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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2020

OR

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

For the transition period from _____ to _____ .

Commission File Number 001-33451

Albireo Pharma, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

As of July 30, 2020, there were 14,990,711 shares of Common Stock, $0.01 par value per share, outstanding.

Albireo Pharma, Inc.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

- any payment that EA Pharma Co., Ltd., or EA Pharma, may make to us or any other action or decision that EA Pharma may make concerning elobixibat or our business relationship;

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

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

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

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

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

obtain marketing approval for odevixibat to treat patients with PFIC, biliary atresia or any other pediatric cholestatic liver disease, for elobixibat to treat NASH, or for A3384 as a potential treatment for gastrointestinal diseases or disorders;

- whether favorable findings from clinical trials of odevixibat to date, including findings in indications other than PFIC, will be predictive of results from future clinical trials, including the trials comprising our Phase 3 PFIC program for odevixibat, pivotal trial of odevixibat in biliary atresia and planned pivotal trial of odevixibat in Alagille syndrome, or ALGS; whether either or both of the U.S. Food and Drug Administration, or FDA, and European Medicines Agency, or EMA, will determine that the primary endpoint and treatment duration of the double blind Phase 3 trial in patients with PFIC are sufficient, even if such primary endpoint is met with statistical significance, to support approval of odevixibat in the United States, or U.S., or the European Union, or E.U., 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 and biliary atresia programs or the planned pivotal trial in ALGS for odevixibat, and the outcomes of such trials;

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

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

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

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

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

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

- the extent to which our agreement with EA Pharma for elobixibat generates 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;
- whether we are able to maintain compliance with the terms and conditions of our loan and security agreement with Hercules Capital, Inc.;
- our ability to expand and protect our intellectual property estate;
- regulatory developments in the United States and other countries;
- the effectiveness of our internal control over financial reporting;
- the performance of our third-party suppliers, manufacturers and contract research organizations and our ability to obtain alternative sources of raw materials;
- our ability to attract and retain key personnel; and
- our ability to comply with regulatory requirements relating to our business, and the costs of compliance with those requirements, including those on data privacy and security.

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

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

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

Albireo Pharma, Inc.

Condensed Consolidated Balance Sheets

(in thousands, except share data)

(unaudited)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 152,020	$ 131,843
Prepaid expenses and other current assets	7,967	9,956
Total current assets	159,987	141,799
Property and equipment, net	597	597
Goodwill	17,260	17,260
Other assets	6,161	5,413
Total assets	$ 184,005	$ 165,069
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,734	$ 4,785
Accrued expenses	11,752	13,486
Other current liabilities	732	653
Total current liabilities	17,218	18,924
Liability related to sale of future royalties	64,351	48,714
Note payable, net of discount	9,400	—
Other long-term liabilities	3,916	4,270
Total liabilities	94,885	71,908
Stockholders’ Equity:		
Common stock, $0.01 par value per share — 30,000,000 authorized at June 30, 2020 and December 31, 2019; 14,989,021 and 12,749,443 issued and outstanding at June 30, 2020 and December 31, 2019, respectively	149	127
Additional paid-in capital	294,075	245,769
Accumulated other comprehensive income	6,174	6,452
Accumulated deficit	(211,278)	(159,187)
Total stockholders’ equity	89,120	93,161
Total liabilities and stockholders’ equity	$ 184,005	$ 165,069

See accompanying notes to Condensed Consolidated Financial Statements.

Albireo Pharma, Inc.

Condensed Consolidated Statements of Operations

(in thousands, except share and per share data)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue	$ 1,912	$ 1,250	$ 3,461	$ 1,820
Operating expenses:				
Research and development	18,397	11,034	34,527	19,363
General and administrative	8,474	5,485	16,627	10,778
Other operating (income) expense, net	(6,744)	8	72	2,304
Total operating expenses	20,127	16,527	51,226	32,445
Operating loss	(18,215)	(15,277)	(47,765)	(30,625)
Interest expense, net	(2,388)	(1,351)	(4,326)	(2,660)
Net loss	$ (20,603)	$ (16,628)	$ (52,091)	$ (33,285)
Net loss per share attributable to holders of common stock:				
Net loss per common share - basic and diluted	$ (1.38)	$ (1.35)	$ (3.58)	$ (2.73)
Weighted-average shares outstanding:				
Weighted-average common shares used to compute basic and diluted net loss per common share	14,981,756	12,355,969	14,556,986	12,178,376

See accompanying notes to Condensed Consolidated Financial Statements.

Albireo Pharma, Inc.

Condensed Consolidated Statements of Comprehensive Loss

(in thousands)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net loss	$ (20,603)	$ (16,628)	$ (52,091)	$ (33,285)
Other comprehensive (loss) income:				
Foreign currency translation adjustment	(6,565)	(9)	(278)	2,289
Total other comprehensive (loss) income	(6,565)	(9)	(278)	2,289
Total comprehensive loss	$ (27,168)	$ (16,637)	$ (52,369)	$ (30,996)

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 (loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance--December 31, 2019	12,749,443	$ 127	$ 245,769	$ 6,452	$ (159,187)	$ 93,161
Share based compensation expense	—	—	2,381	—		2,381
Exercise of options and vesting of RSUs	37,662	—	94	—	—	94
Issuance of common stock, net of costs	2,190,750	22	42,977	—	—	42,999
Other comprehensive income	—	—	—	6,287	—	6,287
Net loss	—	—	—	—	(31,488)	(31,488)
Balance--March 31, 2020	14,977,855	$ 149	$ 291,221	$ 12,739	$ (190,675)	$ 113,434
Share based compensation expense	—	—	2,603	—	—	2,603
Exercise of options and vesting of RSUs	11,166	—	138	—	—	138
Issuance of warrants	—	—	113	—	—	113
Other comprehensive loss	—	—	—	(6,565)	—	(6,565)
Net loss	—	—	—	—	(20,603)	(20,603)
Balance--June 30, 2020	14,989,021	$ 149	$ 294,075	$ 6,174	$ (211,278)	$ 89,120

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance--December 31, 2018	11,969,928	$ 120	$ 214,694	$ 4,293	$ (96,470)	$ 122,637
Share based compensation expense	—	—	1,823	—	—	1,823
Exercise of options and vesting of RSUs	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
Share based compensation expense	—	—	2,049	—	—	2,049
Exercise of options and vesting of RSUs	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

See accompanying notes to Condensed Consolidated Financial Statements.

Albireo Pharma, Inc.

Condensed Consolidated Statements of Cash Flows

(in thousands)

(unaudited)

	Six Months Ended June 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (52,091)	$ (33,285)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accretion of liability related to sale of future royalties	4,385	4,075
Accretion of note payable discount and amortization of issuance costs	27	—
Depreciation and amortization	77	50
Stock-based compensation expense	4,984	3,872
Foreign currency adjustments	93	3,508
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,808	(1,662)
Other assets	171	(414)
Accounts payable	5	(393)
Accrued expenses	(5,313)	(2,272)
Other current and long-term liabilities	(1,008)	8
Net cash used in operating activities	(46,862)	(26,513)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(78)	(409)
Net cash used in investing activities	(78)	(409)
Cash flows from financing activities:		
Proceeds from issuance of note payable, net of issuance costs	9,521	—
Proceeds from issuance of common stock, net of issuance costs	42,999	20,774
Proceeds from royalty agreement, net of issuance costs	14,750	—
Proceeds from exercise of options and vesting or RSUs	232	1,400
Net cash provided by financing activities	67,502	22,174
Effect of exchange rate changes on cash and cash equivalents	(385)	(1,415)
Net increase (decrease) in cash and cash equivalents	20,177	(6,163)
Cash and cash equivalents—beginning of period	131,843	163,885
Cash and cash equivalents—end of period	$ 152,020	$ 157,722
Supplemental disclosures of cash and non-cash activities:		
Warrants issued with long-term note payable	$ 113	$ —
Deferred issuance costs included in accrued expenses	$ 34	$ —

See accompanying notes to Condensed Consolidated Financial Statements.

Albireo Pharma, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Summary of significant accounting policies and basis of presentation

Organization

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

Basis of presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information, and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the audited consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019. In the opinion of management, all adjustments (including normal recurring adjustments) considered necessary for fair presentation have been included in the Condensed Consolidated Financial Statements. The results of operations for the three and six months ended June 30, 2020 are not necessarily indicative of the results that may be expected for the full fiscal year, any other interim period or any future fiscal year. The condensed consolidated financial statements are prepared on a basis consistent with prior periods.

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

Principles of consolidation

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

Foreign currency translation

Functional currency

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

Transactions and balances

Foreign currency transactions in each entity comprising the Company are remeasured into the functional currency of the entity using the exchange rates prevailing at the respective transaction dates. Foreign exchange gains and losses resulting from the settlement of such transactions and from the remeasurement at period-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized within other operating (income) 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 June 30, 2020 and December 31, 2019;

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

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

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

Use of estimates

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

Revenue recognition

Milestone Payments

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

Royalties

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

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

As of June 30, 2020, the Company is eligible to receive an additional regulatory-based milestone payment under the Agreement of $4.8 million if a specified regulatory event is achieved for elobixibat. The cash payments and any other payments for milestones and royalties from EA Pharma are non-refundable, non-creditable and not subject to set-off.

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

Monetization of Future Royalties

In December 2017, the Company entered into a royalty interest acquisition agreement (RIAA) with HealthCare Royalty Partners III, L.P. (HCR) pursuant to which it sold to HCR the right to receive all royalties from sales in Japan and sales milestones achieved from any covered territory potentially payable to the Company under the Agreement, up to a specified maximum "cap" amount of $78.8 million, based on the funds the Company received from HCR. In January 2018, the Company received $44.5 million from HCR, net of certain transaction expenses, under the RIAA. On June 8, 2020, the parties entered into an amendment to the RIAA pursuant to which HCR agreed to pay the Company an additional $14.8 million, net of certain transactions expenses, in exchange for the elimination of the (i) $78.8 million cap amount on HCR's rights to receive royalties on sales in Japan and sales milestones for elobixibat in certain other territories that may become payable by EA Pharma and (ii) the $15.0 million payable to the Company if a specified sales milestone is achieved for elobixibat in Japan. 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 net cash totaling $59.3 million as a liability related to sale of future royalties (royalty obligation). The royalty obligation will be amortized using the effective interest rate method.

The following table shows the activity within the liability account for the six month period ended June 30, 2020:

	June 30, 2020 (in thousands)
Liability related to sale of future royalties—beginning balance	$ 55,144
Proceeds from sale of future royalties, net	14,750
Foreign currency translation loss	(239)
Accretion of interest expense on liability related to royalty monetization	4,385
Repayment of the liability	(7,778)
Liability related to sale of future royalties—ending balance	$ 66,262
Less current portion classified within accrued expenses	(1,911)
Net ending liability related to sale of future royalties	$ 64,351

The Company records estimated royalties due for the current period in accrued other until the payment is received from EA Pharma at which time the Company then remits payment to HCR. As royalties are remitted to HCR, the balance of the royalty obligation will be effectively repaid over the life of the RIAA. In order to determine the accretion of the royalty obligation, the Company is required to estimate the total amount of future royalty payments to be received and submitted to HCR, as noted above. The sum of these amounts less the $59.3 million proceeds the Company received will be recorded as interest expense over the life of the royalty obligation. At June 30, 2020, the Company's estimate of its total interest expense resulted in an annual effective interest rate of approximately 20.4%.

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

Recently adopted accounting pronouncements

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

2. Fair Value of financial instruments

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

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

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

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

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

3. Commitments and contingencies

Agreements with CROs

As of June 30, 2020, the Company had various agreements with CROs for the conduct of specified research and development activities. Based on the terms of the respective agreements, the Company may be required to make future payments of up to $38.5 million to CROs upon the completion of contracted work.

4. Net loss per share

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Basic and Diluted EPS:				
Numerator				
Net loss	$ (20,603)	$ (16,628)	$ (52,091)	$ (33,285)
Denominator				
Weighted average number of shares outstanding	14,981,756	12,355,969	14,556,986	12,178,376
Basic and Diluted EPS	$ (1.38)	$ (1.35)	$ (3.58)	$ (2.73)

The following outstanding common stock equivalents were excluded from the computation of Diluted EPS for the six months ended June 30, 2020 and 2019 because including them would have been anti-dilutive:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Options to purchase common stock, RSUs and warrants	2,439,930	1,820,351	2,439,930	1,820,351

5. Income taxes

The Company did not record a tax provision or benefit for the six months ended June 30, 2020 or 2019. The Company has continued to maintain a full valuation allowance against its net deferred tax assets. The Company has had an overall net operating loss position since its inception.

6. Note Payable

2020 Loan and Security Agreement

On June 8, 2020, the Company entered into a Loan and Security Agreement (the Loan and Security Agreement) with the several banks and other financial institutions or entities from time to time parties to the Loan and Security Agreement, as lenders (collectively, referred to as the “Lender”), and Hercules Capital, Inc., in its capacity as administrative agent and collateral agent for itself and Lender (in such capacity, the “Agent” or “Hercules”) pursuant to which term loans of up to an aggregate principal amount of up to $80.0 million (the “Term Loans”) are available to the Company. The Loan Agreement provides for (i) an initial term loan advance of $10.0 million, which closed on June 8, 2020, and, at the Company’s option, a right to request that the Lender make an additional term loan advance to the Company in an aggregate principal amount of $5.0 million prior to December 15, 2020, (ii) subject to the achievement of certain initial performance milestones (“Performance Milestone I”), a right of the Borrower to request that the Lender make additional term loan advances to the Company in an aggregate principal amount of up to $20.0 million from January 1, 2021 through December 15, 2021 in minimum increments of $10.0 million, and (iii) subject to the Lender’s investment committee’s sole discretion, a right of the Borrower to request that the Lender make additional term loan advances to the Company in an aggregate principal amount of up to $45.0 million through March 31, 2022 in minimum increments of $5.0 million. The Company is required to pay an end of term fee (“End of Term Charge”) equal to 6.95% of the aggregate principal amount of the Term Loans advances upon repayment.

The Term Loans mature on January 1, 2024, which is extendable to June 1, 2024 upon achievement of Performance Milestone I (the “Maturity Date”).

The Term Loan bears interest at an annual rate equal to the greater of 9.15% and 9.15% plus the prime rate of interest minus 3.25%. Borrowings under the Loan and Security Agreement are repayable in monthly interest-only payments through January 1, 2022 and extendable to (i) July 1, 2022 upon achievement of Performance Milestone I and (ii) July 1, 2023 upon achievement of certain additional performance milestones. After the interest-only payment period, borrowings under the Loan and Security Agreement are repayable in equal monthly payments of principal and accrued interest until the Maturity Date. At the Company's option, the Company may elect to prepay all, but not less than all, of the outstanding term loan by paying the entire principal balance and all accrued and unpaid interest thereon plus a prepayment charge equal to the following percentage of the principal amount being prepaid: 3.0% if the term loan is prepaid during the first 6 months following the initial closing date, 2.0% of the principal amount outstanding if the prepayment occurs after the first six months following the Closing Date, but on or prior to 24 months following the Closing Date, and 1.0% of the principal amount outstanding at any time thereafter but prior to the Maturity Date.

In connection with the Loan Agreement, the Company granted Agent a security interest senior to any current and future debts and to any security interest, in all of Borrower's right, title, and interest in, to and under all of Company's property and other assets, and certain equity interests and accounts of Albireo AB, subject to limited exceptions including the Borrower's intellectual property. The Loan Agreement also contains certain events of default, representations, warranties and non-financial covenants of the Company.

Through June 30, 2020, the Company borrowed $10.0 million under the Loan Agreement and incurred $1.3 million of debt discount and issuance costs inclusive of facility fees, legal fees, End of Term Charge and fair value of the warrant. The debt discount and issuance costs are being accreted to the principal amount of debt and being amortized from the date of issuance through the Maturity Date to interest expense using the effective-interest rate method. The effective interest rate of the outstanding debt under the Loan Agreement is approximately 15.3%.

As of June 30, 2020 the carrying value of the note payable consists of the following:

	June 30, 2020 (in thousands)
Note payable, including End of Term Charge	10,695
Debt discount, net of accretion	(1,295)
Note payable net of discount, long-term	$ 9,400

During the three and six months ended June 30, 2020, the Company recognized $0.1 million of interest expense related to the Loan Agreement. No interest expense was associated with the Loan Agreement for the three and six months ended June 30, 2019.

Estimated future principal payments due under the Loan Agreement, including the contractual End of Term Charge are as follows as of June 30, 2020:

	Note Principal Payments (in thousands)
Remainder of 2020	$ —
2021	—
2022	4,553
2023	4,994
2024	1,148

As of June 30, 2020, based on Level 3 inputs and the borrowing rates available to the Company for loans with similar terms and consideration of the Company's credit risk, the carrying value of the Company's variable interest rate debt, excluding unamortized debt issuance costs, approximates fair value.

Warrants

In connection with the entry into the Loan and Security Agreement, the Company will issue to Hercules warrants (the "Warrants") to purchase a number of shares of the Company's common stock, par value $0.01 per share (the "Common Stock") equal to 1% of the aggregate amount of the Term Loans that are funded, as such amounts are funded. On the Closing Date, the Company issued a Warrant for 5,311 shares of Common Stock. The Warrants will be exercisable for a period of seven years from the date of the issuance of each Warrant at a per-share exercise price equal to $18.83, subject to certain adjustments as specified in the Warrants. In addition, the Company has granted to the holders of the Warrants certain registration rights. Specifically, the Company has agreed to use its commercially reasonable efforts to (i) file registration statements with the U.S. Securities and Exchange Commission within 60 days following the date of the issuance of each Warrant for purposes of registering the shares of Common Stock issuable upon exercise of the Warrants for resale by Hercules, and (ii) cause the registration statement to be declared effective as soon as practicable after filing, and in any event no later than 180 days after the date of the issuance of each Warrant.

The Company accounted for the Warrants as equity instruments since they were indexed to the Company's common shares and met the criteria for classification in stockholders' equity. The relative fair value of the Warrants related to the first tranche funding was approximately $0.1 million, and was treated as a discount to the Term Loans. This amount is being amortized to interest expense using the effective interest method over the life of the Term Loans. The Company estimated the fair value of the Warrants using the Black-Scholes option-pricing model.

7. Equity Financings

2020 Underwritten Public Offering

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

8. Stock-based Compensation

For the six months ended June 30, 2020, the Company granted 678,525 options at a weighted average exercise price of $24.39.

The Company recorded the following stock-based compensation expense:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(in thousands)		(in thousands)	
Employee awards:				
Research and development expense	$ 1,042	$ 792	$ 1,922	$ 1,500
General and administrative expense	1,561	1,257	3,062	2,372
Total stock-based compensation expense	$ 2,603	$ 2,049	$ 4,984	$ 3,872

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

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

Overview

We are a biopharmaceutical company focused on the development and commercialization of novel bile acid modulators to treat orphan pediatric liver diseases and other liver or gastrointestinal diseases and disorders. The initial target indication for our lead product candidate, odevixibat (formerly known as A4250), is in progressive familial intrahepatic cholestasis, or PFIC, a rare, life-threatening genetic disorder affecting young children for which there is currently no approved drug treatment. The last patient's last visit is complete in the Phase 3 trial in PFIC, and we expect topline results in the coming weeks. We are also pursuing the development of odevixibat in biliary atresia and in Alagille syndrome, or ALGS, each of which is a rare, life threatening disease that affects the liver and for which there is no approved pharmacologic treatment option. We initiated a pivotal clinical trial of odevixibat in biliary atresia, the BOLD trial, in the first half of 2020, and have enrolled the first patients in the trial. We plan to initiate a pivotal trial in ALGS by the end of 2020. Our most advanced product candidate in addition to odevixibat is elobixibat, which is approved in Japan for the treatment of chronic constipation and for which we are conducting a Phase 2 clinical trial as a treatment for nonalcoholic fatty liver disease, or NAFLD, and nonalcoholic steatohepatitis, or NASH. The last patient's last visit is complete in the Phase 2 trial, and we expect topline results in the coming weeks, ahead of the topline results for the odevixibat Phase 3 trial in PFIC. We are exploring additional clinical development of our product candidate A3384 based on an evaluation of its patent coverage and our overall portfolio. We also have a preclinical program in adult liver disease, and expect to complete investigational new drug enabling studies in a lead preclinical candidate this year.

Odevixibat — our lead product candidate for PFIC.

We completed a Phase 2, open-label, multicenter study, in which patients received 10–200 µg/kg oral odevixibat daily for 4 weeks. Twenty patients were enrolled (8 females; 1–17 years; 4 re-entered at a different dose). Diagnoses included PFIC (n=13; 3 re-entries), Alagille syndrome (n=6), biliary atresia (n=3), and other intrahepatic cholestasis causes (n=2; 1 re-entry). The trial explored changes in serum bile acid levels (primary efficacy endpoint), pruritus using the VAS-itch, Whitington itch, and Partial Patient-Oriented Scoring Atopic Dermatitis (PO-SCORAD) symptom scales, and sleep disturbance. The symptom scales had score ranges as follows: VAS-itch, 0 (no itching) to 10 (worst possible itching); Whitington itch, 0 (no itching) to 4 (cutaneous mutilation, hemorrhage, and scarring evident); PO-SCORAD scales, 0 (no problem at all with itching/sleeping) to 10 (unbearable problem with itching/sleeping). Scores for the previous 24 hours were self- or observer-reported in daily diaries and were averaged over a 7-day period at baseline and at the end of the 4-week treatment period. There were 5 sequentially escalating dose cohorts: 10, 30, 60, 100, or 200 µg/kg. Improvements in mean pruritus scores across 3 separate scales and in mean sleep scores were observed with all doses of odevixibat at the end of the 4-week treatment period versus baseline, except for the lowest dose investigated. For the total population, mean change in VAS-itch scores was −2.2 (range, −6.1 to 1.7); mean change in PO-SCORAD itch score was −2.0 (range, −6.7 to 1.6); mean change in Whitington itch score was −0.8 (range, −3 to 0.8); and mean change in PO-SCORAD sleep disturbance score was −1.8 (range, −5.8 to 0.9). Similar improvements in pruritus and sleep scores were observed in the subgroup of patients with PFIC. In this subgroup, mean change in VAS-itch scores was −2.7 (range, −5.94 to 0.37); mean change in PO-SCORAD itch score was −2.5 (range, −6 to 0.31); mean change in Whitington itch score was −1.1 (range, −3 to 0.14); and mean change in PO-SCORAD sleep disturbance score was −2.4 (range, −5.77 to 0.37).

In May 2018, we enrolled the first patient in our Phase 3 clinical trial for odevixibat, given once per day as an oral capsule or sprinkled over food, in patients ages 6 months to 18 years with PFIC types 1 and 2, with 45 global sites recruiting, which we refer to as PEDFIC 1. PEDFIC 1 is testing two doses of odevixibat, 40 µg/kg/day and 120 µg/kg/day, along with placebo, over a treatment period of 24 weeks. In PEDFIC 1, assessment of change in pruritus is the primary endpoint in the U.S. and a key secondary endpoint in the E.U., and serum bile acid (sBA) responder rate is the primary endpoint in the E.U. and a key secondary endpoint in the U.S. We are using the planned commercial formulation in PEDFIC 1, but any commercial product will include final trade dress. In the first quarter of 2019, we revised our statistical analysis methodology for PEDFIC 1, in line with guidance from the U.S. Food and Drug Administration, or FDA, which resulted in an improvement in the power of the study. The last patient's last visit is complete in PEDFIC 1, and we will collect data from 62 out of a planned 60 patients, with no patients lost to follow-up due to COVID-19. We are in the process of analyzing blinded data sets, and expect topline results in the coming weeks. Additionally, we've conducted an analysis with experts at our external vendor, IQVIA, Inc. to determine a measurement for a clinically relevant drop in pruritis score. Available data, including blinded pruritis data from the PEDFIC 1 study, has been analyzed using an anchor-based approach, and based on that approach a decrease of 1.0 or more on the 0 to 4-point scale represents a clinically meaningful improvement in pruritis. We continue to plan for a potential approval, issuance of a rare pediatric disease priority review voucher, and commercial launch in the second half of 2021. We also submitted a protocol amendment for PEDFIC 2, our long term, open label extension study, which includes an additional cohort of PFIC patients who are not eligible for PEDFIC 1. The first sites have been activated and first patients enrolled in the expanded PEDFIC 2 cohort. In July 2020, we initiated an Expanded Access Program (EAP) for odevixibat in the U.S., Canada, Australia and Europe. The EAP is available for patients with a clinical diagnosis of PFIC who have no other therapeutic options and do not qualify for, or have access to, the second cohort in PEDFIC 2. In June 2018, the FDA granted a rare pediatric disease designation to odevixibat for the treatment of PFIC, which affirms our eligibility to apply for a rare pediatric disease priority review voucher upon submission of a new drug application for odevixibat. In September 2018, the FDA granted fast track designation to odevixibat for the treatment of pruritus associated with PFIC.

The precise prevalence of PFIC is unknown, and we are not aware of any patient registries or other method of establishing with precision the actual number of patients with PFIC in any geography. PFIC has been estimated to affect between one in every 50,000 to 100,000 children born worldwide. Based on the published incidence, published regional populations, and estimated median life expectancies, we estimate the prevalence of PFIC across the spectrum of the disease to be approximately 8,000 to 10,000 patients in the U.S. and E.U., but we are not able to estimate the prevalence of PFIC with precision. We currently have not modeled other regional opportunities in Asia, the Middle East and Latin America. We are aware there may be higher prevalence of disease in some countries such as Saudi Arabia and Turkey. We hold global rights to odevixibat unencumbered. Our current plan is to commercialize odevixibat ourselves in the U.S. and E.U., and we have begun the process of identifying potential partners for other regions. There are currently no drugs approved for the treatment of PFIC. First-line treatment for PFIC is typically off-label ursodeoxycholic acid, or UDCA, which is approved in the U.S. and elsewhere for the treatment of primary biliary cholangitis, or PBC. However, many PFIC patients do not respond well to UDCA, undergo partial external bile diversion, or PEBD, surgery and often require liver transplantation. PEBD surgery is a life-altering and undesirable procedure in which bile is drained outside the body to a stoma bag that must be worn by the patient 24 hours a day.

Other indications under development for Odevixibat. We are also pursuing the development of odevixibat in patients with biliary atresia, another rare, life-threatening disease that affects the liver and for which there is no approved pharmacologic treatment option. In December 2018, the European Commission granted orphan designation to odevixibat for the treatment of biliary atresia, and in January 2019, the FDA granted orphan drug designation to odevixibat for the treatment of biliary atresia. We initiated the BOLD clinical trial, a global pivotal trial and the largest prospective intervention trial ever conducted in biliary atresia, in the first half of 2020. The first patients have been enrolled in the trial, and we plan for full site activation in the first half of 2021, but will monitor any impacts of COVID-19 on the enrollment. We believe biliary atresia is one of the most common rare pediatric liver diseases, and is the leading cause of liver transplants in children. Our double-blind, placebo controlled pivotal trial in biliary atresia is designed to enroll approximately 200 patients at 70 sites globally. Patients will receive either placebo or high-dose (120µg/kg) odevixibat once daily. The primary endpoint is survival with native liver after two years of treatment.

Biliary atresia is a partial or total blocking or absence of large bile ducts that causes cholestasis and resulting accumulation of bile that damages the liver. The estimated worldwide incidence of biliary atresia is between 4.5 and 8.5

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

In addition, we have had productive discussions with the FDA and European Commission and have come to agreement on a single pivotal study design for odevixibat in ALGS, and we plan to initiate the trial by the end of 2020. We expect topline data to be available between the announcements of the topline results from the PEDFIC 1 and BOLD clinical trials. ALGS is a genetic condition associated with liver, heart, eye, kidney and skeletal abnormalities. In particular, ALGS patients have fewer than normal bile ducts inside the liver, which leads to cholestasis and the accumulation of bile and causes scarring in the liver. ALGS is estimated to affect between one in every 30,000 to 70,000 children born worldwide. We estimate the prevalence of ALGS to be approximately 3,000 to 5,000 patients in the U.S. and E.U., but we are not able to estimate the prevalence of ALGS with precision. There are currently no drugs approved for the treatment of ALGS. Current treatment for ALGS is generally in line with current treatments for PFIC as described above. In August 2012, the European Commission granted orphan designation to odevixibat for the treatment of ALGS. In October 2018, the FDA granted orphan drug designation to odevixibat for the treatment of ALGS.

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

Elobixibat as a potential treatment for NASH. NASH is a common, serious and sometimes fatal chronic liver disease that resembles alcoholic liver disease but occurs in people who drink little or no alcohol. Based on multiple epidemiological studies published by third parties in 2014 and 2015, we estimate that NASH affects 2 to 3.5% of adults, representing over 9 million people in the United States and 10 million people in the E.U. There are currently no drugs approved for the treatment of NASH. Lifestyle changes, including modification of diet and exercise to reduce body weight, as well as treatment of concomitant diabetes and dyslipidemia, are commonly accepted as the standard of care for NASH, but have not conclusively been shown to prevent disease progression. Based on findings on parameters relevant to NASH in clinical trials of elobixibat that we previously conducted in patients with chronic constipation and in patients with elevated cholesterol and findings on other parameters relevant to NASH from nonclinical studies that we previously conducted with elobixibat or a different IBAT inhibitor, we believe elobixibat has potential benefit in the treatment of NASH. Prior to the last patient's last visit in the PEDFIC trial, the last patient's last visit was completed in our Phase 2 proof of concept clinical trial of elobixibat in NAFLD and NASH. The trial is designed to assess the combination of improvements in parameters like lipids, glucose, liver inflammation, liver fibrosis and elevated bile acids with a favorable gastrointestinal tolerability profile. We are analyzing full blinded data sets from 43 out of 47 patients, with some data on 4 patients being lost to follow up due primarily to COVID-19, and expect topline results in the coming weeks. In addition, we expect data from a second investigator-initiated study through our partner EA Pharma, which is being conducted in a targeted 100 patients in Japan with elobixibat 10mg and in combination with a bile acid sequestrant, later this year or in early 2021, which we expect will add to the overall pool of data for elobixibat in NAFLD/NASH.

Since inception, we have incurred significant operating losses. As of June 30, 2020, we had an accumulated deficit of $211.3 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 June 30, 2020, we had approximately $152.0 million in cash and cash equivalents.

Financial Operations Overview

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

Revenue

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

Operating Expenses

Research and Development Expenses

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

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

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

General and Administrative Expenses

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

Critical Accounting Policies and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles for interim financial information. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. We base our estimates and assumptions on historical experience and on various assumptions that we believe are reasonable under the circumstances, and we evaluate them on an ongoing basis. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of revenues and expenses that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates and judgments. In addition, our reported financial condition and results of operations could vary if new accounting standards are enacted that are applicable to our business. Our critical accounting policies and the methodologies and assumptions we apply under them have not materially changed since March 2, 2020, the date we filed our Annual Report on Form 10-K for the year ended December 31, 2019. For more information on our critical accounting policies, refer to our Annual Report on Form 10-K for the year ended December 31, 2019.

Results of Operations

Three Months Ended June 30, 2020 and June 30, 2019

Result of Operations

	Three Months Ended June 30,		Change
	2020	2019	$
	(in thousands)		
Revenue	$ 1,912	$ 1,250	$ 662
Operating Expenses			
Research and development	18,397	11,034	7,363
General and Administrative	8,474	5,485	2,989
Other operating (income) expense, net	(6,744)	8	(6,752)
Total operating expenses	20,127	16,527	3,600
Operating loss	(18,215)	(15,277)	(2,938)
Interest expense, net	(2,388)	(1,351)	(1,037)
Net loss	$ (20,603)	$ (16,628)	$ (3,975)

Revenue

	Three Months Ended June 30,		Change
	2020	2019	$
	(in thousands)		
Revenue	$ 1,912	$ 1,250	$ 662

There was $1.9 million in revenue for the three months ended June 30, 2020 compared with $1.3 million for the three months ended June 30, 2019, an increase of $0.7 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 June 30,		Change
	2020	2019	$
	(in thousands)		
Research and development expenses	$ 18,397	$ 11,034	$ 7,363

Research and development expenses were $18.4 million for the three months ended June 30, 2020 compared with $11.0 million for the three months ended June 30, 2019, an increase of $7.4 million. The increased research and

development expenses for the 2020 period were principally due to personnel expenses, and program expenses as we continue to increase our headcount, and program activities, respectively.

The following table summarizes our principal product development programs and the out-of-pocket third-party expenses incurred with respect to each clinical-stage product candidate and our preclinical programs for the three months ended June 30, 2020 and 2019.

	Three Months Ended June 30,		Change
	2020	2019	$
	(in thousands)		
Direct third-party project costs:			
Odevixibat	$ 11,004	$ 4,469	$ 6,535
Elobixibat	889	1,148	(259)
A3384	34	151	(117)
Preclinical	1,188	1,317	(129)
Total	$ 13,115	$ 7,085	$ 6,030
Other project costs[1]:			
Personnel costs	$ 4,632	$ 2,770	$ 1,862
Other costs[2]	650	1,179	(529)
Total	$ 5,282	$ 3,949	$ 1,333
Total research and development costs	$ 18,397	$ 11,034	$ 7,363

(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 June 30,		Change
	2020	2019	$
	(in thousands)		
General and administrative expenses	$ 8,474	$ 5,485	$ 2,989

General and administrative expenses were $8.5 million for the three months ended June 30, 2020 compared with $5.5 million for the three months ended June 30, 2019, an increase of $3.0 million. The increase is attributable to personnel and related expenses as we continue to increase our headcount, and commercialization readiness activity.

Other operating (income) expense, net

	Three Months Ended June 30,		Change
	2020	2019	$
	(in thousands)		
Other operating (income) expense, net	$ (6,744)	$ 8	$ (6,752)

Other operating income, net totaled $6.7 million for the three months ended June 30, 2020 compared with $0.0 million for the three months ended June 30, 2019. The difference primarily relates to changes in exchange rates in the two periods.

Interest expense, net

	Three Months Ended June 30,		Change
	2020	2019	$
	(in thousands)		
Interest expense, net	$ (2,388)	$ (1,351)	$ (1,037)

Interest expense, net totaled $2.4 million of expense for the three months ended June 30, 2020 compared with $1.4 million for the three months ended June 30, 2019. The difference was principally attributable to non-cash interest expense recorded in connection with the sale of future royalties, related to sales of elobixibat in Japan offset by interest income associated with our interest bearing cash and cash equivalents.

Six Months Ended June 30, 2020 and June 30, 2019

Result of Operations

	Six Months Ended June 30,		Change
	2020	2019	$
		(in thousands)	
Revenue	$ 3,461	$ 1,820	$ 1,641
Operating Expenses			
Research and development	34,527	19,363	15,164
General and Administrative	16,627	10,778	5,849
Other operating (income) expense, net	72	2,304	(2,232)
Total operating expenses	51,226	32,445	18,781
Operating loss	(47,765)	(30,625)	(17,140)
Interest expense, net	(4,326)	(2,660)	(1,666)
Net loss	$ (52,091)	$ (33,285)	$ (18,806)

Revenue

	Six Months Ended June 30,		Change
	2020	2019	$
		(in thousands)	
Revenue	$ 3,461	$ 1,820	$ 1,641

There was $3.5 million in revenue for the six months ended June 30, 2020 compared with $1.8 million for the six months ended June 30, 2019, an increase of $1.6 million. The increase in revenue is due to the estimated royalty revenue from EA Pharma for elobixibat for the period.

Research and development expenses

	Six Months Ended June 30,		Change
	2020	2019	$
		(in thousands)	
Research and development expenses	$ 34,527	$ 19,363	$ 15,164

There was $34.5 million in research and development expenses for the six months ended June 30, 2020 compared with $19.4 million for the six months ended June 30, 2019, an increase of $15.2 million. The higher research and development expenses for the 2020 period were principally due to personnel expenses, and program expenses as we continue to increase our headcount, and program activities, respectively.

The following table summarizes our principal product development programs and the out-of-pocket third-party expenses incurred with respect to each clinical-stage product candidate and our preclinical programs for the six months ended June 30, 2020 and 2019.

	Six Months Ended June 30, 2020	2019	Change $
		(in thousands)	
Direct third-party project costs:			
Odevixibat	$ 19,693	$ 7,833	$ 11,860
Elobixibat	1,757	1,371	386
A3384	93	225	(132)
Preclinical	2,483	2,320	163
Total	$ 24,026	$ 11,749	$ 12,277
Other project costs[1]:			
Personnel costs	$ 8,595	$ 5,470	$ 3,125
Other costs[2]	1,906	2,144	(238)
Total	$ 10,501	$ 7,614	$ 2,887
Total research and development costs	$ 34,527	$ 19,363	$ 15,164

(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

	Six Months Ended June 30, 2020	2019	Change $
		(in thousands)	
General and administrative expenses	$ 16,627	$ 10,778	$ 5,849

There was $16.6 million in general and administrative expenses for the six months ended June 30, 2020 compared with $10.8 million for the six months ended June 30, 2019, an increase of $5.8 million. The increase is attributable to personnel and related expenses as we continue to increase our headcount, and commercialization readiness activity.

Other operating expense, net

	Six Months Ended June 30, 2020	2019	Change $
		(in thousands)	
Other operating (income) expense, net	$ 72	$ 2,304	$ (2,232)

Other operating expense, net totaled $0.1 million for the six months ended June 30, 2020 compared with $2.3 million for the six months ended June 30, 2019. The difference resulted primarily from changes in currency exchange rates in the two periods.

Interest expense, net

	Six Months Ended June 30, 2020	2019	Change $
		(in thousands)	
Interest expense, net	$ (4,326)	$ (2,660)	$ (1,666)

Interest expense, net totaled $4.3 million of expense for the six months ended June 30, 2020 compared with $2.7 million of expense for the six months ended June 30, 2019. The difference was principally attributable to non-cash interest expense recorded in connection with the sale of future royalties, related to sales of elobixibat in Japan, offset by interest income.

Liquidity and Capital Resources

Sources of Liquidity

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

Our operations have historically been financed primarily through issuances of equity or convertible debt, upfront fees paid upon entering into license agreements, payments received upon the achievement of specified milestone events under license agreements, grants and venture debt borrowings and the HCR royalty monetization transactions. 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 June 30, 2020, our cash and cash equivalents were approximately $152.0 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. Additionally, this approval triggered a milestone payment to us from EA Pharma of $11.2 million. As of June 30, 2020, we have received approximately $49.9 million in upfront and milestone payments from EA Pharma under a license agreement for the development and commercialization of elobixibat in specified countries in Asia. We are eligible to receive additional amounts of up to $4.7 million under the amended agreement, if a specified regulatory event is achieved for elobixibat.

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

In March 2019, we entered into a new sales agreement, with respect to an at-the-market offering program under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $50.0 million. Subsequently, in May 2019, we sold 637,367 shares of our common stock for net proceeds of approximately $20.8 million pursuant to the sales agreement. This agreement terminated on May 7, 2020.

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

On May 7, 2020, we filed a new universal shelf registration on Form S-3 with the SEC, which was declared effective on May 18, 2020, 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. On May 6, 2020, we also entered into a new sales agreement, with respect to an at-the-market offering program under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $50.0 million. As of June 30, 2020, $200.0 million of securities remained available for issuance under our universal shelf registration statement, including $50.0 million available for sale under our sales agreement.

On June 8, 2020, we entered into a Loan and Security Agreement with the several banks and other financial institutions or entities from time to time parties to the Loan and Security Agreement, as lenders, or collectively referred

to as the Lender, and Hercules Capital, Inc., in its capacity as administrative agent and collateral agent for itself and Lender (in such capacity, the Agent or Hercules). The Loan and Security Agreement provides for term loans in an aggregate principal amount of up to $80.0 million to be delivered in multiple tranches, (the Term Loans). The tranches consist of (i) a term loan advance to Borrower in an aggregate principal amount of up to $15.0 million, of which (A) we agreed to borrow an aggregate principal amount of $10.0 million on the date on which all conditions to the funding of the Term Loans by the Lender were met, (the Closing Date), and (B) a right of the Borrower to request that the Lender make an additional term loan advance to us in an aggregate principal amount of $5.0 million prior to December 15, 2020, (ii) subject to the achievement of certain initial performance milestones, or Performance Milestone I, a right of the Borrower to request that the Lender make additional term loan advances to us in an aggregate principal amount of up to $20.0 million from January 1, 2021 through December 15, 2021 in minimum increments of $10.0 million, and (iii) subject to the Lender's investment committee's sole discretion, a right of the Borrower to request that the Lender make additional term loan advances to us in an aggregate principal amount of up to $45.0 million through March 31, 2022 in minimum increments of $5.0 million. As of June 30, 2020, we borrowed an aggregate principal amount of $10.0 million and an aggregate principal amount of up to $70.0 million remains available for future borrowings.

On June 8, 2020, we entered into an amendment (the Amendment) to the RIAA with HCR pursuant to which HCR agreed to pay us an additional $15.0 million in exchange for the elimination of the (i) $78.8 million cap amount on HCR's rights to receive royalties on sales in Japan and sales milestones for elobixibat in certain other territories that may become payable by EA Pharma and (ii) $15.0 million payable to us if a specified sales milestone is achieved for elobixibat in Japan.

Cash Flows

Six months ended June 30, 2020 and June 30, 2019

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (46,862)	(26,513)
Investing activities	(78)	(409)
Financing activities	67,502	22,174
Total	$ 20,562	$ (4,748)
Effect of exchange rate changes on cash and cash equivalents	(385)	(1,415)
Net increase (decrease) in cash and cash equivalents	20,177	(6,163)

Operating activities

Cash used in operating activities of $46.9 million during the six months ended June 30, 2020 was primarily a result of our $52.1 million net loss from operations and a net decrease in assets and liabilities of $4.3 million. The net decrease in operating assets and liabilities during the six months ended June 30, 2020 was primarily driven by decreases in accrued expenses, prepaid expenses and other current assets, and other current and long-term liabilities, and an increase to accounts payable. This decrease was offset by non cash items, including $5.0 million of stock-based compensation expense, and $4.4 million of accretion of liability related to sale of future royalties. Cash used in operating activities of $26.5 million during the six months ended June 30, 2019 was primarily a result of our $33.3 million net loss from operations and a net decrease in assets and liabilities of $4.7 million. The net decrease in operating assets and liabilities during the six months ended June 30, 2019 was primarily driven by decreases in accounts payable, accrued expenses and an increase to prepaid expenses and other current assets, and other assets. This decrease was offset by non cash items, including $4.1 million of non cash interest expense on liability related to royalty monetization, $3.9 million of stock-based compensation expense and $3.5 million in unrealized foreign exchange loss.

Investing activities

Cash used in investing activities of $0.1 million during the six months ended June 30, 2020 was primarily related to purchase of property, plant and equipment. Cash used in investing activities of $0.4 million during the six months ended June 30, 2019 was primarily due to the purchase of property, plant and equipment.

Financing activities

Cash provided by financing activities of $67.5 million during the six months ended June 30, 2020 was primarily related to proceeds from the issuance of common stock, net of issuance costs of $43.0 million, proceeds from royalty agreement of $14.8 million, and proceeds from issuance of debt, net of issuance costs of $9.5 million. Cash provided by financing activities of $22.2 million during the six months ended June 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 stock options of $1.4 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 into the beginning of 2022, including for our Phase 3 clinical program for odevixibat in PFIC and our pivotal trial of odevixibat in biliary atresia, and to initiate our planned pivotal trial of odevixibat in ALGS. However, our operating plans may change as a result of many factors, including those described below, and we may need additional funds sooner than planned to meet operational needs and capital requirements. In addition, if the conditions for raising capital are favorable we may seek to raise additional funds at any time.

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

- the costs, design, duration and any potential delays of the Phase 3 clinical trial of odevixibat in PFIC, the pivotal clinical trial of odevixibat in biliary atresia and planned pivotal trial of odevixibat in ALGS; the scope, number, progress, initiation, duration, cost, results and timing of clinical trials and nonclinical studies of our current or future product candidates;
- whether and to what extent milestone events are achieved under our license agreement with EA Pharma or any potential future licensee or collaborator;
- the outcomes and timing of regulatory reviews, approvals or other actions;
- our ability to obtain marketing approval for our product candidates;
- our ability to establish and maintain additional licensing, collaboration or similar arrangements on favorable terms and whether and to what extent we retain development or commercialization responsibilities under any new licensing, collaboration or similar arrangement;
- the success of any other business, product or technology that we acquire or in which we invest;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio;
- our ability to manufacture any approved products on commercially reasonable terms;
- our ability to establish a sales and marketing organization or suitable third-party alternatives for any approved product;

- the number and characteristics of product candidates and programs that we pursue;
- the potential impacts of the COVID-19 pandemic on our business;
- the costs of acquiring, licensing or investing in businesses, product candidates and technologies;
- our need and ability to hire additional management and scientific and medical personnel;
- the costs to operate as a public company in the United States, including the need to implement additional financial and reporting systems and other internal systems and infrastructure for our business;
- market acceptance of our product candidates, to the extent any are approved for commercial sale; and
- the effect of competing technological and market developments.

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

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

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

We have an effective universal shelf registration statement on Form S-3 with the SEC, pursuant to which we registered for sale up to $200 million of any combination of our common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that we may determine, including up to $50.0 million of our common stock available for issuance pursuant to an at-the-market offering program sales agreement that we entered into with Cowen and Company, LLC, or Cowen, in in May 2020. As of June 30, 2020, $200.0 million of securities remain available for issuance under the shelf registration statement, including up to $50.0 million of our common stock that we may offer and sell, from time to time at our discretion, through Cowen as sales agent under the at-the-market offering program sales agreement. Under the sales agreement, Cowen may sell the shares by any method permitted by law deemed to be an “at the market” offering as defined in Rule 415 of the Securities Act. The sale of additional equity or convertible debt securities may result in significant dilution to our stockholders, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. The incurrence of additional debt financing would result in debt service obligations and the instruments governing such debt may provide for operating and financing covenants that would restrict our operations. We may also seek to finance future cash needs through potential future licensing, collaboration or similar arrangements. These arrangements may not be available on acceptable terms or at all, and we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our development programs or obtain funds through third-party arrangements that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

On June 8, 2020, we entered into a Loan and Security Agreement with the several banks and other financial institutions or entities from time to time parties to the Loan and Security Agreement, as lenders, or collectively referred

to as the Lender, and Hercules Capital, Inc., in its capacity as administrative agent and collateral agent for itself and Lender (in such capacity, the Agent or Hercules). The Loan and Security Agreement provides for term loans in an aggregate principal amount of up to $80.0 million to be delivered in multiple tranches, or the Term Loans. The tranches consist of (i) a term loan advance to Borrower in an aggregate principal amount of up to $15.0 million, of which (A) we agreed to borrow an aggregate principal amount of $10.0 million on the date on which all conditions to the funding of the Term Loans by the Lender were met, or the Closing Date, and (B) a right of the Borrower to request that the Lender make an additional term loan advance to us in an aggregate principal amount of $5.0 million prior to December 15, 2020, (ii) subject to the achievement of certain initial performance milestones, or Performance Milestone I, a right of the Borrower to request that the Lender make additional term loan advances to us in an aggregate principal amount of up to $20.0 million from January 1, 2021 through December 15, 2021 in minimum increments of $10.0 million, and (iii) subject to the Lender's investment committee's sole discretion, a right of the Borrower to request that the Lender make additional term loan advances to us in an aggregate principal amount of up to $45.0 million through March 31, 2022 in minimum increments of $5.0 million. As of June 30, 2020, we borrowed an aggregate principal amount of $10.0 million and an aggregate principal amount of up to $70.0 million remains available for future borrowings.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not required for smaller reporting companies.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of June 30, 2020, our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Form 10-Q, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

Other than as described above, there were no changes in our internal controls over financial reporting identified in connection with the evaluation of such internal controls that occurred during the three months ended June 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

There have been no material changes to the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the Securities and Exchange Commission, or SEC, on March 2, 2020 as amended and supplemented by the risk factors described in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, filed with the SEC on May 7, 2020, except as noted below.

The terms of our loan and security agreement with Hercules Capital require us to meet certain operating covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

On June 8, 2020, we entered into a loan and security agreement, or the Loan Agreement, with Hercules Capital, Inc., in its capacity as administrative and collateral agent for itself and the other Lenders party to the Loan Agreement. The loan advanced under the Loan Agreement, or the Term Loan, is secured by a security interest covering our assets, other than our intellectual property and other customary collateral exclusions. The Loan Agreement contains customary affirmative and negative covenants and events of default. Affirmative covenants include, among others, covenants requiring us to maintain our legal existence and comply with all applicable laws, deliver certain financial reports, maintain a minimum cash balance, and maintain insurance coverage. Negative covenants include, among others, covenants restricting us from transferring any part of our business or intellectual property, incurring additional indebtedness, engaging in mergers or acquisitions, repurchasing shares, paying dividends or making other distributions, making investments, and creating other liens on our assets, including our intellectual property, in each case subject to customary exceptions. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility. These restrictions may include, among other things, limitations on borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem capital stock or make investments. If we default under the terms of the Loan Agreement or any future debt facility, the Lenders may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the Lenders' right to repayment would be senior to the rights of the holders of our common stock. The Lenders could declare a default upon the occurrence of any event that it interprets as a material adverse effect as defined under the Loan Agreement. Any declaration by the Lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Repayment of the Term Loan will require a significant amount of cash, and we may not have sufficient cash flow from our business to make payments on our indebtedness.

Our ability to pay the principal of and/or interest on the Term Loan depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service the Term Loan or other future indebtedness and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt and implement one or more alternatives, such as selling assets, restructuring indebtedness or obtaining additional debt financing or equity financing on terms that may be onerous or highly dilutive. Our ability to refinance the Term Loan or other future indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, including the Term Loan.

Item 6. Exhibits

Exhibit No.	Description	Filed Herewith	Incorporated by Reference Herein from Form or Schedule	Filing Date	SEC File/ Req. Number
4.1	Form of Warrant issued by the Registrant to Hercules Capital, Inc.		Form 8-K (Exhibit 10.2)	6/9/20	001-33451
10.1	Second Amendment to Lease dated as of May 4, 2020, by and between NS Boston III PO Owner LLC and the Registrant.		Form 10-Q (Exhibit 10.2)	5/7/20	00133451
10.2	Sales Agreement, dated as of May 7, 2020, by and between the Registrant and Cowen and Company, LLC.		Form S-3 (Exhibit 1.2)	5/7/20	333-238063
10.3	Loan and Security Agreement, dated as of June 8, 2020, by and between the Registrant and Hercules Capital, Inc.		Form 8-K (Exhibit 10.1)	6/9/20	001-33451
10.4*	Amendment No 1. to Royalty Interest Acquisition Agreement, dated as of June 8, 2020, by and among Elobix AB, HealthCare Royalty Partners III, L.P. and, solely for the purposes specified therein, the Registrant .		Form 8-K (Exhibit 10.3)	6/9/20	001-33451
31.1	Certification of the Registrant's Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of the Registrant's Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets (unaudited) at June 30, 2020 and December 31, 2019, (ii) Condensed Consolidated Statements of Operations (unaudited) for the three and six months ended June 30, 2020 and 2019, (iii) Condensed Consolidated Statements of Comprehensive Income (Loss) (unaudited) for the three and six months ended June 30, 2020 and 2019, (iv) Condensed Consolidated Statement of Stockholders' Equity (unaudited) for the three and six months ended June 30, 2020 and 2019, (v) Condensed Consolidated Statements of Cash Flows (unaudited) for the six months ended June 30, 2020 and 2019, and (vi) Notes to Condensed Consolidated Financial Statements (unaudited).	X			
104	Cover Page Interactive Date File (formatted as Inline XBRL and contained in Exhibit 101).	X			

* Confidential portions of this exhibit have been omitted from this exhibit.

SIGNATURES

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

ALBIREO PHARMA, INC.

Dated: August 6, 2020

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

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

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

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

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

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

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

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

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

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

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

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

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

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

Date: August 6, 2020

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

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

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

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

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

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

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

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

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

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

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

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

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

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

Date: August 6, 2020

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

Exhibit 32.1

CERTIFICATIONS UNDER SECTION 906

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

The Quarterly Report for the quarter ended June 30, 2020 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 6, 2020

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

Dated: August 6, 2020

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