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 September 30, 2019

OR

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

For the transition period from_____ to _____ .

Commission File Number 001-33451

Albireo Pharma, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☐

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

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

As of October 30, 2019, there were 12,686,576 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, number, scope, cost, duration or results of our development activities, nonclinical studies and clinical trials of odevixibat (formerly known as A4250), elobixibat, A3384 or any of our other product candidates or programs, such as the target indication(s) for development or approval, the size, design, population, conduct, cost, objective or endpoints of any clinical trial, or the timing for initiation or completion of or availability of results from any clinical trial (including PEDFIC 1, our Phase 3 clinical trial of odevixibat in patients with progressive familial intrahepatic cholestasis, or PFIC), for submission or approval of any regulatory filing, or for meeting with regulatory authorities;

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

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

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

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

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

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

- the design, size, duration and endpoints for, and results from, PEDFIC 1, our Phase 3 clinical trial of odevixibat in patients with PFIC or our related extension study, or any other trials that will be required to obtain marketing approval for odevixibat to treat patients with PFIC or any other pediatric cholestatic liver disease, for elobixibat to treat nonalcoholic steatohepatitis, or NASH, or for A3384 as a potential treatment for other gastrointestinal diseases or disorders;

- whether favorable findings from clinical trials of odevixibat to date, including findings in indications other than PFIC, will be predictive of results from future clinical trials, including the trials comprising our Phase 3 PFIC program for odevixibat;

- whether either or both of the U.S. Food and Drug Administration, or FDA, and European Medicines Agency, or EMA, will determine that the primary endpoint and treatment duration of the double blind Phase 3 trial in patients with PFIC are sufficient, even if such primary endpoint is met with statistical significance, to support approval of odevixibat in the United States or the European Union, to treat PFIC, a symptom of PFIC, a specific PFIC subtype(s) or otherwise;

- the outcome and interpretation by regulatory authorities of an ongoing third-party study pooling and analyzing long-term PFIC patient data;

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

- delays or other challenges in the recruitment of patients for the double blind Phase 3 trial of odevixibat;

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

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

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

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

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

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

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

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

- whether findings from nonclinical studies and clinical trials of IBAT inhibitors will be predictive of future clinical success for a product candidate of ours in the treatment of NASH;

- the accuracy of our estimates regarding expenses, costs, future revenues, uses of cash and capital requirements;

- our ability to obtain additional financing on reasonable terms, or at all;

- our ability to establish additional licensing, collaboration or similar arrangements on favorable terms and our ability to attract collaborators with development, regulatory and commercialization expertise;
- the success of competing third-party products or product candidates;
- our ability to successfully commercialize any approved product candidates, including their rate and degree of market acceptance;
- our ability to expand and protect our intellectual property estate;
- regulatory developments in the United States and other countries;
- our ability to fully remediate our identified internal control material weaknesses;
- the performance of our third-party suppliers, manufacturers and contract research organizations and our ability to obtain alternative sources of raw materials;
- our ability to attract and retain key personnel; and
- our ability to comply with regulatory requirements relating to our business, and the costs of compliance with those requirements, including those on data privacy and security.

These and other risks and uncertainties are described in greater detail under the caption "Risk Factors" in Item 1A of Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, in Item 1A of Part II of this quarterly report, in Item 1A of Part II of our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2019, and in other filings that we make with the Securities and Exchange Commission, or SEC. As a result of the risks and uncertainties, the results or events indicated by the forward-looking statements may not occur. We caution you not to place undue reliance on any forward-looking statement.

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

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

Albireo Pharma, Inc.

Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)

(unaudited)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 142,666	$ 163,885
Prepaid expenses and other current assets	5,353	3,765
Total current assets	148,019	167,650
Property and equipment, net	633	187
Goodwill	17,260	17,260
Other assets	5,578	369
Total assets	$ 171,490	$ 185,466
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,185	$ 4,352
Accrued expenses	8,459	8,165
Other current liabilities	683	308
Total current liabilities	12,327	12,825
Liability related to sale of future royalties	53,073	49,969
Other long-term liabilities	4,418	35
Total liabilities	69,818	62,829
Stockholders' Equity:		
Common stock, $0.01 par value per share — 30,000,000 authorized at September 30, 2019 and December 31, 2018; 12,685,326 and 11,969,928 issued and outstanding at September 30, 2019 and December 31, 2018	126	120
Additional paid in capital	242,638	214,694
Accumulated other comprehensive income	10,573	4,293
Accumulated deficit	(151,665)	(96,470)
Total stockholders' equity	101,672	122,637
Total liabilities and stockholders' equity	$ 171,490	$ 185,466

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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue	$ 1,385	$ 237	$ 3,205	$ 12,169
Operating expenses:				
Research and development	11,996	9,666	31,359	22,228
General and administrative	6,010	3,850	16,788	12,216
Other operating expense (income), net	4,015	(614)	6,319	1,377
Total operating expenses	22,021	12,902	54,466	35,821
Operating loss	(20,636)	(12,665)	(51,261)	(23,652)
Interest expense, net	(1,274)	(1,367)	(3,934)	(4,049)
Non-operating income (expense), net	—	7	—	(2,546)
Net loss	$ (21,910)	$ (14,025)	$ (55,195)	$ (30,247)
Net loss per common share - basic and diluted	$ (1.73)	$ (1.17)	$ (4.47)	$ (2.60)
Weighted-average common shares used to compute basic and diluted net loss per common share	12,685,000	11,969,791	12,349,870	11,612,760

See accompanying notes to Condensed Consolidated Financial Statements.

Albireo Pharma, Inc.

Condensed Consolidated Statements of Comprehensive Loss

(in thousands)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss	$ (21,910)	$ (14,025)	$ (55,195)	$ (30,247)
Other comprehensive income (loss):				
Foreign currency translation adjustment	3,991	(618)	6,280	3,149
Total other comprehensive income (loss)	3,991	(618)	6,280	3,149
Total comprehensive loss	$ (17,919)	$ (14,643)	$ (48,915)	$ (27,098)

See accompanying notes to Condensed Consolidated Financial Statements.

Albireo Pharma, Inc.

Condensed Consolidated Statements of Stockholders' Equity

(in thousands, except share and per share data)

(unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance--December 31, 2018	11,969,928	$ 120	$ 214,694	$ 4,293	$ (96,470)	$ 122,637
Stock-based compensation expense	—	—	1,823	—	—	1,823
Exercise of options	68,908	—	1,290	—	—	1,290
Other comprehensive income	—	—	—	2,298	—	2,298
Net loss	—	—	—	—	(16,657)	(16,657)
Balance--March 31, 2019	12,038,836	$ 120	$ 217,807	$ 6,591	$ (113,127)	$ 111,391
Stock-based compensation expense	—	—	2,049	—	—	2,049
Exercise of awards	9,123	—	110	—	—	110
Issuance of common stock, net of costs	637,367	6	20,768	—	—	20,774
Other comprehensive loss	—	—	—	(9)	—	(9)
Net loss	—	—	—	—	(16,628)	(16,628)
Balance--June 30, 2019	12,685,326	$ 126	$ 240,734	$ 6,582	$ (129,755)	$ 117,687
Stock-based compensation expense	—	—	1,826	—	—	1,826
Exercise of awards	—	—	78	—	—	78
Other comprehensive income	—	—	—	3,991	—	3,991
Net loss	—	—	—	—	(21,910)	(21,910)
Balance--September 30, 2019	12,685,326	$ 126	$ 242,638	$ 10,573	$ (151,665)	$ 101,672

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive		Total Stockholders'
	Shares	Amount	Capital	Income	Accumulated Deficit	Equity
Balance--December 31, 2017	8,902,784	$ 89	$ 114,521	$ 1,001	$ (50,359)	$ 65,252
Stock-based compensation expense	—	—	1,189	—	—	1,189
Issuance of common stock, net of costs	2,994,362	30	94,120	—	—	94,150
Other comprehensive income	—	—	—	1,194	—	1,194
Net loss	—	—	—	—	(1,619)	(1,619)
Balance--March 31, 2018	11,897,146	$ 119	$ 209,830	$ 2,195	$ (51,978)	$ 160,166
Stock-based compensation expense	—	—	1,056	—	—	1,056
Exercise of options	60,345	1	254	—	—	255
Other comprehensive income	—	—	—	2,573	—	2,573
Net loss	—	—	—	—	(14,605)	(14,605)
Balance--June 30, 2018	11,957,491	$ 120	$ 211,140	$ 4,768	$ (66,583)	$ 149,445
Stock-based compensation expense	—	—	1,623	—	—	1,623
Exercise of options	12,437	—	252	—	—	252
Issuance of common stock, net of costs	—	—	(10)	—	—	(10)
Other comprehensive loss	—	—	—	(618)	—	(618)
Net loss	—	—	—	—	(14,025)	(14,025)
Balance--September 30, 2018	11,969,928	$ 120	$ 213,005	$ 4,150	$ (80,608)	$ 136,667

Albireo Pharma, Inc.

Condensed Consolidated Statements of Cash Flows

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (55,195)	$ (30,247)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non cash interest expense on liability related to royalty monetization	6,179	4,880
Depreciation and amortization	89	33
Change in fair value of financial instruments	—	(1)
Gain on sale of property, plant and equipment	—	(14)
Stock-based compensation expense	5,698	3,868
Foreign currency adjustments	8,317	4,802
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,861)	(1,122)
Other assets	(238)	379
Accounts payable	(935)	2,292
Accrued expenses	(2,397)	(1,516)
Other current and long-term liabilities	(176)	(160)
Net cash used in operating activities	(40,519)	(16,806)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(523)	(61)
Proceeds from sale of property, plant and equipment	—	14
Net cash used in investing activities	(523)	(47)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	20,774	94,139
Royalty monetization	—	44,525
Proceeds from exercise of options	1,478	507
Net cash provided by financing activities	22,252	139,171
Effect of exchange rate changes on cash and cash equivalents	(2,429)	(1,947)
Net (decrease) increase in cash and cash equivalents	(21,219)	120,371
Cash and cash equivalents—beginning of period	163,885	53,231
Cash and cash equivalents—end of period	$ 142,666	$ 173,602
Supplemental disclosures of cash and non-cash activities:		
Purchase of property, plant and equipment in accounts payable	$ 17	$ —
Right of use assets obtained in exchange for operating lease obligation	4,665	—

See accompanying notes to Condensed Consolidated Financial Statements.

1. Summary of significant accounting policies and basis of presentation

Organization

Albireo Pharma, Inc. (Parent), together with its direct and indirect subsidiaries (the Company), is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel bile acid modulators to treat orphan pediatric liver diseases and other liver and gastrointestinal diseases and disorders. The Company's clinical pipeline includes a Phase 3 lead product, a Phase 2 product candidate, and elobixibat, which is approved in Japan for the treatment of chronic constipation. Odevixibat, the Company's Phase 3 lead product, is in development as a once per-day treatment given orally in a capsule or sprinkled over food, initially being evaluated using the planned commercial formulation in patients with progressive familial intrahepatic cholestasis (PFIC) types 1 and 2. PFIC is a rare, life-threatening genetic disorder affecting young children.

Basis of presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information, and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the audited consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018. The Company combined prepaid expenses and other assets with other receivables and reflected this in the Condensed Consolidated Balance Sheets. The Company combined prepaid expenses and other assets with other receivables and trade receivables in the Condensed Consolidated Statements of Cash Flows. These combinations are reflected at September 30, 2019 and December 31, 2018, and for the nine months ended September 30, 2019 and 2018, respectively, with a change in the prior period presentation being made to conform to the current period presentation. There was no change to previously reported net loss or total comprehensive loss in the prior period presented as a result. In the opinion of management, all adjustments (including normal recurring adjustments) considered necessary for fair presentation have been included in the Condensed Consolidated Financial Statements. The results of operations for the nine months ended September 30, 2019 are not necessarily indicative of the results that may be expected for the full fiscal year, any other interim period or any future fiscal year. The condensed consolidated financial statements are prepared on a basis consistent with prior periods except for the adoption of the new leasing standard discussed below.

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

Principles of consolidation

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

Foreign currency translation

Functional currency

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

Transactions and balances

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

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

a. assets and liabilities presented are translated at the closing exchange rate as of September 30, 2019 and December 31, 2018;

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

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

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

Use of estimates

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

Revenue recognition

Milestone Payments

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

Royalties

In 2012, the Company entered into a license agreement (the Agreement) with EA Pharma Co., Ltd. (EA Pharma, formerly Ajinomoto Pharmaceuticals Co., Ltd.) to develop a select product candidate (elobixibat) for registration and subsequent commercialization in select markets. In conjunction with the Agreement, the Company granted EA Pharma an exclusive license to its intellectual property for development and commercialization activities in the designated field and territories. The Company is entitled to payments resulting from pharmaceutical ingredient or related procurement services if provided as part of a development plan. Revenue related to these payments is recorded on a net basis; in this

instance, the Company acts as an agent, as it does not have discretion to change suppliers and does not perform any part of the services or manufacture of the subject pharmaceutical ingredients. The costs associated with these activities are netted against the related revenue in the condensed consolidated statements of operations.

As of September 30, 2019, the Company is eligible to receive a regulatory-based milestone payment under the Agreement of €4.3 million ($4.7 million based on the Euro to USD exchange rate as of September 30, 2019) if a specified regulatory event is achieved for elobixibat. The cash payments and any other payments for milestones and royalties from EA Pharma are non-refundable, non-creditable and not subject to set-off.

In January 2018, the Japanese Ministry of Health Labour and Welfare (MHLW) approved a new drug application filed by EA Pharma for elobixibat for the treatment of chronic constipation, for which the Company received a milestone payment of $11.2 million. Based on the regulatory approval, the Company determined that the milestone was no longer at risk of significant reversal. As such, because the single performance obligation had previously been satisfied, the Company recognized this amount in full in the first quarter of 2018 and there was no deferred revenue or contract asset as of December 31, 2018. The Company recognizes the royalty revenue based on the estimated qualifying sales by EA Pharma each period.

Monetization of Future Royalties

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

The following table shows the activity within the liability account for the period ended September 30, 2019:

	September 30, 2019 (in thousands)
Liability related to sale of future royalties—beginning balance	$ 50,546
Foreign currency translation gain	73
Accretion of interest expense on liability related to royalty monetization	6,179
Repayment of the liability	(2,343)
Liability related to sale of future royalties—ending balance	$ 54,455
Less current portion classified within accrued expenses	(1,382)
Net ending liability related to sale of future royalties	$ 53,073

The Company records estimated royalties due for the current period in accrued other expenses until the payment is received from EA Pharma at which time the Company then remits payment to HCR. As royalties are remitted to HCR, the balance of the royalty obligation will be effectively repaid over the life of the RIAA. In order to determine the amortization of the royalty obligation, the Company is required to estimate the total amount of future royalty payments to be received and submitted to HCR, as noted above, based on the Company's best estimate of the time it will take to reach the cap amount and when milestones will be received. The sum of these amounts less the $44.5 million proceeds the Company received will be recorded as interest expense over the life of the royalty obligation. Since inception, the Company's estimate of its total interest expense resulted in a quarterly effective interest rate of approximately 4.03%.

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

Recently adopted accounting pronouncements

As of January 1, 2019, the Company adopted 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. The Company has applied the transition provisions at the beginning of the period of adoption, which results in recording the cumulative adjustment to the opening balance sheet as of January 1, 2019. Under this transition provision, the Company will continue to apply the legacy guidance under ASC 840, *Leases*, including its disclosure requirements, in the comparative periods presented in fiscal 2019. On the date of the adoption, the Company recorded a ROU asset of $1.2 million and lease liabilities of $1.2 million. Additionally, the Company elected the following practical expedients: the Company has elected to not separate lease components from non-lease components in its lease contract; the Company will not apply the recognition requirements of ASC 842 to its leases with lease terms of 12 months or less but rather recognize the lease expense on a straight-line basis over the lease term; *Relief package* – the Company has not reassessed whether expired or existing contracts may contain a lease, the lease classification of expired or existing leases and whether previously capitalized indirect costs would qualify for capitalization under ASC 842. *Use of hindsight* – the Company has elected to use hindsight in assessing the likelihood of renewals, terminations and purchase options and in assessing impairment of ROU assets. *Portfolio approach* – the Company has elected to not apply the portfolio approach for groups of leases with similar characteristics.

2. Fair Value of financial instruments

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

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

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

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

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

3. Commitments and contingencies

Commercial real estate leases

The Company's portfolio of commercial real estate leases consists of office space for its corporate headquarters in Boston, Massachusetts and for administrative space in Göteborg, Sweden, both of which are accounted for as operating leases. These leases include renewal rights and, as for the corporate headquarters lease, escalating payments. On March 28, 2019, the Company entered into an amendment to the Boston, Massachusetts lease to (i) replace the Company's prior office space with a new office space that is being leased from the same landlord and (ii) extend the term of the lease through the date ending eighty-eight months following July 1, 2019, when the Company took control of the new leased space. The new leased space contains monthly lease payments subject to annual escalations of $1.00 per square foot for the remaining term of the lease with the Company obligated to make approximately $6.6 million of aggregate lease payments over the term of the lease, or approximately $900,000 annually.

The Company's lease in Göteborg, Sweden includes the rental of office and contained an original expiration date in November 2019. This lease includes annual rent escalations based on the changes in the Swedish Consumer Price Index. This lease renews automatically for consecutive three year terms unless notice of non-renewal is given by either party at least nine months prior to the end of the current term and subject to the Company's right to terminate the lease at any time upon six months' notice. Subsequent to the year ended December 31, 2018, this lease was renewed for an additional three year period through February 2022, with quarterly payments of $32,000.

As of September 30, 2019, the net balance of ROU assets totaled $4.8 million and were classified within other non-current assets. The current and long-term balances of lease liabilities at September 30, 2019 were $0.5 million and $4.3 million, respectively, and were classified within other liabilities, and long-term liabilities, respectively. Operating lease expense under ASC 842 was $0.3 million and $0.4 million, respectively, for the three months and nine months ended September 30, 2019. There were no short-term lease or variable lease costs incurred for the three months and nine months ended September 30, 2019. As of September 30, 2019, the weighted average remaining lease term for the Company's operating leases was 6.87 years. As of September 30, 2019, the weighted- average discount rate was 9.95%. Rent expense recognized under legacy GAAP for the Company's operating leases was $0.1 million and $0.3 million for the three and nine months ended September 30, 2018, respectively.

The following table summarizes the Company's significant contractual obligations under operating leases as of payment due date by period at September 30, 2019:

	Total Minimum Lease Payments (in thousands)
2019 (Remainder of year)	$ 224
2020	1,003
2021	1,007
2022	906
2023	921
2024 and beyond	2,690
Total minimum lease payments	$ 6,751
Less imputed interest	(1,910)
Total lease liability	$ 4,841
Reported as:	
Other current liabilities	$ 514
Other long-term liabilities	4,327
Total lease liabilities	$ 4,841

Agreements with CROs

As of September 30, 2019, the Company had various agreements with CROs for the conduct of specified research and development activities. Based on the terms of the respective agreements, the Company may be required to make future payments of up to $20.3 million to CROs upon the completion of contracted work.

Legal Contingency

On February 19, 2019, the Company filed a complaint for breach of contract and breach of implied covenant of good faith and fair dealing against Ferring International Center S.A. (the Respondent) in the United States District Court for the Southern District of New York. Based on procedural considerations, we decided to refile the complaint in the Supreme Court of the State of New York, County of New York on April 26, 2019. We previously entered into the License Agreement, dated July 2, 2012, as amended as of October 2013 (the License Agreement), by and between Respondent and us, pursuant to which Respondent, among other things, conducted two Phase 3 clinical trials to evaluate the efficacy and safety of elobixibat as a treatment for chronic idiopathic constipation, known as Echo 1 and Echo 2, which ended in 2014. As previously disclosed, Respondent stopped Echo 1 and Echo 2 early citing an issue related to the distribution of study drug to study sites that was unrelated to the performance of elobixibat and terminated the License Agreement. The complaint alleges that Respondent breached its obligations under the License Agreement to (1) make earned milestone payments, (2) use good clinical practices, good laboratory practices and good manufacturing practices, and (3) use commercially reasonable efforts. The complaint also alleges that Respondent violated the covenant of good faith and fair dealing implied in the License Agreement. In the complaint, the Company is seeking, among other things, compensatory damages of at least € 37 million (converted to $40.5 million as of September 30, 2019). On July 31, 2019 Respondent filed a motion to dismiss the complaint. The Company filed an answer to Respondent's motion on September 30, 2019.

The Company has retained outside counsel under a contingency fee arrangement, and as a result, the Company will not incur attorneys' fees for litigating the matter, but counsel will receive a contingent fee of 33 1/3% of the net recovery (after deduction of expenses) in the event a recovery is received.

Due to their nature, it is difficult to predict the outcome, or the costs involved in any litigation. Furthermore, Respondent may have significant resources and interest to litigate and therefore, although we have a contingency fee arrangement, this litigation could be protracted and may ultimately involve significant legal expenses.

4. Net loss per share

Basic net loss per share, or Basic EPS, is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding. Diluted net loss per share, or Diluted EPS, is calculated by dividing the net loss by the weighted-average number of shares of common stock plus 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Basic and Diluted EPS:				
Numerator				
Net loss	$ (21,910)	$ (14,025)	$ (55,195)	$ (30,247)
Denominator				
Weighted average number of shares outstanding	12,685,000	11,969,791	12,349,870	11,612,760
Basic and Diluted EPS	$ (1.73)	$ (1.17)	$ (4.47)	$ (2.60)

The following outstanding common stock equivalents were excluded from the computation of Diluted EPS for the three and nine months ended September 30, 2019 and 2018 because including them would have been anti-dilutive:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Options to purchase common stock and RSUs	1,759,963	1,442,361	1,759,963	1,442,361

5. Income taxes

The Company did not record a tax provision or benefit for the three months ended September 30, 2019 or 2018. The Company has continued to maintain a full valuation allowance against its net deferred tax assets. The Company has had an overall net operating loss position since its inception.

6. Financings

At-the-Market Offering Program

In October 2017, the Company entered into an at-the-market offering program, which we refer to as the 2017 Sales Agreement relating to the sale of shares of the Company's common stock having an aggregate offering price of up to $50.0 million. In February 2018, the Company sold an aggregate of 728,862 shares of common stock pursuant to the 2017 Sales Agreement and received proceeds, net of offering expenses, of approximately $24.2 million. On March 6, 2019, the Company terminated the 2017 Sales Agreement and entered into a new sales agreement, which we refer to as the 2019 Sales Agreement, with respect to an at-the-market offering program relating to the sale of shares of the Company's common stock having an aggregate offering price of up to $50.0 million. In May 2019, the Company sold an aggregate of 637,367 shares of common stock pursuant to the 2019 Sales Agreement and received proceeds, net of offering expenses, of approximately $20.8 million.

January 2018 Underwritten Public Offering

On January 9, 2018, the Company completed an underwritten public offering of 2,265,500 shares of its common stock, at a price to public of $33.00 per share. The Company received net proceeds from this offering of $69.9 million, after deducting underwriting discounts, commission and offering expenses.

7. Stock-based Compensation

The Company granted 496,361 options at a weighted average price of $25.64 and 52,000 RSUs with a weighted average grant date fair value of $26.31 during the nine months ended September 30, 2019.

The Company recorded the following stock-based compensation expense:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
Employee awards:				
Research and development expense	$ 742	$ 549	$ 2,242	$ 1,260
General and administrative expense	1,084	1,074	3,456	2,608
Total stock-based compensation expense	$ 1,826	$ 1,623	$ 5,698	$ 3,868

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, 2018, 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, 2018, in Item 1A of Part II of this Quarterly Report on Form 10-Q, in Item 1A of part II of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, or in other filings that we make with the SEC.

Overview

We are a biopharmaceutical company focused on the development and commercialization of novel bile acid modulators to treat orphan pediatric liver diseases and other liver or gastrointestinal diseases and disorders. The initial target indication for our lead product candidate, odevixibat, 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 completed a Phase 2 clinical trial of odevixibat in children with chronic cholestasis and pruritus, and in May of 2018 we enrolled the first patient in our Phase 3 clinical trial for odevixibat, given once per day as an oral capsule or sprinkled over food, in patients with PFIC types 1 and 2, which we refer to as PEDFIC 1. We are using the planned commercial formulation in PEDFIC 1, but any commercial product will include final trade dress. In the first quarter 2019, we revised our statistical analysis methodology for PEDFIC 1, in line with guidance from the FDA. One result of the revision is an improvement in the power of the study. We expect to have top line data from PEDFIC 1 in mid-2020. We also submitted a protocol amendment for PEDFIC 2, our long term, open label extension study, which includes an additional cohort of PFIC patients who are not eligible for PEDFIC 1. The first sites have been activated and first patients enrolled in the expanded PEDFIC 2 cohort. In June of 2018, the FDA granted a rare pediatric disease designation to odevixibat for the treatment of PFIC, which affirms our eligibility to apply for a rare pediatric disease priority review voucher upon submission of a new drug application for odevixibat. In September of 2018, the FDA granted fast track designation for odevixibat for the treatment of pruritus associated with PFIC. In October of 2018, the FDA granted orphan drug designation to odevixibat for the treatment of Alagille syndrome, or ALGS, a rare, life threatening disease that affects the liver and for which there is no approved pharmacologic treatment option. In December of 2018, the European Commission granted orphan designation to odevixibat for the treatment of biliary atresia, another rare, life threatening disease that affects the liver and for which there is no approved pharmacologic treatment option. In January of 2019, the FDA granted orphan drug designation to odevixibat for the treatment of biliary atresia. In addition to PFIC, we plan to initiate a pivotal clinical trial for odevixibat in biliary atresia, which we believe to be one of the most common rare pediatric liver diseases, in 2020, and we plan to conduct clinical development of odevixibat in 2020 as a treatment for one or more other pediatric cholestatic liver diseases and disorders. Our most advanced product candidates in addition to odevixibat include elobixibat, which is approved in Japan for the treatment of chronic constipation and for which we initiated a Phase 2 clinical trial as a treatment for nonalcoholic fatty liver disease, or NAFLD, and NASH, with the first patients enrolled in June 2019. A3384 is another product candidate for which we are exploring additional clinical development based on an evaluation of its patent coverage and our overall portfolio. We have method of use patents for odevixibat with a natural expiry in 2031, but which can run through 2034 with potential patent term extensions. In June 2018, we were granted a patent for a method of using elobixibat to treat NASH in both the U.S. and Europe. We also have a preclinical program in NASH.

The precise prevalence of PFIC is unknown, and we are not aware of any patient registries or other method of establishing with precision the actual number of patients with PFIC in any geography. PFIC has been estimated to affect between one in every 50,000 to 100,000 children born worldwide. Based on the published incidence, published regional populations, and estimated median life expectancies, we estimate the prevalence of PFIC across the spectrum of the disease to be approximately 8,000 to 10,000 patients in the U.S. and E.U., but we are not able to estimate the prevalence of PFIC with precision.

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

Other Indications Under Development for Odevixibat. We plan to initiate a pivotal clinical trial with odevixibat in biliary atresia in 2020. We plan to conduct clinical development of odevixibat in 2020 as a treatment for other pediatric cholestatic liver diseases and disorders as well, which may include ALGS and primary sclerosing cholangitis.

Biliary atresia is a partial or total blocking or absence of large bile ducts that causes cholestasis and resulting accumulation of bile that damages the liver. The estimated worldwide incidence of biliary atresia is between 4.5 and 8.5 for every 100,000 live births. There are currently no drugs approved for the treatment of biliary atresia. The current standard of care is a surgery known as the Kasai procedure, or hepatoportoenterostomy, in which the obstructed bile ducts are removed and a section of the small intestine is connected to the liver directly. However, only an estimated 25% of those initially undergoing the Kasai procedure will survive to their twenties without need for liver transplantation. The European Commission granted orphan designation to odevixibat for the treatment of biliary atresia in December of 2018. In January of 2019, the FDA granted orphan drug designation to odevixibat for the treatment of biliary atresia. We intend to initiate a pivotal clinical trial with odevixibat for the treatment of biliary atresia in 2020.

ALGS is a genetic condition associated with liver, heart, eye, kidney and skeletal abnormalities. In particular, ALGS patients have fewer than normal bile ducts inside the liver, which leads to cholestasis and the accumulation of bile and causes scarring in the liver. ALGS is estimated to affect between one in every 30,000 to 70,000 children born worldwide. There are currently no drugs approved for the treatment of ALGS. Current treatment for ALGS is generally in line with current treatments for PFIC as described above. In October of 2018, the FDA granted orphan drug designation to odevixibat for the treatment of ALGS.

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

Elobixibat as a potential treatment for NASH. NASH is a common, serious and sometimes fatal chronic liver disease that resembles alcoholic liver disease but occurs in people who drink little or no alcohol. Based on multiple epidemiological studies published by third parties in 2014 and 2015, we estimate that NASH affects 2 to 3.5% of adults, representing over 9 million people in the United States and 10 million people in the European Union. There are currently no drugs approved for the treatment of NASH. Lifestyle changes, including modification of diet and exercise to reduce body weight, as well as treatment of concomitant diabetes and dyslipidemia, are commonly accepted as the standard of care for NASH, but have not conclusively been shown to prevent disease progression. Based on findings on parameters relevant to NASH in clinical trials of elobixibat that we previously conducted in patients with chronic constipation and in patients with elevated cholesterol and findings on other parameters relevant to NASH from nonclinical studies that we previously conducted with elobixibat or a different IBAT inhibitor, we believe elobixibat has potential benefit in the treatment of NASH. We initiated our Phase 2 clinical trial of elobixibat in NAFLD and NASH, with the first patients enrolled in June 2019.

Since inception, we have incurred significant operating losses. As of September 30, 2019, we had an accumulated deficit of $151.7 million. We expect to continue to incur significant expenses and increasing operating losses as we continue our development of, and seek marketing approvals for, our product candidates, prepare for and begin the

commercialization of any approved products, and add infrastructure and personnel to support our product development efforts and operations as a public company in the United States.

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

As of September 30, 2019, we had approximately $142.7 million in cash and cash equivalents.

Financial Operations Overview

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

Revenue

We generate revenue primarily from the receipt of royalty revenue, upfront or license fees and milestone payments. License agreements with commercial partners generally include nonrefundable upfront fees and milestone payments, the receipt of which is dependent upon the achievement of specified development, regulatory or commercial milestone events, as well as royalties on product sales of licensed products, if and when such product sales occur, and payments for pharmaceutical ingredient or related procurement services. For these agreements, management applies judgment in the allocation of total agreement consideration to the performance obligations on a reliable basis that reasonably reflects the selling prices that might be expected to be achieved in stand-alone transactions. For additional information about our revenue recognition, refer to Note 1 to our condensed consolidated financial statements included in this quarterly report.

Operating Expenses

Research and Development Expenses

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

Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of external costs such as fees paid to CROs and others in connection with our nonclinical and clinical development activities and related manufacturing. We do not allocate employee costs or facility expenses, including depreciation or other indirect costs, to specific product development programs because these costs are deployed across multiple product development programs and, as such, are not separately classified.

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

General and Administrative Expenses

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

Critical Accounting Policies and Estimates

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

Our critical accounting policies and the methodologies and assumptions we apply under them have not materially changed since March 6, 2019, the date we filed our Annual Report on Form 10-K for the year ended December 31, 2018, except for the adoption of ASC 842, Leases as further described in the footnotes to the condensed consolidated financial statements. For more information on our critical accounting policies, refer to our Annual Report on Form 10-K for the year ended December 31, 2018.

Results of Operations

Three Months Ended September 30, 2019 and September 30, 2018

Result of Operations

	Three Months Ended September 30,		Change
	2019	2018	$
	(in thousands)		
Revenue	$ 1,385	$ 237	$ 1,148
Operating Expenses			
Research and development	11,996	9,666	2,330
General and Administrative	6,010	3,850	2,160
Other operating expense (income), net	4,015	(614)	4,629
Total operating expenses	22,021	12,902	9,119
Operating loss	(20,636)	(12,665)	(7,971)
Interest income (expense), net	(1,274)	(1,367)	93
Non-operating expense, net	-	7	(7)
Net loss	$ (21,910)	$ (14,025)	$ (7,885)

Revenue

	Three Months Ended September 30,		Change
	2019	2018	$
	(in thousands)		
Revenue	$ 1,385	$ 237	$ 1,148

There was $1.4 million in revenue for the three months ended September 30, 2019 compared with $0.2 million for the three months ended September 30, 2018, an increase of $1.2 million. The higher revenue is due to the estimated royalty revenue received from EA Pharma for elobixibat for the treatment of chronic constipation.

Research and development expenses

	Three Months Ended September 30,		Change
	2019	2018	$
	(in thousands)		
Research and development expenses	$ 11,996	$ 9,666	$ 2,330

Research and development expenses were $12.0 million for the three months ended September 30, 2019 compared with $9.7 million for the three months ended September 30, 2018, an increase of $2.3 million. The higher research and development expenses for the 2019 period were principally due to personnel expenses, and program expenses as we continue to increase our headcount, and program activities, respectively.

The following table summarizes our principal product development programs and the out-of-pocket third-party expenses incurred with respect to each clinical-stage product candidate and our preclinical programs for the three months ended September 30, 2019 and 2018.

	Three Months Ended September 30,		Change
	2019	2018	$
	(in thousands)		
Direct third-party project costs:			
Odevixibat	$ 5,754	$ 5,351	$ 403
Elobixibat	1,102	284	818
A3384	141	162	(21)
Preclinical	689	794	(105)
Total	$ 7,686	$ 6,591	$ 1,095
Other project costs[1]:			
Personnel costs	$ 2,944	$ 2,048	$ 896
Other costs[2]	1,366	1,027	339
Total	$ 4,310	$ 3,075	$ 1,235
Total research and development costs	$ 11,996	$ 9,666	$ 2,330

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

General and administrative expenses

	Three Months Ended September 30,		Change
	2019	2018	$
	(in thousands)		
General and administrative expenses	$ 6,010	$ 3,850	$ 2,160

General and administrative expenses were $6.0 million for the three months ended September 30, 2019 compared with $3.9 million for the three months ended September 30, 2018, an increase of $2.1 million. The increase is primarily attributable to personnel and related expenses as we continue to increase our headcount.

Other operating expense, net

	Three Months Ended September 30,		Change
	2019	2018	$
	(in thousands)		
Other operating expense (income), net	$ 4,015	$ (614)	$ 4,629

Other operating expense, net totaled $4.0 million for the three months ended September 30, 2019 compared with $0.6 million of other operating income for the three months ended September 30, 2018. The difference primarily relates to translation exchange rates in the two periods..

Interest expense, net

	Three Months Ended September 30,		Change
	2019	2018	$
	(in thousands)		
Interest expense, net	$ (1,274)	$ (1,367)	$ 93

Interest expense, net totaled $1.3 million of expense for the three months ended September 30, 2019 compared with $1.4 million of expense for the three months ended September 30, 2018. The difference was principally attributable to interest income associated with our interest bearing cash and cash equivalents offset by non-cash interest expense recorded in connection with the sale of future royalties, related to sales of elobixibat in Japan.

Non-operating income, net

	Three Months Ended September 30,		Change
	2019	2018	$
	(in thousands)		
Non-operating income, net	$ —	$ 7	$ (7)

Non-operating income, net for the three months ended September 30, 2018 was approximately $0.0 million primarily related to the gain in foreign currency associated with our royalty monetization in 2018. There was no other non-operating expense, net for the three months ended September 30, 2019.

Nine Months Ended September 30, 2019 and September 30, 2018

	Nine Months Ended September 30,		Change
	2019	2018	$
	(in thousands)		
Revenue	$ 3,205	$ 12,169	$ (8,964)
Operating Expenses			
Research and development	31,359	22,228	9,131
General and Administrative	16,788	12,216	4,572
Other operating expense (income), net	6,319	1,377	4,942
Total operating expenses	54,466	35,821	18,645
Operating loss	(51,261)	(23,652)	(27,609)
Interest income (expense), net	(3,934)	(4,049)	115
Non-operating expense, net	-	(2,546)	2,546
Net loss	$ (55,195)	$ (30,247)	$ (24,948)

Revenue

	Nine Months Ended September 30,		Change
	2019	2018	$
	(in thousands)		
Revenue	$ 3,205	$ 12,169	$ (8,964)

There was $3.2 million in revenue for the nine months ended September 30, 2019 compared with $12.2 million for the nine months ended September 30, 2018, a decrease of $9.0 million. The decrease in revenue is due to a milestone payment received in the second quarter of 2018 from EA Pharma due to the approval by the Japanese MHLW of the drug application for elobixibat for the treatment of chronic constipation and the estimated royalty revenue from EA Pharma for elobixibat for the period.

Research and development expenses

	Nine Months Ended September 30,		Change
	2019	2018	$
	(in thousands)		
Research and development expenses	$ 31,359	$ 22,228	$ 9,131

There was $31.4 million in research and development expenses for the nine months ended September 30, 2019 compared with $22.2 million for the nine months ended September 30, 2018, an increase of $9.2 million. The higher research and development expenses for the 2019 period were principally due to personnel expenses, and program expenses as we continue to increase our headcount, and program activities, respectively.

The following table summarizes our principal product development programs and the out-of-pocket third-party expenses incurred with respect to each clinical-stage product candidate and our preclinical programs for the nine months ended September 30, 2019 and 2018.

	Nine Months Ended September 30,		Change
	2019	2018	$
	(in thousands)		
Direct third-party project costs:			
Odevixibat	$ 13,587	$ 12,202	$ 1,385
Elobixibat	2,473	379	2,094
A3384	366	495	(129)
Preclinical	3,009	1,595	1,414
Total	$ 19,435	$ 14,671	$ 4,764
Other project costs[1]:			
Personnel costs	$ 8,414	$ 4,805	$ 3,609
Other costs[2]	3,510	2,752	758
Total	$ 11,924	$ 7,557	$ 4,367
Total research and development costs	$ 31,359	$ 22,228	$ 9,131

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

General and administrative expenses

	Nine Months Ended September 30,		Change
	2019	2018	$
	(in thousands)		
General and administrative expenses	$ 16,788	$ 12,216	$ 4,572

There was $16.8 million in general and administrative expenses for the nine months ended September 30, 2019 compared with $12.2 million for the nine months ended September 30, 2018, an increase of $4.6 million. The increase is primarily attributable to personnel and related expenses as we continue to increase our headcount.

Other operating expense, net

	Nine Months Ended September 30,		Change
	2019	2018	$
	(in thousands)		
Other operating expense (income), net	$ 6,319	$ 1,377	$ 4,942

Other operating expense, net totaled $6.3 million for the nine months ended September 30, 2019 compared with $1.4 million for the nine months ended September 30, 2018. The difference primarily relates to translation from changes in exchange rates in the two periods

Interest expense, net

	Nine Months Ended September 30,		Change
	2019	2018	$
	(in thousands)		
Interest expense, net	$ (3,934)	$ (4,049)	$ 115

Interest expense, net totaled $3.9 million of expense for the nine months ended September 30, 2019 compared with $4.0 million of expense for the nine months ended September 30, 2018. The difference was principally attributable to non-cash interest expense recorded in connection with the sale of future royalties, related to sales of elobixibat in Japan, offset by interest income.

Non-operating expense, net

	Nine Months Ended September 30,		Change
	2019	2018	$
		(in thousands)	
Non-operating expense, net	$ —	$ (2,546)	$ 2,546

Non-operating expense, net for the nine months ended September 30, 2018 was $2.5 millionprimarily related to the foreign currency expense associated with our royalty monetization in 2018. There was no other non-operating expense, net for the nine months ended September 30, 2019.

Liquidity and Capital Resources

Sources of Liquidity

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

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

As of September 30, 2019, our cash and cash equivalents were approximately $142.7 million.

During the first quarter of 2018, following the Japanese MHLW's approval of elobixibat for the treatment of chronic constipation in January 2018, we received a $44.5 million payment, net of certain transaction expenses, from HCR under our RIAA. Under the terms of the RIAA, we are eligible to receive an additional $15.0 million if a specified sales milestone is achieved for elobixibat in Japan. Additionally, this approval triggered a milestone payment to us from EA Pharma of $11.2 million. As of September 30, 2019, we have received approximately $45.4 million in upfront and milestone payments from EA Pharma under a license agreement for the development and commercialization of elobixibat in specified countries in Asia. We are eligible to receive additional amounts of up to $4.7 million under the amended agreement, if a specified regulatory event is achieved for elobixibat. In addition, subject to the terms of the RIAA with HCR, we may in the future also become eligible under the license agreement to receive up to $31.9 million, if specified sales milestones are achieved for elobixibat and stepped royalties at rates beginning in the high single digits on any future elobixibat product sales.

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

These sales were registered on our universal shelf registration statement on Form S-3, which was declared effective on December 5, 2017, or the 2017 Form S-3.

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

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

Cash Flows

Nine Months Ended September 30, 2019 and September 30, 2018

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (40,519)	(16,806)
Investing activities	(523)	(47)
Financing activities	22,252	139,171
Total	$ (18,790)	$ 122,318
Effect of exchange rate changes on cash and cash equivalents	(2,429)	(1,947)
Net (decrease) increase in cash and cash equivalents	(21,219)	120,371

Operating activities

Cash used in operating activities of $40.5 million during the nine months ended September 30, 2019 was primarily a result of our $55.2 million net loss from operations and a net decrease in assets and liabilities of $5.6 million. The net decrease in operating assets and liabilities during the nine months ended September 30, 2019 was primarily driven by decreases in accounts payable and, accrued expenses and an increase to prepaid expenses and other current assets, and other assets. This decrease was offset by non cash items, including $8.3 million of foreign currency adjustments, $6.2 million of non cash interest expense on liability related to royalty monetization, and $5.7 million of stock-based compensation expense. Cash used in operating activities was $16.8 million during the nine months ended September 30, 2018. The cash used in operating activities was primarily a result of our $30.2 million net loss from operations offset by non-cash items, including $4.9 million of non cash interest expense on liability related to royalty monetization, $4.8 million in foreign currency adjustments, and $3.9 million of stock-based compensation expense.

Investing activities

Cash used in investing activities of $0.5 million during the nine months ended September 30, 2019 was primarily due to the purchase of property, plant and equipment. Cash used in investing activities of $0.1 million during the nine months ended September 30, 2018 was primarily due to the purchase of property, plant and equipment.

Financing activities

Cash provided by financing activities of $22.3 million during the nine months ended September 30, 2019 was primarily related to proceeds from the issuance of common stock, net of issuance costs of $20.8 million and proceeds from exercise of options of $1.5 million. Cash provided by financing activities of $139.2 million during the nine months ended

September 30, 2018 was primarily related to proceeds from the issuance of common stock, net of issuance costs of $94.1 million and royalty monetization of $44.5 million.

Funding Requirements

Cash used to fund operating expenses is affected by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. We believe that our existing cash and cash equivalents will be sufficient to meet our projected operating requirements at least into 2021, including for our Phase 3 clinical program for odevixibat in PFIC, but we will need additional financing to develop odevixibat for the treatment of one or more pediatric liver diseases in 2020. However, our operating plans may change as a result of many factors, including those described below, and we may need additional funds sooner than planned to meet operational needs and capital requirements. In addition, if the conditions for raising capital are favorable we may seek to raise additional funds at any time.

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

- the costs, design, duration and any potential delays of the Phase 3 clinical trial of odevixibat;
- the scope, number, progress, duration, cost, results and timing of clinical trials and nonclinical studies of our current or future product candidates;
- whether and to what extent milestone events are achieved under our license agreement with EA Pharma, our RIAA with HCR or any potential future licensee or collaborator;
- the outcomes and timing of regulatory reviews, approvals or other actions;
- our ability to obtain marketing approval for our product candidates;
- our ability to establish and maintain additional licensing, collaboration or similar arrangements on favorable terms and whether and to what extent we retain development or commercialization responsibilities under any new licensing, collaboration or similar arrangement;
- the success of any other business, product or technology that we acquire or in which we invest;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio;
- our ability to manufacture any approved products on commercially reasonable terms;
- our ability to establish a sales and marketing organization or suitable third-party alternatives for any approved product;
- the number and characteristics of product candidates and programs that we pursue;
- the costs of acquiring, licensing or investing in businesses, product candidates and technologies;
- our need and ability to hire additional management and scientific and medical personnel;
- the costs to operate as a public company in the United States, including the need to implement additional financial and reporting systems and other internal systems and infrastructure for our business;
- market acceptance of our product candidates, to the extent any are approved for commercial sale; and
- the effect of competing technological and market developments.

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

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

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

We filed a new universal shelf registration on Form S-3 with the SEC on March 6, 2019, which was declared effective on April 30, 2019, pursuant to which we registered for sale up to $200.0 million of any combination of our common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that we may determine, which we refer to as the 2019 Form S-3. On March 6, 2019, we terminated the 2017 Sales Agreement and entered into a new sales agreement, which we refer to as the 2019 Sales Agreement, with respect to an at-the-market offering program under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate value up to $50.0 million. In May 2019, we sold 637,367 shares of our common stock under the 2019 Sales Agreement for an aggregate of $21.4 million of gross proceeds, which results in $178.6 million of securities remaining available for issuance under the 2019 Form S-3, including $28.6 million of shares of common stock remaining available for issuance under the 2019 Sales Agreement. We make no assurances as to the continued effectiveness of the 2019 Form S-3. No additional securities registered under the 2017 Form S-3 will be offered or sold.

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 in our "Management's Report on Internal Control over Financial Reporting" in our Form 10-K for the year ended December 31, 2018 and 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.

Our management assessed the effectiveness of the Company's internal controls over financial reporting as of September 30, 2019. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013 framework).

Based on our assessment, our management concluded that the material weaknesses reported in our Annual Report on Form 10-K for the year ended December 31, 2018 remain un-remediated as of September 30, 2019.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. As previously disclosed, the identified material weaknesses relate to our internal control processes and involve the control environment, risk assessment, control activity and monitoring activities. During the nine-month period ended September 30, 2019, significant work has been undertaken to remediate the causes of the material weaknesses. Specifically, we have increased the staff of our finance organization including hiring individuals with experience in U.S. GAAP and SEC reporting and/or skills in and ability to focus on internal control over financial reporting matters. Revised processes and redesigned financial reporting controls have been implemented. General information technology controls to support the effective operation of financial controls have been enhanced to address insufficient design. The material weaknesses will not be considered remediated until the redesigned and enhanced controls operate for a sufficient period of time and management has concluded, through testing, that the controls are operating effectively. Because of the material weaknesses described above, our management believes that, as of September 30, 2019, our internal controls over financial reporting were not effective.

Our management remains committed to taking remediating actions to ensure that we become compliant with the requirements of Section 404 of the Sarbanes-Oxley Act 2002. Even though significant progress has been made to strengthen our controls, further remediation may be needed. As we continue to evaluate and work to improve our internal controls over financial reporting, our management may take additional measures.

Changes in Internal Control over Financial Reporting

Other than as described above, there were no changes in our internal controls over financial reporting identified in connection with the evaluation of such internal controls that occurred during the three months ended September 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

On February 19, 2019, the Company filed a complaint for breach of contract and breach of implied covenant of good faith and fair dealing against Ferring International Center S.A. (the "Respondent") in the United States District Court for the Southern District of New York. Based on procedural considerations, we decided to refile the complaint in the Supreme Court of the State of New York, County of New York on April 26, 2019. We previously entered into the License Agreement, dated July 2, 2012, as amended as of October 2013 (the "License Agreement"), by and between Respondent and us, pursuant to which Respondent, among other things, conducted two Phase 3 clinical trials to evaluate the efficacy and safety of elobixibat as a treatment for chronic idiopathic constipation, known as Echo 1 and Echo 2, which ended in 2014. As previously disclosed, Respondent stopped Echo 1 and Echo 2 early citing an issue related to the distribution of study drug to study sites that was unrelated to the performance of elobixibat and terminated the License Agreement. The complaint alleges that Respondent breached its obligations under the License Agreement to (1) make earned milestone payments, (2) use good clinical practices, good laboratory practices and good manufacturing practices, and (3) use commercially reasonable efforts. The complaint also alleges that Respondent violated the covenant of good faith and fair dealing implied in the License Agreement. In the complaint, the Company is seeking, among other things, compensatory damages of at least € 37 million (Converted to $40.5 million as of September 30, 2019). On July 31, 2019, Respondent filed a motion to dismiss the complaint. The Company filed an answer to Respondent's motion on September 30, 2019.The Company has retained outside counsel under a contingency fee arrangement, and as a result, the Company will not incur attorneys' fees for litigating the matter, but counsel will receive a contingent fee of 33 1/3% of the net recovery (after deduction of expenses) in the event a recovery is received.

Due to their nature, it is difficult to predict the outcome, or the costs involved in any litigation. Furthermore, Respondent may have significant resources and interest to litigate and therefore, although we have a contingency fee arrangement, this litigation could be protracted and may ultimately involve significant legal expenses.

Item 1A. Risk Factors

There have been no material changes to the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission, or SEC, on March 6, 2019, as updated by the risk factosrs described in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, filed with the SEC on August 8, 2019.

Item 6. Exhibits

Exhibit No.	Description	Filed Herewith	Incorporated by Reference Herein from Form or Schedule	Filing Date	SEC File/ Req. Number
10.1*	Employment Agreement dated as of October 31, 2019 by and between the Registrant and Michelle Graham.	X			
31.1	Certification of the Registrant's Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of the Registrant's Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets (unaudited) at September 30, 2019 and December 31, 2018, (ii) Condensed Consolidated Statements of Operations (unaudited) for the three and nine months ended September 30, 2019 and 2018, (iii) Condensed Consolidated Statements of Comprehensive Income (Loss) (unaudited) for the three and nine months ended September 30, 2019 and 2018, (iv) Condensed Consolidated Statement of Stockholders' Equity (unaudited) for the three and nine months ended September 30, 2019 and 2018, (v) Condensed Consolidated Statements of Cash Flows (unaudited) for the three and nine months ended September 30, 2019 and 2018, and (vi) Notes to Condensed Consolidated Financial Statements (unaudited).	X			

* Management contract or compensatory plan or arrangement

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ALBIREO PHARMA, INC.

Dated: November 6, 2019

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

EMPLOYMENT AGREEMENT

This EMPLOYMENT AGREEMENT (this "Agreement") is made and entered into effective as of October 31, 2019 (the "Effective Date") by and between Albireo Pharma, Inc., a Delaware corporation (the "Company"), and Michelle Graham (the "Executive").

RECITALS

WHEREAS, the Company desires to continue to employ the Executive and the Executive desires to be employed on the terms and conditions set forth in this Agreement.

NOW THEREFORE, in consideration of the foregoing premises and the mutual promises, terms, provisions and conditions set forth in this Agreement, the parties hereby agree:

1. Employment. The Executive's employment will commence on or about November 4, 2019.

2. Term. This Agreement will continue in effect until terminated in accordance with Section 5. The term of this Agreement is hereafter referred to as the "Term." The effective date of Executive's termination of employment with the Company is hereafter referred to as the "Termination Date."

3. Duties and Performance.

(a) During the Term, the Executive shall serve the Company as its Chief Human Resources Officer. In addition, and without further compensation, the Executive shall serve as a director and/or officer of the Company and/or one or more of the Company's Affiliates to the extent so elected or appointed from time to time.

(b) During the Term, the Executive shall be employed by the Company on a full-time basis and shall perform the duties and responsibilities of her position and such other duties and responsibilities on behalf of the Company and its Affiliates as reasonably may be designated from time to time by the Company's Chief Executive Officer (the "CEO") or the Company's Board of Directors (the "Board"). The Executive's principal work location shall be in Boston, Massachusetts, subject to such business travel as is customary for Executive's position and, in particular, regular travel to the offices of the Company's Affiliate in Sweden.

(c) During the Term, the Executive shall devote her full business time and best efforts, business judgment, skill and knowledge exclusively to the advancement of the business and interests of the Company and its Affiliates and to the discharge of her duties and responsibilities hereunder. The Executive shall not engage in any other business activity or serve in any industry, trade, professional, governmental or academic position during the term of this Agreement, except as may be expressly approved in advance by the CEO in writing; provided, however, that the Executive may without advance consent participate in charitable activities and passive personal investment activities, provided that such activities do not, individually or in the aggregate: (i) interfere with the performance of the Executive's duties under this Agreement; (ii) conflict with the business interests of the Company or any of its Affiliates; and (iii) violate Sections 7, 8 and 9 of this Agreement.

(d) During the Term, the Executive shall comply with all Company policies, practices, and procedures and all codes of ethics or business conduct applicable to the Executive's position, as in effect from time to time.

4. Compensation and Benefits. As compensation for all services performed by the Executive hereunder during the Term, and subject to performance of the Executive's duties and responsibilities to the Company and its Affiliates, pursuant to this Agreement or otherwise:

(a) Base Salary. During the Term, the Company shall pay the Executive a base salary at a rate of $375,000 per year as of the Effective Date (the "Base Salary"), payable in accordance with the normal payroll practices of the Company as in effect from time to time.

(b) Annual Bonus Compensation. For each full fiscal year completed during the Term, the Executive shall be eligible to participate in an annual bonus plan provided by the Company. The Executive's annual target bonus opportunity shall be thirty-five percent (35%) of the Base Salary (the "Target Bonus"), with the actual amount of the bonus, if any, to be determined by the Board or the Compensation Committee of the Board, in accordance with applicable performance criteria reasonably established by the Board or the CEO. In order to earn an annual bonus under this Section 4(b) for any fiscal year, the Executive must be employed by the Company on the last date of the applicable fiscal year. Any annual bonus payable hereunder will be paid at the same time as such bonuses are paid to similarly situated Company executives, but in no event later than two and one-half months following the end of the fiscal year for which the bonus is earned.

(c) Employee Benefit Plans. During the Term, the Executive shall be eligible to participate in such employee benefit plans from time to time in effect for similarly-situated employees of the Company, which may include short-term disability, long term disability, and 401(k) retirement savings plans, except to the extent any employee benefit plan provides for benefits otherwise provided to the Executive hereunder (e.g., a severance pay plan). Such participation shall be subject to (i) the terms of the applicable plan documents and (ii) generally applicable Company policies. The Executive shall have no recourse against the Company in the event that the Company should alter, modify, add to or eliminate any or all of its employee benefit plans.

(d) Business Expenses. The Company shall pay or reimburse the Executive for reasonable, customary, and necessary business expenses incurred or paid by the Executive in the performance of her duties and responsibilities hereunder, subject to such reasonable substantiation and documentation and to travel and other policies as may be required by the Company from time to time.

(e) Stock Options. The Company shall grant to the Executive a stock option exercisable for 37,500 shares of the Company's common stock, par value $0.01, at an exercise price equal to the fair market value per share on the date of grant (as determined pursuant to the Plan), such stock option to (i) be subject to the terms of the Company's 2018 Equity Incentive Plan, as may be amended from time to time (the "Plan"), and (ii) vest as to 25% of the underlying shares on the first anniversary of the Start Date and thereafter the remaining 75% of the underlying shares shall vest in equal quarterly installments through the fourth anniversary of the Start Date, conditioned upon Executive's continuing employment, and subject to other terms and conditions set forth in an award agreement to be provided by the Company. Nothing herein requires the Board to make additional grants of options or other awards in any year.

(f) Signing Bonus. The Executive shall be eligible to receive a signing bonus of $25,000 (the "Signing Bonus"), which will be paid in a single lump-sum on the first payroll date following January 1, 2020 . Executive shall repay the Signing Bonus to the Company, within thirty (30) days of the Termination Date, if within twelve (12) months of the Start Date: (i) the Executive terminates her employment with the Company; or (ii) the Company terminates his employment for Cause (as defined herein).

5. Termination of Employment; Severance Benefits. The Executive's employment shall terminate under the following circumstances:

(a) Death. In the event of the Executive's death during the Term, the date of death shall be the Termination Date and the Company shall pay or provide to the Executive's designated beneficiary or, if no beneficiary has been designated by the Executive in a notice received by the Company, to her estate: (i) any Base Salary earned but not paid through the Termination Date; (ii) any business expenses incurred by the Executive but unreimbursed on the Termination Date, provided that such expenses and required substantiation and documentation are submitted within sixty (60) days following the Termination Date, that such expenses are reimbursable under Company policy, and that any such expenses subject to Section 5(h)(iv) shall be paid not later than the deadline specified therein; and (iii) any annual bonus earned but not paid for the fiscal year preceding the fiscal year in which the Termination Date occurs (all of the foregoing, payable subject to the timing limitations described herein, the "Final Compensation"). Other than the Final Compensation, the Company shall have no further obligation or liability to the Executive. Other than business expenses described in Section 5(a)(ii), the Final Compensation shall be paid to the Executive's designated beneficiary or estate at the time prescribed by applicable law and in all events within thirty (30) days following the Termination Date.

(b) Disability.

(i) The Company may terminate the Executive's employment, upon notice to the Executive, in the event that the Executive becomes disabled during her employment hereunder through any illness, injury, accident or condition of either a physical or psychological nature and, as a result, is unable to perform substantially all of her duties and responsibilities hereunder (notwithstanding the provision of any reasonable accommodation) for one hundred and eighty (180) days during any period of three hundred and sixty-five (365) consecutive calendar days, whether or not consecutive. In the event of such termination, the Company shall have no further obligation or liability to the Executive, other than for payment of the Final Compensation due the Executive. Other than business expenses described in Section 5(a)(ii), the Final Compensation shall be paid to the Executive at the time prescribed by applicable law and in all events within thirty (30) days following the Termination Date.

(ii) If any question shall arise as to whether the Executive is disabled through any illness, injury, accident or condition of either a physical or psychological nature so as to be unable to perform substantially all of her duties and responsibilities hereunder, the Executive may, and at the request of the Company shall, submit to a medical examination by a physician selected by the Company to whom the Executive or her duly appointed guardian, if any, has no reasonable objection, to determine whether the Executive is disabled, and such determination shall for the purposes of this Agreement be conclusive. If such question shall arise and the Executive shall fail to submit to such medical examination, the Company's determination of the issue shall be binding on the Executive.

(c) By the Company for Cause. The Company may terminate the Executive's employment for Cause at any time upon notice to the Executive setting forth in reasonable detail the nature of such Cause. The following, as determined by the Board in its reasonable judgment, shall constitute Cause for termination:

(i) The Executive's willful failure to perform, or gross negligence in the performance of, the Executive's material duties and responsibilities to the Company or any of its Affiliates that, if capable of cure, is not cured within thirty (30) days of written notice of such failure or negligence by the Company to the Executive; provided, that the Company will not have to provide more than one notice and opportunity to cure with respect to any multiple, repeated, related or substantially similar events or circumstances;

(ii) Conduct by the Executive that constitutes fraud, embezzlement or other material dishonesty with respect to the Company or any of its Affiliates;

(iii) The Executive's commission of, or plea of nolo contendere to, (A) a felony or (B) other crime involving moral turpitude; or

(iv) The Executive's material breach of this Agreement, any material written policies of the Company, or any other agreement between the Executive and the Company or any of its Affiliates or of any fiduciary duty that the Executive has to the Company or any of its Affiliates that, if capable of cure, is not cured within thirty (30) days of written notice of such breach by the Company to the Executive; provided, that the Company will not have to provide more than one notice and opportunity to cure with respect to any multiple, repeated, related or substantially similar events or circumstances.

Upon the giving of notice of termination of the Executive's employment hereunder for Cause, the Company shall have no further obligation or liability to the Executive, other than for the Final Compensation due to the Executive. Other than business expenses described in Section 5(a)(ii), the Final Compensation shall be paid to the Executive at the time prescribed by applicable law and in all events within thirty (30) days following the Termination Date.

(d) By the Company without Cause. The Company may terminate the Executive's employment hereunder without Cause at any time upon notice to the Executive. In the event of such termination at a time other than during the twelve (12) month period following a Change of Control (as defined in the Company's 2018 Equity Incentive Plan, as may be amended from time to time), in addition to the Final Compensation due to the Executive, the Company will pay or provide the Executive the following (the "Severance Benefits"):

(i) the Company will continue to pay the Executive severance pay, at the same monthly rate as the Base Salary, for the twelve (12) month period following the Termination Date (the "Severance Period"); and

(ii) the Company will pay the Executive an amount equal to her then current Target Bonus, payable in substantially equal monthly installments during the Severance Period.

Other than business expenses described in Section 5(a)(ii), the Final Compensation shall be paid to the Executive at the time prescribed by applicable law and in all events within thirty (30) days following the Termination Date. Any obligation of the Company to provide the Severance Benefits is conditioned, however, on the Executive signing and returning to the Company (without revoking) a timely and effective general release of claims in the form provided by the Company by the deadline specified therein, all of which (including the lapse of the period for revoking the release of claims as specified in the release of claims) shall have occurred no later than the sixtieth (60th) calendar day following the date of termination (any such separation agreement submitted by such deadline, the "Release of Claims") and on the Executive's continued compliance in material respects with the obligations of the Executive to the Company and its Affiliates that survive termination of her employment, including without limitation under Sections 7, 8 and 9 of this Agreement. Subject to Section 5(h) below, all Severance Benefits to which the Executive is entitled hereunder shall be payable in accordance with the normal payroll practices of the Company, with the first payment, which shall be retroactive to the day immediately following the Termination Date, being due and payable on the Company's next regular payday for executives that follows the effective date of the Release of Claims. Notwithstanding the foregoing, if the time period to consider, return and revoke the Release of Claims covers two of the Executive's taxable years, any portion of the Severance Benefits that constitutes deferred compensation subject to Section 409A (as defined below) shall in all events be paid in the later taxable year. The Release of Claims required for Severance Benefits in accordance with this Section 5(d) creates legally

binding obligations on the part of the Executive and the Company therefore advises the Executive to seek the advice of an attorney before signing the Release of Claims.

(e) By the Executive for Good Reason. The Executive may terminate her employment for Good Reason by (A) providing notice to the Company specifying in reasonable detail the condition giving rise to the Good Reason no later than the thirtieth (30th) day following the occurrence of that condition; (B) providing the Company a period of thirty (30) days to remedy the condition and so specifying in the notice; and (C) terminating her employment for Good Reason within thirty (30) days following the expiration of the period to remedy if the Company fails to remedy the condition. The following, if occurring without the Executive's consent, shall constitute "Good Reason" for termination by the Executive:

(i) a material diminution in the nature or scope of the Executive's title, duties, authority or responsibilities;

(ii) a requirement that the Executive report to any person other than the CEO or the Board;

(iii) a requirement that the Executive relocate her principal work location to a location more than thirty (30) miles outside of Boston, Massachusetts; or

(iv) a material reduction in Base Salary, which for purposes of this Agreement shall mean a reduction of more than fifteen percent (15%) in the aggregate.

In the event of a termination of employment in accordance with this Section 5(e) at a time other than during the twelve (12) month period following a Change of Control, the Executive will be entitled to receive the Severance Benefits she would have been entitled to receive had she been terminated by the Company without Cause pursuant to Section 5(d) above, provided that the Executive signs and returns (without revoking) a timely and effective Release of Claims as set forth in Section 5(d).

(f) By the Executive without Good Reason. The Executive may terminate her employment hereunder at any time upon thirty (30) days' prior written notice to the Company. In the event of termination of the Executive's employment in accordance with this Section 5(f), the Board may elect to waive the period of notice, or any portion thereof, and, if the Board so elects, the Company will pay the Executive the Base Salary for the period so waived. The Company shall also pay the Executive the Final Compensation due to her (other than business expenses described in Section 5(a)(ii)) at the time prescribed by applicable law and in all events within thirty (30) days following the Termination Date.

(g) Termination Following a Change of Control. In the event of a termination of the Executive's employment within twelve (12) months following a Change of Control either by the Company without Cause (in accordance with Section 5(d)) or by the Executive for Good Reason (in accordance with Section 5(e)) and provided that the Executive signs and returns (without revoking) a timely and effective Release of Claims as set forth in Section 5(d):

(i) The Executive will be entitled to receive the Severance Benefits he would have been entitled to receive had he been terminated by the Company without Cause pursuant to Section 5(d) above, except that the Severance Period shall equal the fifteen (15) month period following the Termination Date; and

(ii) Notwithstanding anything to the contrary, including, without limitation, the Equity Plan or any subsequent equity plan, all equity awards held by the Executive that are outstanding prior to the Change of Control shall, to the extent unvested or subject to vesting-like restrictions, be fully

vested and exercisable (and any vesting-like restrictions shall lapse in full). The foregoing sentence shall be (A) deemed incorporated into each option agreement or similar agreement evidencing awards made to the Executive after the Effective Date and (B) without prejudice to the Executive's right to any earlier acceleration of vesting, continued period of vesting or post-termination rights for the Executive provided for in the applicable plan or program under which such equity award was granted or under applicable law.

The Company shall also pay the Executive the Final Compensation due to him (other than business expenses described in Section 5(a)(ii)) at the time prescribed by applicable law and in all events within thirty (30) days following the Termination Date.

(h) Timing of Payments and Section 409A.

(i) This Agreement and any payments or benefits provided hereunder shall be interpreted, operated and administered in a manner intended to avoid the imposition of additional taxes under Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"). Further, the Company and Executive hereto acknowledge and agree that the form and timing of the payments and benefits to be provided pursuant to this Agreement are intended to be exempt from, or to comply with, one or more exceptions to the requirements of Section 409A of the Code ("Section 409A"). Notwithstanding anything to the contrary in this Agreement, if at the time of the Executive's termination of employment, the Executive is a "specified employee," as defined below, any and all amounts payable under this Section 5 or Section 9(a) on account of such separation from service that constitute deferred compensation and would (but for this provision) be payable within six (6) months following the date of termination, shall instead be paid on the next business day following the expiration of such six (6) month period or, if earlier, upon the Executive's death; except (A) to the extent of amounts that do not constitute a deferral of compensation within the meaning of Treasury regulation Section 1.409A-1(b) (including without limitation by reason of the safe harbor set forth in Section 1.409A-1(b)(9)(iii), as determined by the Company in its reasonable good faith discretion); (B) benefits that qualify as excepted welfare benefits pursuant to Treasury regulation Section 1.409A-1(a)(5); or (C) other amounts or benefits that are not subject to the requirements of Section 409A.

(ii) For purposes of this Agreement, all references to "termination of employment" and correlative phrases shall be construed to require a "separation from service" (as defined in Section 1.409A-1(h) of the Treasury regulations after giving effect to the presumptions contained therein), and the term "specified employee" means an individual determined by the Company to be a specified employee under Treasury regulation Section 1.409A-1(i).

(iii) Each payment made under this Agreement shall be treated as a separate payment and the right to a series of installment payments under this Agreement is to be treated as a right to a series of separate payments.

(iv) Any payment of or reimbursement for expenses that would constitute nonqualified deferred compensation subject to Section 409A shall be subject to the following additional rules: (i) no reimbursement or payment of any such expense shall affect the Executive's right to reimbursement or payment of any such expense in any other calendar year; (ii) reimbursement or payment of the expense shall be made, if at all, promptly, but not later than the end of the calendar year following the calendar year in which the expense was incurred; and (iii) the right to reimbursement or payment shall not be subject to liquidation or exchange for any other benefit.

(v) In no event shall the Company have any liability relating to the failure or alleged failure of any payment or benefit under this Agreement to comply with, or be exempt from, the requirements of Section 409A.

(i) Exclusive Right to Severance. The Executive agrees that the Severance Benefits to be provided to him in accordance with the terms and conditions set forth in this Agreement are intended to be exclusive with respect to severance or termination pay and post-employment employee benefits. The Executive hereby knowingly and voluntarily waives any right he might otherwise have to participate in or receive benefits under any other plan, program or policy of the Company providing for severance or termination pay or benefits.

6. Effect of Termination. The provisions of this Section 6 shall apply to any termination of the Executive's employment under this Agreement, whether pursuant to Section 5 or otherwise.

(a) Provision by the Company of Final Compensation and Severance Benefits, if any, that are due the Executive in each case under the applicable termination provision of Section 5 shall constitute the entire obligation of the Company to the Executive with respect to severance or termination pay and post-employment employee benefits.

(b) Except for any right of the Executive to continue group health plan participation in accordance with applicable law, the Executive's participation in all employee benefit plans shall terminate pursuant to the terms of the applicable plan documents based on the date of termination of the Executive's employment without regard to any Base Salary for notice waived pursuant to Section 5(f) hereof or to any Severance Benefits or other payment made to or on behalf of the Executive following such date of termination.

(c) Provisions of this Agreement shall survive any termination of the Executive's employment if so provided herein or if necessary or desirable fully to accomplish the purposes of other surviving provisions, including without limitation the obligations of the Executive under Sections 7, 8 and 9. The obligation of the Company to provide Severance Benefits hereunder, and Executive's right to retain such payments, is expressly conditioned on the Executive's continued compliance in all material respects with Sections 7, 8 and 9. The Executive recognizes that, except as expressly provided in Sections 5(d), 5(e), and 5(g) or with respect to Base Salary paid for notice waived pursuant to Section 5(f), no cash compensation or benefits will be earned after termination of employment.

7. Confidential Information.

(a) The Executive acknowledges that the Company and its Affiliates continually develop Confidential Information, that the Executive will develop Confidential Information for the Company or its Affiliates and that the Executive will learn of Confidential Information during the course of employment. All Confidential Information which the Executive creates or to which he has access as a result of her employment or other associations with the Company or any of its Affiliates is and shall remain the sole and exclusive property of the Company or its Affiliate, as applicable. The Executive shall comply with the policies and procedures of the Company and its Affiliates for protecting Confidential Information and shall never disclose to any Person (except as required by applicable law or for the proper performance of her duties and responsibilities to the Company and its Affiliates), or use for her own benefit or gain or the benefit or gain of any other Person, any Confidential Information obtained by the Executive incident to her employment or any other association with the Company or any of its Affiliates. The Executive understands that this restriction shall continue to apply after her employment terminates, regardless of the reason for such termination. Further, the Executive shall furnish prompt notice to the Company of any required disclosure of Confidential Information sought pursuant to subpoena, court order or any other legal process or requirement, and provide the Company a reasonable opportunity to seek protection of the Confidential Information prior to any such disclosure. The confidentiality obligation under this Section 7 shall not apply to information that has become generally known through no wrongful act on the part of the Executive or any other Person having an obligation of confidentiality to the Company or any of its Affiliates. Nothing in this Agreement limits, restricts

or in any other way affects the Executive from communicating with any governmental agency or entity, or communicating with any official or staff person of a governmental agency or entity, concerning matters relevant to the governmental agency or entity.

(b) All documents, records, tapes and other media of every kind and description relating to the business, present or otherwise, of the Company or any of its Affiliates and any copies or derivatives (including without limitation electronic), in whole or in part, thereof (the "Documents"), whether or not prepared by the Executive, shall be the sole and exclusive property of the Company and its Affiliates. Except in the proper performance of the Executive's regular duties for the Company or as expressly authorized in writing in advance by the Board or its expressly authorized designee, the Executive will not copy any Documents or remove any Documents or copies or derivatives thereof from the premises of the Company. The Executive shall safeguard all Documents and shall surrender to the Company at the time her employment terminates, and at such earlier time or times as the Board or its designee may specify, all Documents and other property of the Company or any of its Affiliates and all documents, records and files of the customers and other Persons with whom the Company or any of its Affiliates does business ("Third Party Documents") and each individually a "Third Party Document") then in the Executive's possession or control; provided, however, that if a Document or Third-Party Document is on electronic media, the Executive may, in lieu of surrendering the Document or Third-Party Document, provide a copy to the Company on electronic media and delete and overwrite all other electronic media copies thereof. Upon request of any duly authorized officer of the Company, the Executive shall disclose all passwords and passcodes necessary or desirable to enable the Company or any of its Affiliates or the Persons with whom the Company or any of its Affiliates do business to obtain access to the Documents and Third-Party Documents.

(c) Under the Defend Trade Secrets Act of 2016, the Company hereby provides notice and Executive hereby acknowledges that Executive may not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (i) is made (A) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney and (B) is solely for the purpose of reporting or investigating a suspected violation of law; or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

8. Assignment of Rights to Intellectual Property. The Executive shall promptly and fully disclose all Intellectual Property to the Company. The Executive hereby assigns and agrees to assign to the Company (or as otherwise directed by the Company) the Executive's full right, title and interest in and to all Intellectual Property. The Executive shall execute any and all applications for domestic and foreign patents, copyrights or other proprietary rights and to do such other acts (including without limitation the execution and delivery of instruments of further assurance or confirmation) requested by the Company to assign the Intellectual Property to the Company (or as otherwise directed by the Company) and to permit the Company to enforce any patents, copyrights or other proprietary rights to the Intellectual Property. The Executive will not charge the Company for time spent in complying with these obligations. All copyrightable works that the Executive creates shall be considered "work made for hire" and shall, upon creation, be owned exclusively by the Company.

9. Restricted Activities. The Executive agrees that the following restrictions on her activities during and after her employment are necessary to protect the goodwill, Confidential Information and other legitimate interests of the Company and its Affiliates:

(a) During the Term and during the twelve (12) month period following the date of the Executive's termination of employment either by the Company for Restricted Cause (as defined below) or by the Executive for any reason (such period, the "Non-Compete Period"), the Executive shall not, directly or indirectly, whether as owner, partner, investor, consultant, agent, employee, co-venturer or

otherwise: (x) control or own any interest in a Person that engages in the Competitive Business in the Restricted Area; or (y) render any services to, or engage in any activities for, any Person that engages in the Competitive Business in the Restricted Area. Nothing in this Section 9(a), however, shall prevent the Executive's passive ownership of two (2) percent or less of the equity securities of any publicly traded company.

(i) In consideration of the Executive's agreement not to compete under this Section 9(a), the Company shall pay the Executive, on a pro-rata basis, an amount equal to fifty (50%) of the Executive's then-current Base Salary, reduced by any Severance Benefits the Executive is eligible to receive from the Company, if any (such payments, the "Non-Compete Payments"). The Company, in its sole discretion, may elect at any time prior to the Termination Date to waive the restrictions set forth in Section 9(a), which such waiver shall automatically terminate the Company's obligations to compensate the Executive under this Section 9(a)(i). The Executive agrees that nothing in this Section 9(a)(i) gives the Executive an election as to her compliance with Section 9(a). Any obligation of the Company to provide the Non-Compete Payments is conditioned on the Executive signing and returning to the Company (without revoking) a timely and effective Release of Claims as set forth in Section 5(d).

(ii) If the Executive breaches any obligations under Section 9(a) at any time during the Non-Compete Period, then, in addition to any other remedies that the Company may have against the Executive, the Executive shall no longer be entitled to the Non-Compete Payments and shall be obligated to immediately return any and all payments made to the Executive pursuant to Section 9(a)(i).

(iii) For purposes of this Agreement, the "Competitive Business" means the business of developing, marketing or selling (i) therapeutic drugs to treat liver disease or constipation or (ii) any other drug that has a therapeutic purpose that is the same or substantially similar to the therapeutic purpose of any drug that the Company or any of its Affiliates is developing, marketing or selling during the Executive's employment with the Company or, with respect to the portion of the Non-Compete Period that follows termination of the Executive's employment, at the time of such termination.

(iv) For purposes of this Agreement, "Restricted Cause" means the Board's determination, in its reasonable judgement, that: (A) the Executive failed to materially perform her duties; (B) the Executive acted or failed to act in any way that materially injures the Company; or (C) there exists any reason constituting Cause.

(v) For purposes of this Agreement, the "Restricted Area" means any geographic area in which the Company or any of its Affiliates engages in any business activity or is actively planning to engage in any business activity at any time during the Executive's employment with the Company or, with respect to the portion of the Non-Compete Period that follows termination of the Executive's employment, at the time of such termination.

(b) During the Term, the Executive shall not, directly or indirectly, undertake any outside activity, whether or not competitive with the business of the Company or its Affiliates that could reasonably give rise to a conflict of interest or otherwise interfere with any of her duties for, or obligations to, the Company or any of its Affiliates.

(c) During the Term and during the twelve (12) month period following the Termination Date (the "Nonsolicitation Period"), regardless of the reason for such termination, the Executive shall not, directly or indirectly: (i) solicit or encourage any customer, client, business partner, or other business relation of the Company or any of its Affiliates (each, a "Business Relationship") to terminate or diminish its relationship with them; or (ii) seek to persuade any Business Relationship or any prospective Business Relationship to conduct with anyone other than the Company or any of its Affiliates any business

or activity which such Business Relationship conducts, or such prospective Business Relationship could conduct, with the Company or any of its Affiliates; provided, however, that these restrictions shall apply (A) only with respect to those Persons who are or have been a Business Relationship at any time within the immediately preceding two (2)-year period or whose business has been solicited on behalf of the Company or any of the Affiliates by any of their officers, employees or agents within such two (2)-year period, other than by form letter, blanket mailing or published advertisement, and (B) only if the Executive has performed work for such Person during her employment with the Company or one of its Affiliates or been introduced to, or otherwise had contact with, such Person as a result of her employment or other associations with the Company or one of its Affiliates or has had access to Confidential Information which would assist in the Executive's solicitation of such Person.

(d) During the Nonsolicitation Period (excluding any activities undertaken on behalf of the Company or any of its Affiliates in the course of her duties hereunder), the Executive shall not, directly or indirectly, and will not assist any other Person to: (i) hire, engage or solicit for hiring or engagement any employee of the Company or any of its Affiliates or seek to persuade any employee of the Company or any of its Affiliates to discontinue employment; or (ii) solicit or encourage any independent contractor providing services to the Company or any of its Affiliates to terminate or diminish its relationship with them; provided, however, that these restrictions shall apply only to employees and independent contractors who have provided services to the Company or any of its Affiliates at any time within the immediately preceding two-(2) year period.

10. Enforcement of Covenants. The Executive acknowledges that he was provided with at least ten (10) days to carefully read and consider all the terms and conditions of this Agreement, including the restraints imposed upon him pursuant to Sections 7, 8 and 9, and has had the opportunity to consult with legal counsel of Executive's choosing regarding such terms and conditions. The Executive agrees without reservation that each of the restraints contained herein is necessary for the reasonable and proper protection of the goodwill, Confidential Information and other legitimate interests of the Company and its Affiliates; that each and every one of these restraints is reasonable in respect to subject matter, length of time and geographic area; and that these restraints, individually or in the aggregate, will not prevent him from obtaining other suitable employment during the period in which the Executive is bound by them. The Executive further agrees that he will never assert, or permit to be asserted on her behalf, in any forum, any position contrary to the foregoing. The Executive further acknowledges that, were he to breach any of the covenants contained in Sections 7, 8 or 9, the damage to the Company and its Affiliates would be irreparable. The Executive therefore agrees that the Company, in addition to any other remedies available to it, shall be entitled to preliminary and permanent injunctive relief against any breach or threatened breach by the Executive of any of said covenants, without having to post bond, and will additionally be entitled to an award of attorney's fees incurred in connection with securing any relief hereunder. The parties further agree that, in the event that any provision of Section 7, 8 or 9 shall be determined by any court of competent jurisdiction to be unenforceable by reason of its being extended over too great a time, too large a geographic area or too great a range of activities, such provision shall be deemed to be modified to permit its enforcement to the maximum extent permitted by law. The Executive agrees that the Nonsolicitation Period shall be tolled, and shall not run, during any period of time in which he is in violation of the terms thereof, in order that the Company and its Affiliates shall have all of the agreed-upon temporal protection recited herein. No breach of any provision of this Agreement by the Company, or any other claimed breach of contract or violation of law, or change in the nature or scope of the Executive's employment relationship with the Company, shall operate to extinguish the Executive's obligation to comply with Sections 7, 8 and 9. Each of the Company's Affiliates shall have the right to enforce all of the Executive's obligations to that Affiliate under this Agreement, including without limitation pursuant to Section 7, 8 or 9.

11. No Conflicting Agreements. The Executive hereby represents and warrants that the execution of this Agreement and the performance of her obligations hereunder will not breach or be in

conflict with any other agreement to which the Executive is a party or is bound and that the Executive is not now subject to any covenants against competition or similar covenants or any other obligations to any Person or to any court order, judgment or decree that would affect the performance of her obligations hereunder. The Executive will not disclose to or use on behalf of the Company any proprietary information of a third party without such party's consent.

12. Definitions. Capitalized words or phrases shall have the meanings provided in this Section 12 and as provided elsewhere herein:

(a) "Affiliate" means any person or entity directly or indirectly controlling, controlled by or under common control with the Company, where control may be by either management authority or equity interest.

(b) "Code" means the Internal Revenue Code of 1986, as amended.

(c) "Confidential Information" means any and all information of the Company and its Affiliates that is not generally available to the public, and any and all information, publicly known in whole or in part or not, which, if disclosed by the Company or any of its Affiliates, would assist in competition against any of them. Confidential Information includes without limitation such information relating to (i) the development, research, testing, manufacturing, marketing and financial activities of the Company and its Affiliates, (ii) the Products, (iii) the costs, sources of supply, financial performance and strategic plans of the Company and its Affiliates, (iv) the identity and special needs of the patients of the Company and its Affiliates and (v) the people and organizations with whom the Company and its Affiliates have business relationships and the nature and substance of those relationships. Confidential Information also includes information that the Company or any of its Affiliates has received, or may receive hereafter, belonging to others or that was received by the Company or any of its Affiliates with any understanding, express or implied, that it would not be disclosed.

(d) "Intellectual Property" means inventions, discoveries, developments, methods, processes, compositions, works, concepts and ideas (whether or not patentable or copyrightable or constituting trade secrets) conceived, made, created, developed or reduced to practice by the Executive (whether alone or with others, whether or not during normal business hours or on or off Company premises) during the Executive's employment and during the period of six (6) months immediately following termination of her employment that relate either to the Products or to any prospective activity of the Company or any of its Affiliates or that result from any work performed by the Executive for the Company or any of its Affiliates or that make use of Confidential Information or any of the equipment or facilities of the Company or any of its Affiliates.

(e) "Person" means a natural person, a corporation, a limited liability company, an association, a partnership, an estate, a trust and any other entity or organization, other than the Company or any of its Affiliates.

(f) "Products" means all products planned, researched, developed, tested, sold, licensed, leased, or otherwise distributed or put into use by the Company or any of its Affiliates, together with all services provided or otherwise planned by the Company or any of its Affiliates, during the Executive's employment.

13. Withholding. All payments made by the Company under this Agreement shall be reduced by any tax or other amounts required to be withheld by the Company under applicable law.

14. Section 280G.

(a) In the event that the Company undergoes a "change in ownership or control" (within the meaning of Section 280G of the Code and the regulations and guidance promulgated thereunder ("Section 280G")) and all, or any portion, of the payments provided under this Agreement, either alone or together with other payments or benefits which the Executive receives or is entitled to receive from the Company (collectively, the "Total Payments"), could constitute an "excess parachute payment" within the meaning of Section 280G, then the Executive shall be entitled to receive (i) an amount limited (to the minimum extent necessary) so that no portion of the Total Payments shall be non-deductible for US federal income taxes by reason of Section 280G (the "Limited Amount"), or (ii) if the amount of the Total Payments (without regard to clause (i)) reduced by the excise tax imposed by Section 4999 of the Code (the "Excise Tax") and the amount of all other applicable federal, state and local taxes (with income taxes all computed at the highest applicable marginal rate) is greater than the Limited Amount reduced by the amount of all taxes applicable thereto (with income taxes all computed at the highest marginal rate), the amount of the Total Payments otherwise payable without regard to clause (i). If it is determined that the Limited Amount will maximize the Employee's after-tax proceeds, the Total Payments shall be reduced to equal the Limited Amount in the following order: (i) first, by reducing cash severance payments that are exempt from Section 409A, (ii) second, by reducing other payments and benefits that are exempt from Section 409A and to which Q&A 24(c) of Section 1.280G-1 of the Treasury Regulations does not apply, (iii) third, by reducing all remaining payments and benefits that are exempt from Section 409A and (iv) finally, by reducing payments and benefits that are subject to Section 409A, in each case, with all such reductions done on a pro rata basis.

(b) All determinations made pursuant this Section 14 will be made at the Company's or its Affiliates' expense by an accounting firm or consulting group with experience in performing calculations regarding the applicability of Section 280G and Section 4999 of the Code selected by the Company for such purpose (the "Independent Advisors"). For purposes of such determinations, no portion of the Total Payments shall be taken into account which, in the opinion of the Company and its legal advisors, (y) does not constitute a "parachute payment" within the meaning of Section 280G(b)(2) of the Code (including by reason of Section 280G(b)(4)(A) of the Code) or (z) constitutes reasonable compensation for services actually rendered, within the meaning of Section 280G(b)(4)(B) of the Code, in excess of the "base amount" (as defined in Section 280G(b)(3) of the Code) allocable to such reasonable compensation. In the event it is later determined that (A) a greater reduction in the Total Payments should have been made to implement the objective and intent of this Section 14, the excess amount shall be returned immediately by the Executive to the Company or (B) a lesser reduction in the Total Payments should have been made to implement the objective and intent of this Section 14, the additional amount shall be paid immediately by the Company, or any Affiliate of the Company, as applicable, to the Executive.

15. Assignment. Neither the Company nor the Executive may make any assignment of this Agreement or any interest herein, by operation of law or otherwise, without the prior written consent of the other; provided, however, that (a) the Company may assign its rights and obligations under this Agreement without the consent of the Executive to one of its Affiliates, or in the event that the Company shall hereafter effect a reorganization with, consolidate with, or merge into, an Affiliate or any Person or transfer or have transferred all or substantially all of its properties, outstanding stock, or assets to an Affiliate or any Person and (b) in the event that all of the Company's rights and obligations under this Agreement are assigned pursuant to this Section 15, each reference to Company herein shall be deemed from and after such assignment instead to be a reference to the assignee. This Agreement shall inure to the benefit of and be binding upon the Company and the Executive, and their respective successors, executors, administrators, heirs and permitted assigns.

16. Severability. If any portion or provision of this Agreement shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the

application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

17. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of either party to require the performance of any term or obligation of this Agreement, or the waiver by either party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

18. Notices. Any and all notices, requests, demands and other communications provided for by this Agreement shall be in writing and shall be effective when delivered in person, consigned to a reputable national courier service or deposited in the United States mail, postage prepaid, registered or certified, and addressed to the Executive at her last known address on the books of the Company or, in the case of the Company, at its principal place of business, attention of the CEO, or to such other address as either party may specify by notice to the other actually received.

19. Entire Agreement. This Agreement constitutes the entire agreement between the parties and supersedes and terminates all prior communications, agreements and understandings, written or oral, with respect to the terms and conditions of the Executive's employment relationship with the Company (including, without limitation, the Original Employment Agreement).

20. Amendment. This Agreement may be amended or modified only by a written instrument signed by the Executive and by an expressly authorized representative of the Company.

21. Headings. The headings and captions in this Agreement are for convenience only and in no way define or describe the scope or content of any provision of this Agreement.

22. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be an original and all of which together shall constitute one and the same instrument.

23. Governing Law. This is a Massachusetts contract and shall be construed and enforced under and be governed in all respects by the laws of Massachusetts, without regard to any conflict of laws principles that would result in the application of the laws of any other jurisdiction.

[The remainder of this page has been left blank intentionally.]

IN WITNESS WHEREOF, this Agreement has been executed as a sealed instrument by the Company, by its duly authorized representative, and by the Executive, as of the date first above written.

ALBIREO PHARMA, INC.

By:
Name: Ron Cooper
Title: President & Chief Executive Officer

EXECUTIVE

Michelle Graham

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: November 6, 2019

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

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

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

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

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

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

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

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

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

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

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

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

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

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

Date: November 6, 2019

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

Exhibit 32.1

CERTIFICATIONS UNDER SECTION 906

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

The Quarterly Report for the quarter ended September 30, 2019 (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: November 6, 2019

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

Dated: November 6, 2019

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