4 million compared to net cash provided by operating activities of $1.6 million for the corresponding 2016 period. The change in operating net cash for the 2017 period compared to the corresponding 2016 period was primarily driven by the one-time payment from EA Pharma of $8.0 million received in April 2016 in connection with a renegotiated payment stream and lower accrued expenses, mainly due to severance paid to former Biodel personnel in the 2017 period.

Investing activities

Net cash used in investing activities was $146,000 for the six months ended June 30, 2017 compared to $3,000 for the corresponding 2016 period. The increase was due to greater property and equipment purchases in connection with our move to different offices in Boston.

Financing activities

Net cash provided by financing activities for the six months ended June 30, 2017 was $46.9 million compared to net cash used in financing activities of $635,000 for the corresponding 2016 period. The difference was principally due to our receipt of $48.5 million in net proceeds from a public offering in May 2017, partially offset by higher principal payments under the loan facility with Kreos in the 2017 period, as the terms were amended in February 2016 to reduce principal payments for six months.

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 through at least 2019. 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 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. We filed a universal shelf registration statement on Form S-3 with the SEC, which was declared

effective on January 10, 2017 and pursuant to which we registered for sale of $100 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. On May 30, 2017, we closed an underwritten public offering of 2,530,000 shares of our common stock for gross proceeds of $51.9 million under the shelf registration statement. Following that closing, approximately $48.1 million of securities remains available for issuance under the shelf registration statement. This shelf registration statement will remain in effect for up to three years from the date it was declared effective. Additionally, if we need to raise additional capital to fund our operations, complete our ongoing and planned 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.

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

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not required for smaller reporting companies.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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.

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 appropriately designed and operating controls over our financial statement close process.

As previously reported in connection with our 2016 financial statements, we identified a material weakness in our internal control over financial reporting, specifically a lack of controls over the identification and review of complex accounting issues involving significant judgment or estimates in the financial statement closing process resulting from our limited in-house accounting and finance team. We currently rely on consultants and external advisors to provide assistance with financial reporting in accordance with the requirements of U.S. generally accepted accounting principles (GAAP) and the rules and regulations of the SEC, and these consultants and external advisors may not have direct knowledge of all of our business, transactions and contracts. Specifically, we determined that we did not have sufficient resources with GAAP and SEC financial reporting knowledge to ensure a timely and

sufficient financial statement close process that includes resolution of complex accounting issues involving significant judgment and estimates.

Additionally, our financial accounting information system has limited functionality and certain closing and consolidating activities are managed and processed outside of the system. These system limitations, as well as a lack of sufficient accounting staff, negatively affect the design and operation of our financial statement close process. Deficiencies in our financial statement close process have limited our ability to adequately monitor certain adjustments and perform appropriate account analyses and reconciliations. These deficiencies constitute a material weakness in internal control over financial reporting and have resulted in financial statement errors not being identified on a timely basis.

We are working to remediate the material weaknesses. In particular, we hired a full-time chief financial officer in July 2016, a controller in March 2017 and a staff accountant in Sweden who was hired in the second quarter of 2017 and has a scheduled start date in September 2017. Also, we expect to implement a new accounting information system in the fourth quarter of this year and we will be redesigning our close process upon implementation of this new system. The material weaknesses will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

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 June 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1A. Risk Factors

In addition to the other information set forth in this report and the risk factors discussed in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2016, you should carefully consider the "Risk Factors" discussed in Exhibit 99.3 to our Current Report on Form 8-K, as filed with the Securities and Exchange Commission on May 23, 2017, which could materially affect our business, financial condition or results of operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

(a) Recent Sales of Unregistered Equity Securities

In connection with the completion of our share exchange transaction in November 2016, we issued a warrant to purchase 67,271 shares of our common stock to Kreos Capital IV (Expert Fund) Limited, or Kreos Capital, in replacement of a warrant instrument that had previously been issued by Albireo Limited to Kreos Capital. On May 10, 2017, Kreos Capital exercised the warrant on a "cashless" basis at an exercise price of $11.78 per share, resulting in the issuance of 29,831 shares of our common stock. These shares of common stock were issued pursuant to an exemption from registration under Section 3(a)(9) of the Securities Act of 1933, as amended.

Item 6. Exhibits

The exhibits listed in the accompanying exhibit index are filed as part of this quarterly report.

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: August 21, 2017

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

Exhibit No.	Description	Filed Herewith	Incorporated by Reference Herein from Form or Schedule	Filing Date	SEC File/ Req. Number
3.1.1	Restated Certificate of Incorporation of the Registrant, filed with the Secretary of State of the State of Delaware on May 17, 2007.		S-1 (Exhibit 3.1)	2/7/2007	333-140504
3.1.2	Certificate of Designation of Series A Convertible Preferred Stock of the Registrant, filed with the Secretary of State of the State of Delaware on May 17, 2011.		8-K (Exhibit 4.6)	5/19/2011	001-33451
3.1.3	Certificate of Amendment to the Restated Certificate of Incorporation, filed with the Secretary of State of the State of Delaware on June 11, 2012.		8-K (Exhibit 3.1)	6/11/2012	001-33451
3.1.4	Certificate of Designation of Series B Convertible Preferred Stock of the Registrant, filed with the Secretary of State of the State of Delaware on June 26, 2012.		8-K (Exhibit 4.8)	6/27/2012	001-33451
3.1.5	Certificate of Amendment to the Restated Certificate of Incorporation, filed with the Secretary of State of the State of Delaware on December 20, 2012.		10-K (Exhibit 3.5)	12/21/2012	001-33451
3.1.6	Certificate of Amendment to the Restated Certificate of Incorporation, filed with the Secretary of State of the State of Delaware on March 17, 2015.		8-K (Exhibit 3.1)	3/18/2015	001-33451
3.1.7	Certificate of Amendment to the Restated Certificate of Incorporation, filed with the Secretary of State of the State of Delaware on November 3, 2016 (Reverse Stock Split).		8-K (Exhibit 3.1)	11/4/2016	001-33451
3.1.8	Certificate of Amendment to the Restated Certificate of Incorporation, filed with the Secretary of State of the State of Delaware on November 3, 2016 (Name Change).		8-K (Exhibit 3.2)	11/4/2016	001-33451
3.1.9	Certificate of Amendment to the Restated Certificate of Incorporation, filed with the Secretary of State of the State of Delaware on June 12, 2017.		8-K (Exhibit 3.1)	06/15/2017	001-33451
31.1	Certification of the Registrant's Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of the Registrant's Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets (unaudited) at June 30, 2017 and December 31, 2016, (ii) Condensed Consolidated Statements of Operations (unaudited) for the three and six months ended June 30, 2017 and 2016, (iii) Condensed Consolidated Statements of Comprehensive Income (Loss) (unaudited) for the three and six months ended June 30, 2017 and 2016, (iv) Condensed Consolidated Statements of Cash Flows (unaudited) for the six months ended June 30, 2017 and 2016, and (v) Notes to Condensed Consolidated Financial Statements (unaudited).	X			

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

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

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

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

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

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

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

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

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

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

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

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

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

Date: August 21, 2017

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

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, 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: August 21, 2017

/s/ Thomas A. Shea
Thomas A. Shea
Chief Financial Officer and Treasurer (principal financial officer and principal accounting officer)

Exhibit 32.1

CERTIFICATIONS UNDER SECTION 906

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

The Quarterly Report for the quarter ended June 30, 2017 (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: August 21, 2017

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

Dated: August 21, 2017

/s/ Thomas A. Shea
Thomas A. Shea
Chief Financial Officer and Treasurer
(principal financial officer and principal accounting officer)