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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, 2022

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.)**
53 State Street, 19th Floor, 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, par value $0.01 per share	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 August 8, 2022, there were 19,612,509 shares of Common Stock, $0.01 par value per share, outstanding.

Albireo Pharma, Inc.

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, which we refer to as the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act, that relate to future events or to our future operating 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:

- our commercialization plans and expectations for commercializing Bylvay™ (odevixibat) globally;
- the progress, number, scope, cost, duration or results of our development activities, nonclinical studies and clinical trials of Bylvay, elobixibat, A3907, A2342 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 BOLD, our pivotal clinical trial of Bylvay in patients with biliary atresia, or ASSERT, our pivotal trial of Bylvay in Alagille syndrome, or ALGS) for submission, review or approval of any regulatory filing, or for meeting with regulatory authorities;
- the potential benefits that may be derived from any of our product candidates;
- the timing of and our ability to obtain and maintain regulatory approval of our existing product candidates, any product candidates that we may develop, and any related restrictions, limitations, or warnings in the label of any approved product candidates;
- any payment that 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 operations or financial condition;
- 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:

- our ability to effectively commercialize Bylvay for its approved indications;
- the design, size, duration and endpoints for, and results from BOLD, our pivotal trial of Bylvay in biliary atresia, and ASSERT, our pivotal trial of Bylvay in ALGS, or any other trials that will be required to obtain

marketing approval for Bylvay to treat patients with progressive familial intrahepatic cholestasis, or PFIC, biliary atresia, ALGS or any other pediatric cholestatic liver disease or for A3907 and A2342 as potential treatments for adult liver and viral diseases;

- whether favorable findings from clinical trials of Bylvay to date, including findings in our completed Phase 3 clinical trial in PFIC and findings in indications other than PFIC, will be predictive of results from future clinical trials, including our pivotal trial of Bylvay in biliary atresia and pivotal trial of Bylvay in ALGS;
- the outcome and interpretation by regulatory authorities of an ongoing third-party study pooling and analyzing long-term PFIC patient data;
- the timing for completion of, or for availability of data from, our pivotal trial of Bylvay in biliary atresia and our pivotal trial of Bylvay in ALGS, and the outcomes of such trials;
- delays or other challenges in the recruitment of patients for the pivotal trial of Bylvay in biliary atresia;
- 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 treatment for PFIC and potentially other orphan pediatric cholestatic liver diseases;
- the conduct and results of clinical trials and nonclinical studies and assessments of Bylvay, A3907, A2342 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 Bylvay, A3907, A2342 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;
- whether we are able to effectively commercialize Bylvay in patients with PFIC;
- the significant control or influence that EA Pharma has over the commercialization of elobixibat in Japan, and through its sublicensee in Thailand, 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;
- the accuracy of our estimates regarding expenses, costs, revenues, uses of cash and capital requirements;
- our ability to obtain additional financing on reasonable terms, or at all;
- our ability to establish and maintain additional licensing, collaboration or similar arrangements on favorable terms and our ability to attract collaborators with development, regulatory and commercialization expertise;
- the success of competing third-party products or product candidates;

- our ability to successfully commercialize any approved product candidates, including their rate and degree of market acceptance;
- our ability to expand and protect our intellectual property estate;
- regulatory developments in the United States and other countries;
- the effectiveness of our internal control over financial reporting;
- the performance of our third-party suppliers, manufacturers and contract research organizations and our ability to obtain alternative sources of raw materials;
- our ability to attract and retain key personnel; and
- our ability to comply with regulatory requirements relating to our business, and the costs of compliance with those requirements, including those on data privacy and security.

These and other risks and uncertainties are described in greater detail under the caption “Risk Factors” in Item 1A of Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, 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)

	June 30, 2022	December 31, 2021
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 180,971	$ 248,107
Accounts receivable, net	1,849	3,272
Inventory	2,096	194
Prepaid expenses	8,170	5,261
Other current assets	2,666	12,096
Total current assets	195,752	268,930
Property and equipment, net	1,388	668
Goodwill	17,260	17,260
Other assets	14,614	15,193
Total assets	$ 229,014	$ 302,051
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,394	$ 6,516
Accrued expenses	23,034	35,951
Current portion of note payable, net of discount	10,158	—
Other current liabilities	5,005	2,880
Total current liabilities	43,591	45,347
Liability related to sale of future royalties	61,493	60,132
Note payable, net of discount	—	10,004
Other long-term liabilities	10,253	10,960
Total liabilities	115,337	126,443
Stockholders' Equity:		
Preferred stock, $0.01 par value per share — 50,000,000 shares authorized at June 30, 2022 and December 31, 2021; 0 and 0 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	—	—
Common stock, $0.01 par value per share — 60,000,000 shares authorized at June 30, 2022 and December 31, 2021; 19,610,205 and 19,602,445 shares issued and outstanding at June 30, 2022, respectively, and 19,304,312 and 19,296,552 shares issued and outstanding at December 31, 2021, respectively	196	193
Additional paid-in capital	488,692	475,390
Accumulated other comprehensive income	8,252	1,105
Accumulated deficit	(383,233)	(300,850)
Treasury stock at cost, 7,760 shares at June 30, 2022 and December 31 2021, respectively	(230)	(230)
Total stockholders' equity	113,677	175,608
Total liabilities and stockholders' equity	$ 229,014	$ 302,051

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,	
	2022	2021	2022	2021
Revenue:				
Product revenue, net	$ 5,891	$ —	$ 10,547	$ —
Royalty revenue	2,315	2,428	4,491	4,394
Total revenue	8,206	2,428	15,038	4,394
Cost and operating expenses:				
Cost of product revenue	776	—	1,010	—
Research and development	22,888	20,894	44,791	40,837
Selling, general and administrative	21,600	16,940	38,455	32,213
Other operating expense (income), net	145	(2,374)	7,543	4,154
Total cost and operating expenses	45,409	35,460	91,799	77,204
Operating loss	(37,203)	(33,032)	(76,761)	(72,810)
Other loss:				
Interest expense, net	(2,746)	(3,389)	(5,622)	(7,344)
Net loss	$ (39,949)	$ (36,421)	$ (82,383)	$ (80,154)
Net loss per share attributable to holders of common stock:				
Net loss per common share - basic and diluted	$ (2.04)	$ (1.90)	$ (4.23)	$ (4.18)
Weighted-average common shares used to compute basic and diluted net loss per common share	19,585,164	19,200,747	19,482,943	19,196,798

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,	
	2022	2021	2022	2021
Net loss	$ (39,949)	$ (36,421)	$ (82,383)	$ (80,154)
Other comprehensive income (loss):				
Foreign currency translation adjustment	23	(2,721)	7,147	4,233
Total other comprehensive income (loss)	23	(2,721)	7,147	4,233
Total comprehensive loss	$ (39,926)	$ (39,142)	$ (75,236)	$ (75,921)

See accompanying notes to Condensed Consolidated Financial Statements.

Albireo Pharma, Inc.

Condensed Consolidated Statements of Stockholders' Equity

(in thousands, except share data)

(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Treasury Stock At Cost		Total Stockholders' Equity
	Shares	Amount				Shares	Amount	
Balance--December 31, 2021	19,304,312	$ 193	$ 475,390	$ 1,105	$ (300,850)	(7,760)	$ (230)	$ 175,608
Stock-based compensation expense	—	—	3,508	—	—	—	—	3,508
Exercise of options and vesting of RSUs	223,683	2	4,378	—	—	—	—	4,380
Other comprehensive income	—	—	—	7,124	—	—	—	7,124
Net loss	—	—	—	—	(42,434)	—	—	(42,434)
Balance--March 31, 2022	19,527,995	$ 195	$ 483,276	$ 8,229	$ (343,284)	(7,760)	$ (230)	$ 148,186
Stock-based compensation expense	—	—	3,616	—	—	—	—	3,616
Exercise of options and vesting of RSUs	82,565	1	1,800	—	—	—	—	1,801
Other comprehensive income	—	—	—	23	—	—	—	23
Net loss	—	—	—	—	(39,949)	—	—	(39,949)
Balance--June 30, 2022	19,610,560	$ 196	$ 488,692	$ 8,252	$ (383,233)	(7,760)	$ (230)	$ 113,677

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Treasury Stock At Cost		Total Stockholders' Equity
	Shares	Amount				Shares	Amount	
Balance--December 31, 2020	19,107,040	$ 191	$ 456,472	$ (8,612)	$ (266,820)	—	$ —	$ 181,231
Stock-based compensation expense	—	—	3,062	—	—	—	—	3,062
Exercise of options and vesting of RSUs	85,765	1	403	—	—	—	—	404
Other comprehensive income	—	—	—	6,954	—	—	—	6,954
Net loss	—	—	—	—	(43,733)	—	—	(43,733)
Balance--March 31, 2021	19,192,805	$ 192	$ 459,937	$ (1,658)	$ (310,553)	—	$ —	$ 147,918
Stock-based compensation expense	—	—	3,504	—	—	—	—	3,504
Exercise of options and vesting of RSUs	47,490	—	1,224	—	—	—	—	1,224
Other comprehensive loss	—	—	—	(2,721)	—	—	—	(2,721)
Net loss	—	—	—	—	(36,421)	—	—	(36,421)
Balance--June 30, 2021	19,240,295	$ 192	$ 464,665	$ (4,379)	$ (346,974)	—	$ —	$ 113,504

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,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (82,383)	$ (80,154)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accretion of liability related to sale of future royalties	5,474	6,248
Accretion of debt discount and amortization of issuance costs	154	235
Depreciation and amortization	198	75
Share based compensation expense	7,124	6,566
Foreign currency adjustments	7,100	4,127
Changes in operating assets and liabilities:		
Accounts receivable, net	1,276	—
Inventory	(1,908)	—
Prepaid expenses and other current assets	6,294	1,596
Other assets	474	159
Accounts payable	(1,026)	478
Accrued expenses	(12,074)	(1,103)
Other current and long-term liabilities	(2,504)	(4,412)
Net cash used in operating activities	(71,801)	(66,185)
Cash flows from investing activities:		
Purchase of property and equipment	(920)	(279)
Net cash used in investing activities	(920)	(279)
Cash flows from financing activities:		
Proceeds from exercise of options	6,181	1,627
Net cash provided by financing activities	6,181	1,627
Effect of exchange rate changes on cash and cash equivalents	(596)	(149)
Net decrease in cash and cash equivalents	(67,136)	(64,986)
Cash and cash equivalents—beginning of period	248,107	251,272
Cash and cash equivalents—end of period	$ 180,971	$ 186,286
Supplemental disclosures of cash and non-cash activities		
Fixed assets included in accrued expenses	$ —	$ 186

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 commercial-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 product pipeline includes Bylvay (odevixibat) approved in the United States and Europe, elobixibat, approved in Japan and Thailand for the treatment of chronic constipation, A3907, our Phase 1 lead candidate for the treatment of adult liver diseases, A2342, our lead preclinical candidate for the treatment of adult viral and liver diseases, and multiple other preclinical candidates. Bylvay was approved by the U.S. Food and Drug Administration (FDA) on July 20, 2021 for the treatment of pruritus in patients with progressive familial intrahepatic cholestasis (PFIC) ages 3 months or older, and authorized by the European Medicines Agency on July 16, 2021 for the treatment of PFIC in patients 6 months or older. Bylvay was also granted marketing authorization by the UK Medicines and Healthcare Products Regulatory Agency (MHRA) in September 2021 for the treatment of PFIC in patients 6 months or older. Bylvay is also in Phase 3 development for the treatment of biliary atresia and Alagille syndrome (ALGS), each a rare, life-threatening disorder affecting young children.

Since its inception, the Company has devoted substantially all of its resources to its research and development efforts, including activities to develop its product candidates, to commercialize Bylvay in PFIC, to prepare for the commercialization of Bylvay in other indications, if approved, and to provide general and administrative support for these operations.

The Company has primarily funded its operations with proceeds from the sales of common stock, the sale of future royalties, upfront and milestone payments for regional agreements, proceeds from the issuance of debt, and the sale of a Priority Review Voucher (PRV). As of June 30, 2022, the Company has raised an aggregate of $356.9 million through the issuance of common stock, net of issuance costs, $59.3 million from the sale of its future royalties, $9.5 million through the Loan and Security Agreement (see Note 7), net of issuance costs, and net proceeds of $103.4 million, after deducting commission costs, from the sale of the PRV.

The Company has incurred significant operating losses and negative cash flows from operations since inception. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future. In addition, the Company anticipates that its expenses will increase significantly in connection with ongoing activities to support the commercialization of Bylvay for PFIC and the advancement of Bylvay in its later stage clinical trials and providing administrative support.

As a result, the Company will need substantial additional funding to support its continued operations and growth strategy. Until such a time as the Company can generate significant revenue from product sales, if ever, the Company expects to finance its operations through the sale of equity, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. The Company may be unable to raise additional funds or enter into such other agreements on favorable terms, or at all. If the Company fails to raise capital or enter into such agreements as, and when, needed, the Company may have to significantly delay, scale back or discontinue the development and commercialization of one or more of its product candidates or delay its pursuit of potential in-licenses or acquisitions.

As of June 30, 2022, the Company had cash and cash equivalents of $181.0 million. Management believes that its cash and cash equivalents at June 30, 2022 will be sufficient to allow the Company to fund its current operating plan through at least the next twelve months from the issuance of these financial statements.

The Company is subject to those risks associated with any biopharmaceutical company that has substantial expenditures for research and development. There can be no assurance that the Company's research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable. In addition, the Company operates in an environment of rapid technological change and is largely dependent on the services of its employees and consultants. If the Company fails to become profitable or is unable to sustain profitability on a continuing basis, then it may be unable to continue its operations at planned levels and be forced to reduce its operations.

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 the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021. 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, 2022 and 2021 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 and presentation currency

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

Transactions and balances

Foreign currency transactions in each entity comprising the Company are remeasured into the functional currency of the entity using the exchange rates prevailing at the respective transaction dates. Foreign exchange gains and losses resulting from the settlement of such transactions and from the remeasurement at period-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized within other operating expense (income), net except for changes in the liability related to the sale of future royalties which are recorded in interest expense, net in the Condensed Consolidated Statements of Operations.

The results and financial position of the Company's subsidiaries' 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, 2022 and December 31, 2021;

b. income and expenses for the statement of operations and comprehensive loss are translated at the average exchange rates that are relevant for the respective periods for which the income and expenses occur; and

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

All resulting exchange differences arising from such translations are recognized directly in other comprehensive income 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, including its clinical trial accruals and revenue deductions related to rebates, chargebacks and other discounts, realizability of deferred tax assets and the accretion of interest on the monetization liability. Actual results could materially differ from these estimates.

Revenue recognition

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services in accordance with ASC 606 *Revenue from Contracts with Customers*. To determine revenue recognition for contracts with its customers, the Company performs the following five step assessment: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception and once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract, determines which goods and services are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Revenue, net

The Company recognizes revenue on sales of Bylvay when a customer obtains control of the product, which occurs at a point in time and upon delivery. The Company sells Bylvay to a limited number of specialty pharmacies and a specialty distributor in the United States which dispense the product directly to patients. The specialty pharmacies and specialty distributor are referred to as the Company's customers. The Company also sells Bylvay to its customers in the European Union, which includes a limited number of pharmacies.

The Company provides the right of return to its customers for unopened product for a limited time before and after its expiration date. We currently estimate product returns using available industry data as well as the Company's visibility into the inventory remaining in the distribution channel.

The Company has written contracts with each of its customers that have a single performance obligation to deliver products upon receipt of a customer order and these obligations are satisfied when delivery occurs and the customer

receives Bylvay. The Company evaluates creditworthiness of each of its customers to determine whether collection is reasonably assured. The wholesale acquisition cost that the Company charges its customers for Bylvay is adjusted to arrive at the Company's estimated net product revenues by deducting components of variable consideration which include (i) estimated government rebates and discounts related to Medicaid and other government programs, (ii) estimated costs of incentives offered to certain indirect customers including patients, (iii) trade allowances, such as invoice discounts for prompt payment and customer fees, and (iv) allowance for sales returns. Product revenue, net was $3.5 million in the United States and $2.4 million in Europe for the three months ended June 30, 2022. Product revenue, net was $6.3 million in the United States and $4.2 million in Europe for the six months ended June 30, 2022. There was no product revenue for the three or six months ended June 30, 2021.

Rebates and Discounts

The Company contracts with the Centers for Medicare & Medicaid Services and other government agencies in the U.S. to make Bylvay available to eligible patients. As a result, the Company estimates any rebates and discounts, including chargebacks related to Section 340B of the Public Health Service Act, and deducts these estimated amounts from its gross product revenues at the time the revenues are recognized. The Company's estimates of rebates and discounts are based on the government mandated discounts, which are statutorily-defined and applicable to these government funded programs and assumptions developed using historical experience with actual payments and redemptions. The Company recorded $1.1 million and $0.7 million in such estimates as of June 30, 2022 and December 31, 2021, respectively, in accounts receivable, net and other current liabilities on the consolidated balance sheets.

The Company contracts with national authorities in Europe to make Bylvay available to eligible patients. In jurisdictions in which final pricing is subject to ongoing negotiations with the government, the Company estimates the rebate expected to be due and deducts these estimated amounts from its gross product revenues at the time the revenues are recognized. The Company's estimates of such liabilities are based on current invoice pricing and total prior units sold and assumptions developed using benchmarks of Bylvay pricing approved in other relevant European jurisdictions. The Company recorded $0.5 million and $0.2 million in such estimates as of June 30, 2022 and December 31, 2021, respectively, in other current liabilities on the consolidated balance sheets.

Other Incentives

Other incentives that the Company offers to indirect customers include co-pay assistance cards provided by the Company for patients who reside in states that permit co-pay assistance programs. The Company's co-pay assistance program is intended to reduce each participating patient's portion of the financial responsibility for Bylvay's purchase price to a specified dollar amount. The Company estimates the amount of co-pay assistance provided to eligible patients based on the terms of the program when product is dispensed by the specialty pharmacies to the patients. These estimates are based on redemption information provided by third-party claims processing organizations. The Company funds this incentive program through upfront payments. There were no upfront payments made during the quarter ended June 30, 2022. The Company recorded less than $0.1 million in such estimates as of June 30, 2022 and December 31, 2021 in prepaid expenses on the consolidated balance sheets.

Trade Allowances

The Company provides invoice discounts on Bylvay sales to its customers for prompt payment and records these discounts as a reduction to gross product revenues. These discounts are based on contractual terms. The Company also pays fees to its distributors for their services as well as data that they provide to the Company. Prompt payment allowances are recorded in accounts receivable, net on the consolidated balance sheets. There were no prompt payment allowances as of June 30, 2022. Prompt payment allowances were less than $0.1 million at December 31, 2021. The other distributor fees are recorded as other current liabilities on the consolidated balance sheets and was $0.1 million as of June 30, 2022 and December 31, 2021.

Milestone Payments

At the inception of each arrangement that includes development milestone payments or upfront payment, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price, which includes any upfront payments, 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. Once the estimated transaction price is established, the associated consideration is allocated to the performance obligations that have been identified in the respective agreement. 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 in which 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, 2022, the Company is eligible to receive an additional regulatory-based milestone payment under the Agreement of $4.5 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 transaction 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 and milestones as revenue. Upon receipt of the payments from HCR 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, 2022:

	June 30, 2022 (in thousands)
Liability related to sale of future royalties—beginning balance	$ 71,667
Accretion of interest expense on liability related to royalty monetization	5,474
Repayment of the liability	(13,353)
Liability related to sale of future royalties—ending balance	$ 63,788
Less current portion classified within accrued expenses	(2,295)
Long-term liability related to sale of future royalties	$ 61,493

The Company records estimated royalties due for the current period in accrued expenses until the payment is received from EA Pharma at which time the Company then remits payment to HCR. As royalties are remitted to HCR, the balance of the royalty obligation will be effectively repaid over the life of the RIAA. In order to determine the 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. 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, 2022, the Company's estimate of its total interest expense resulted in an annual effective interest rate of approximately 18.0%.

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.

Trade Receivables, net

Accounts receivable, net related to product sales, which are recorded in accounts receivable, net on the consolidated balance sheets, were approximately $1.8 million and $3.3 million as of June 30, 2022 and December 31, 2021, respectively. As of June 30, 2022 and December 31, 2021, we had no allowance for doubtful accounts. An allowance for doubtful accounts is determined based on the Company's assessment of the credit worthiness and financial condition of its customers, aging of receivables, as well as the general economic environment. Any allowance would reduce the net receivables to the amount that is expected to be collected. Payment terms for U.S. customers are typically 31 - 36 days from receipt of invoice and for European customers are typically 45 days from receipt of invoice.

Inventory

The Company commenced capitalizing inventory for Bylvay upon FDA approval on July 20, 2021. All commercial manufacturing expenses were expensed as research and development expenses prior to FDA approval. Manufacturing costs incurred prior to FDA approval totaled approximately $1.6 million and were not capitalized, and instead were

expensed as research and development expenses from 2020 to 2021. All manufacturing subsequent to FDA approval is capitalized in inventory.

Recent accounting pronouncements

There are no recently issued accounting pronouncements the Company has not yet adopted that will materially impact the Company's 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.

The following tables represent information about the Company's financial assets that are measured at fair value on a recurring basis (in thousands):

	June 30, 2022		
	Level 1	Level 2	Level 3
Cash Equivalents:			
Money market funds	$ 176,504	$ —	$ —
Total	$ 176,504	$ —	$ —

	December 31, 2021		
	Level 1	Level 2	Level 3
Cash Equivalents:			
Money market funds	$ 243,180	$ —	$ —
Total	$ 243,180	$ —	$ —

The Company's financial instruments consist mainly of cash equivalents, prepaid expenses and other current assets, accounts payable, accrued expenses, other current liabilities, and note payable. The carrying amounts of cash equivalents, prepaid expenses and other current assets, accounts payable, accrued expenses, and other current liabilities approximate their estimated fair value due to their short-term maturities. At June 30, 2022, the carrying value of the Loan and Security Agreement (see Note 7) approximates the fair value of the note payable, considering that it bears interest that is similar to prevailing market rates.

3. Commitments and contingencies

Agreements with CROs and CMOs

As of June 30, 2022, the Company had various agreements with CROs and CMOs for the conduct of specified research and development activities and based on the terms of the respective agreements, the Company is contractually obligated to make future payments of up to $10.2 million upon the completion of contracted work.

4. Net loss per share

Basic net loss per share, is calculated by dividing the net loss attributable to holders of common stock by the weighted average number of shares of common stock outstanding. When the Company is in a net loss position, diluted net loss per share is calculated by dividing the net loss attributable to holders of common stock by the weighted average number of shares of common stock outstanding, excluding dilutive common stock equivalents outstanding. When the Company is in a net income position, diluted net income per share would be calculated by dividing the net income attributable to holders of common stock by the weighted-average number of shares of common stock plus dilutive common stock equivalents outstanding.

The following table sets forth the computation of basic and diluted net loss per share (in thousands, except for share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Basic and Diluted net loss per share:				
Numerator				
Net loss	$ (39,949)	$ (36,421)	$ (82,383)	$ (80,154)
Denominator				
Weighted average number of shares outstanding	19,585,164	19,200,747	19,482,943	19,196,798
Basic and Diluted net loss per share	$ (2.04)	$ (1.90)	$ (4.23)	$ (4.18)

For purposes of a dilutive net loss per share calculation, stock options, restricted stock units (RSUs) and warrants are considered to be common stock equivalents but are excluded from the calculation of diluted net loss per share in the periods where the Company has incurred a net loss, as their effect would be anti-dilutive given the Company's net loss. Common stock equivalents may also be excluded from the calculation of diluted net income per share if the exercise prices exceed the average market price for the reporting period.

The following outstanding common stock equivalents were excluded from the computation of diluted net loss per share for the three and six months ended June 30, 2022 and 2021 because including them would have been anti-dilutive:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Options to purchase common stock, RSUs and warrants	3,536,437	3,178,079	3,536,437	3,178,079

5. Income taxes

The Company did not record a tax provision or benefit for the six months ended June 30, 2022 or 2021. The Company expects to maintain a full valuation allowance against its net deferred tax assets for the year.

6. Inventory

Inventory consists of the following (in thousands):

	June 30, 2022	December 31, 2021
Raw materials	$ 955	$ —
Work-in-process	536	—
Finished goods	605	194
Total inventory	$ 2,096	$ 194

There were no write downs for excess and obsolete inventory during the three and six months ended June 30, 2022 based on the finished goods inventory shelf life of 24 months, and an analysis over the future demand for Bylvay relative to the remaining shelf life of inventory as of June 30, 2022.

7. Note Payable

2020 Loan and Security Agreement

On June 8, 2020, the Company entered into a Loan and Security Agreement with several banks and other financial institutions or entities from time to time parties to the Loan and Security Agreement (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), which provided for term loans up to an aggregate principal amount of $80.0 million (the Term Loans) to the Company. The Loan Agreement provided for (i) an initial term loan advance of $10.0 million, which closed on June 8, 2020, (ii) subject to the achievement of certain initial performance milestones (Performance Milestone I), the Company had the right 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, which Company did not exercise, and (iii) subject to the Lender's investment committee's sole discretion, the Company had the right 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, which the Company did not exercise. As of June 30, 2022, the Company borrowed an aggregate principal amount of $10.0 million and there were no additional term loans available to the Company for advance under the Loan and Security Agreement. The Company is required to pay an end of term fee (the 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 was extended to July 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 10.65% and 10.65% plus the prime rate of interest minus 4.75%. Borrowings under the Loan and Security Agreement are repayable in monthly interest-only payments through January 1, 2022, which was extended to (i) July 1, 2022 upon the Company's achievement of Performance Milestone I and (ii) July 1, 2023 upon the Company's 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: 2.0% of the principal amount outstanding if the prepayment occurs after the first nine

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 and Security Agreement, the Company granted Agent a security interest senior to any current and future debts and to any security interest, in all of the Company'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 Company's intellectual property. The Loan and Security Agreement also contains certain events of default, representations, warranties and non-financial covenants of the Company.

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 and Security Agreement as of June 30, 2022 is approximately 14.6%.

As of June 30, 2022 the carrying value of the note payable consists of the following:

	June 30, 2022 (in thousands)
Note payable, including End of Term Charge	10,695
Debt discount, net of accretion	(537)
Current portion of note payable, net of discount	$ 10,158

During the three months ended June 30, 2022 and 2021, the Company recognized $0.3 million and $0.4 million, respectively, of interest expense related to the Loan and Security Agreement. During the six months ended June 30, 2022 and 2021, the Company recognized $0.6 million and $0.7 million, respectively, of interest expense related to the Loan and Security Agreement.

Estimated future principal payments due under the Loan and Security Agreement, including the contractual End of Term Charge, are as follows as of June 30, 2022:

	Note Principal Payments (in thousands)
Remainder of 2022	$ 10,695

As of June 30, 2022, 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, approximated fair value.

Warrants

Under the Loan and Security Agreement, the Company agreed to issue to Hercules warrants (the Warrants) to purchase a number of shares of 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 are 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 stock 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.

8. Equity Financings

2021 At-the-Market Offering Program Sales Agreement

In February 2021 the Company filed an automatic shelf registration statement on Form S-3 with the SEC (the 2021 Form S-3), which became effective upon filing, pursuant to which the Company registered for sale an unlimited amount of any combination of its common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that the Company may determine, so long as the Company continued to satisfy the requirements of a "well-known seasoned issuer" under SEC rules.

In February 2021, the Company entered into a new sales agreement (the "2021 Sales Agreement") with respect to an at-the-market offering program under which the Company may offer and sell, from time to time at the Company's sole discretion, shares of common stock having an aggregate offering price of up to $100.0 million. Subsequently in July 2021, the Company sold 7,508 shares of common stock for net proceeds of approximately $0.2 million pursuant to the 2021 Sales Agreement. Because the Company was no longer a well-known seasoned issuer following the filing of the Annual Report on Form 10-K for the year ended December 31, 2021, the 2021 Form S-3 is no longer available for the Company to offer and sell securities pursuant to the 2021 Form S-3. Since the 2021 Form S-3 is no longer available, unless and until the Company registers the offer and sale of securities pursuant to the 2021 Sales Agreement in the future, the Company will not be able to make any further sales of securities under the 2021 Sales Agreement.

9. Stock-based Compensation

For the six months ended June 30, 2022, the Company granted 295,200 options at a weighted average exercise price per share of $25.95. For the six months ended June 30, 2022, the Company granted 561,400 RSUs.

The Company recorded the following stock-based compensation expense:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(in thousands)			
Employee awards:				
Cost of product revenue	$ 90	$ —	$ 177	$ —
Research and development expense	1,254	1,377	2,975	2,513
Selling, general and administrative expense	2,272	2,127	3,972	4,053
Total stock-based compensation expense	$ 3,616	$ 3,504	$ 7,124	$ 6,566

10. Subsequent Events

Termination of the Loan and Security Agreement with Hercules

On July 27, 2022, the Loan and Security Agreement was terminated upon the receipt by Hercules of a payoff amount of $10.9 million from the Company; provided that the Company continues to be bound by certain indemnification obligations under the Loan and Security Agreement. The payoff amount paid by the Company in connection with the termination of the Loan and Security Agreement was pursuant to a payoff letter with Hercules and included payment of (a) $0.7 million as an End of Term Charge and (b) $0.1 million as a Prepayment Charge.

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, 2021, 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, 2021, 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 commercial-stage 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. Our product Bylvay has been approved in the United States for the treatment of pruritus in patients with progressive familial intrahepatic cholestasis (PFIC) ages 3 months or older, and authorized in Europe for the treatment of PFIC in patients ages 6 months or older. In October 2021, the U.S. Food and Drug Administration, or FDA, granted the Company orphan drug exclusivity for Bylvay for the treatment of pruritus in patients ages 3 months or older with PFIC. In July 2021, the European Medicines Agency, or EMA, granted the Company orphan drug exclusivity for Bylvay for the treatment of patients 6 months or older with PFIC. In September 2021, Bylvay was also granted marketing authorization by the UK Medicines and Healthcare Products Regulatory Agency, or MHRA, for the treatment of PFIC in patients 6 months or older. Bylvay is available by prescription to patients in the U.S. and became available by prescription to patients in Germany in September 2021 and in the United Kingdom in the second quarter of 2022. PFIC is a rare, life-threatening genetic disorder affecting young children and Bylvay is the first approved drug treatment in the disease.

We are also pursuing the development of Bylvay 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 Bylvay in biliary atresia, the BOLD trial, in the first half of 2020. At the end of 2021, we had enrolled over 50% of the targeted patients in the trial. We expect topline results from the BOLD trial in 2024. We also initiated a pivotal trial of Bylvay in ALGS, the ASSERT trial, in the fourth quarter of 2020. In March 2022, we announced the completion of enrollment in the ASSERT trial and we expect topline results from the trial in the fall of 2022.

We are expanding development to compounds that are intended for adult liver and viral diseases. Our lead candidate for adult liver diseases, A3907, is a selective inhibitor of the apical sodium-dependent bile acid transporter (ASBT) that has, based on animal studies, high predicted oral bioavailability and systemic exposures in man. As a result, A3907 has the potential to not only affect the bile acid pool by increased bile acid excretion in the stools but also through other pathways, including increased urinary bile acid excretion. This unique approach may yield greater dosing flexibility, greater efficacy and lower rates of adverse events, such as diarrhea, associated with the non-systemic IBAT inhibitors acting locally in the intestine. In December 2021, we announced topline results from our Phase 1 clinical trial in healthy adult subjects to investigate the safety, tolerability, pharmacokinetics of orally administered A3907. In the top-line results the trial achieved both primary and secondary objectives. A3907 demonstrated a positive safety profile and was well tolerated in the Phase 1 clinical trial at systemic exposures that demonstrated therapeutic benefits in preclinical models. With the potential to inhibit ileal, renal and hepatic ASBT, we hope A3907 will provide the optimal balance of efficacy and tolerability in patients in multiple liver diseases. A composition of matter patent for A3907 has been granted, with expiration in 2040 without patent term extension. We expect to initiate a Phase 2 trial for A3907 in adult liver disease by the end of 2022.

We also have a preclinical program in adult liver and viral diseases. Our lead preclinical candidate for adult viral and liver diseases is A2342, a potent small molecule inhibitor of the sodium-taurocholate co-transporting peptide (NTCP). NTCP is a key transporter of bile acids into the liver cells and also serves as the entry mechanism for the hepatitis B (HBV) and hepatitis D (HDV) viruses. A2342 protects primary human hepatocytes from HBV infection in vitro. In addition, A2342 reduces markers of infection in HBV-infected humanized mice. A2342 has demonstrated target engagement in non-human primates with biomarker increases comparable to increases achieved in humans by a now commercial subcutaneous peptide NTCP inhibitor. A composition of matter patent for A2342 has been granted, with expiration in 2040 without patent term extensions, and IND enabling studies are being completed. We expect to initiate a Phase 1 trial for A2342 in healthy volunteers by the end of 2022. Preclinical efforts with other bile acid modulator approaches continue. The first IBAT inhibitor developed by Albireo is elobixibat, which was approved in Japan and Thailand for the treatment of chronic constipation and is marketed by our partner EA Pharma in Japan and its sublicensee in Thailand.

Bylvay — Our Lead Product for PFIC.

Bylvay (odevixibat) was approved by the FDA on July 20, 2021 for the treatment of pruritus in patients ages 3 months or older with PFIC, and authorized by the EMA on July 16, 2021 for the treatment of patients 6 months or older with PFIC. Bylvay was also granted marketing authorization by the MHRA on September 7, 2021 for the treatment of patients 6 months or older with PFIC. We also received a rare pediatric disease priority review voucher (PRV) from the FDA in connection with the U.S. approval of Bylvay. In September 2021, we sold the PRV for $105.0 million. Bylvay is available for reimbursement by prescription to patients in the U.S., Germany and the United Kingdom. In July 2021, the EMA granted the Company orphan drug exclusivity for Bylvay for the treatment of patients 6 months or older with PFIC. In October 2021, the FDA granted the Company orphan drug exclusivity for Bylvay for the treatment of pruritus in PFIC patients ages 3 months or older.

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 75,000 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 15,000 patients worldwide, not including China and India, but we are not able to estimate the prevalence of PFIC with precision. Apart from rights we granted to third parties in the below agreements, we hold global rights to Bylvay unencumbered. Our current plan is to commercialize Bylvay ourselves in the United States and Europe. We entered into a co-promotion agreement with Travere Therapeutics, Inc. to promote Bylvay in the United States. The initial term of the co-promotion was two years from the July 2021 launch of Bylvay, terminable at will by either party after one year following launch. In June 2022, the parties mutually agreed to terminate the agreement upon the one year anniversary of the launch, with such termination effective July 20, 2022. We are continuing to commercialize Bylvay ourselves in the United States. We have also entered into license agreements with third parties to commercialize Bylvay in certain other jurisdictions, subject to regulatory approval in those jurisdictions including Medison Pharma Canada Inc. for Canada, Medison Pharma Ltd. for Israel, Gen İlaç ve Sağlık Ür✔nleri Sanayi ve Ticaret A.Ş. for Turkey, Genpharm Services for Saudi Arabia, Bahrain, Kuwait, Oman, Qatar, and the UAE, Jadeite Medicines Inc. for Japan, and Swixx Biopharma AG for Central and Eastern European Countries, and we are identifying potential partners for other regions. Bylvay is currently the only approved drug for the treatment of patients with PFIC. Ursodeoxycholic acid, or UDCA, is approved in France only for PFIC type 3, and in the United States and elsewhere for the treatment of primary biliary cholangitis, or PBC. However, many PFIC patients do not respond well to UDCA, undergo partial external bile diversion, or PEBD, surgery and often require liver transplantation. PEBD surgery is a life-altering and undesirable procedure in which bile is drained outside the body to a stoma bag that must be worn by the patient 24 hours a day.

Other Indications Under Development for Bylvay.

We are also pursuing the development of Bylvay 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. At the end of 2021, we had enrolled over 50% of the targeted patients in the trial and we expect topline results in 2024. 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 odevixibat once daily at 120μg/kg. 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 6 and 10 for every 100,000 live births. We estimate the prevalence of biliary atresia to be approximately 18,000 patients across the U.S. and Europe, and approximately 27,000 combined in other jurisdictions worldwide, 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 initiated a pivotal trial of Bylvay in ALGS, the ASSERT trial, in the fourth quarter of 2020. The trial is fully enrolled with 52 patients aged 0 to 17 years of age with a genetically confirmed diagnosis of ALGS across 35 sites in North America, Europe, Middle East and Asia Pacific. We expect topline data to be available in the fall of 2022. 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 50,000 children born worldwide. We estimate the prevalence of ALGS to be approximately 12,000 patients across the U.S. and Europe, and approximately 13,000 combined in other jurisdictions worldwide, but we are not able to estimate the prevalence of ALGS with precision. 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 9 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.

Since inception, we have incurred significant operating losses. As of June 30, 2022, we had an accumulated deficit of $383.2 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, commercialize Bylvay, prepare for and begin the commercialization of any other approved products in the future, and add infrastructure and personnel to support our product development and commercialization efforts and operations as a public company in the United States.

As a commercial-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, 2022, we had approximately $181.0 million in cash and cash equivalents.

Recent Developments

Termination of the Loan and Security Agreement with Hercules

As previously disclosed, on July 27, 2022, the Loan and Security Agreement was terminated upon the receipt by Hercules of a payoff amount of $10.9 million from us; provided that we continue to be bound by certain indemnification obligations under the Loan and Security Agreement. The payoff amount paid by us in connection with the termination of the Loan and Security Agreement was pursuant to a payoff letter with Hercules and included payment of (a) $0.7 million as an End of Term Charge and (b) $0.1 million as a Prepayment Charge.

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

We commenced our commercial launch of Bylvay for the treatment of pruritus in patients with PFIC ages 3 months or older in the United States in July 2021 after we received FDA approval of Bylvay on July 20, 2021.

We sell Bylvay to a limited number of specialty pharmacies and a specialty distributor which dispense the product directly to patients. The specialty pharmacies and specialty distributor are referred to as our customers. We also sell Bylvay to our customers in the European Union, which includes a limited number of pharmacies. Bylvay was authorized by the European Medicines Agency on July 16, 2021 for the treatment of PFIC in patients 6 months or older. Bylvay was also granted marketing authorization by the UK Medicines and Healthcare Products Regulatory Agency (MHRA) in September 2021 for the treatment of PFIC in patients 6 months or older.

Product Revenue, Net

We recognize revenue on sales of Bylvay when a customer obtains control of the product, which occurs at a point in time and upon delivery. We provide the right of return to our customers for unopened product for a limited time before and after its expiration date.

Under Accounting Standards Codification (“ASC”) Topic 606, *Revenue from Contracts with Customers* (“ASC 606”), we have written contracts with each of our customers that have a single performance obligation - to deliver products upon receipt of a customer order - and these obligations are satisfied when delivery occurs and the customer receives Bylvay. We evaluate the creditworthiness of each of our customers to determine whether collection is reasonably assured. The wholesale acquisition cost that we charge our customers for Bylvay is adjusted to arrive at our estimated net product revenues by deducting (i) estimated government rebates and discounts related to Medicaid and other government programs, (ii) estimated costs of incentives offered to certain indirect customers including patients, (iii) trade allowances, such as invoice discounts for prompt payment and customer fees, and (iv) allowance for sales returns.

For the three and six months ended June 30, 2022, we recognized net sales of Bylvay totaling approximately $5.9 million and $10.5 million, respectively. No revenue was recognized for the three and six months ended June 30, 2021.

Royalty Revenue

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, we recognize 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).

For the three months ended June 30, 2022 and 2021, we recognized revenue of $2.3 million and $2.4 million, respectively, related to our agreement with EA Pharma. For the six months ended June 30, 2022 and 2021, we recognized revenue of $4.5 million and $4.4 million, respectively, related to our agreement with EA Pharma. We expect that any future revenue recognized under our license agreement with EA Pharma will fluctuate from quarter to quarter and year to year as a result of royalties for the period from EA Pharma, as well as the uncertain timing of future milestone payments, if any.

In October 2021, Albireo entered into an agreement with Jadeite Medicines Inc. to license, develop and commercialize Bylvay within Japan. For the three and six months ended June 30, 2022, no revenue was recognized under the agreement. Currently, Jadeite is commencing bridging and other clinical studies to pursue New Drug Application (NDA) filings and obtain approval in Japan for PFIC, ALGS, and biliary atresia indications. Future royalty revenue recognized under our license agreement with Jadeite will not commence until after NDA approval in Japan. The next anticipated milestone payment will be received upon NDA filings in Japan for Bylvay and the timing of future milestone payments, if any, is uncertain.

Costs and Operating Expenses

Cost of Product Revenue

Cost of product revenue consists of manufacturing and quality headcount costs for sales of Bylvay. All manufacturing costs incurred prior to FDA approval totaled approximately $1.6 million and were not capitalized, and instead were expensed as research and development expenses from 2020 to July 2021. As a result, these costs were excluded from cost of product revenue for sales during the three and six months ended June 30, 2022.

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.

Selling, General and Administrative Expenses

Selling, 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, selling, general and administrative expenses include fees for third-party professional services, including consulting, information technology, legal and accounting services. Other selling, general and administrative expenses include marketing expenses related to the commercial launch of Bylvay, as well as corporate expenses.

Other Operating Expense (Income), Net

Other operating expense (income), net consists primarily of foreign currency exchange gains or losses associated with revaluation of intercompany loans.

Interest Expense, Net

Interest expense, net consists primarily of non-cash interest expense recorded in connection with the sale of future royalties, related to sales of elobixibat in Japan, in addition to both cash and non-cash interest expense associated with our note payable. In addition, interest expense, net includes interest income associated with our interest-bearing cash and cash equivalents.

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 1, 2022, the date we filed our Annual Report on Form 10-K for the year ended December 31, 2021. Due to the commercialization of Bylvay (odevixibat) the Company implemented accounting policies related to revenue recognition and inventory. See Note 1, "*Summary of significant accounting policies and basis of presentation*" for more information on revenue recognition and inventory accounting policies. For more information on other critical accounting policies, refer to our Annual Report on Form 10-K for the year ended December 31, 2021.

Results of Operations

Three Months Ended June 30, 2022 and June 30, 2021

Result of Operations

	Three Months Ended June 30,		Change
	2022	2021	$
		(in thousands)	
Revenue			
Product revenue, net	$ 5,891	$ —	$ 5,891
Royalty revenue	2,315	2,428	(113)
Total revenue	8,206	2,428	5,778
Cost and operating expenses:			
Cost of product revenue	776	—	776
Research and development	22,888	20,894	1,994
Selling, general and administrative	21,600	16,940	4,660
Other operating expense (income), net	145	(2,374)	2,519
Total cost and operating expenses	45,409	35,460	9,949
Operating loss	(37,203)	(33,032)	(4,171)
Other loss			
Interest expense, net	(2,746)	(3,389)	643
Net loss	$ (39,949)	$ (36,421)	$ (3,528)

Revenue

	Three Months Ended June 30,		Change
	2022	2021	$
		(in thousands)	
Product revenue, net	$ 5,891	$ —	$ 5,891
Royalty revenue	2,315	2,428	(113)
Total revenue	$ 8,206	$ 2,428	$ 5,778

Product revenue, net was $5.9 million for the three months ended June 30, 2022 due to Bylvay product sales. Product revenue, net was $3.5 million in the United States and $2.4 million in international markets. There was no product revenue for the three months ended June 30, 2021.

Royalty revenue was $2.3 million for the three months ended June 30, 2022 compared with $2.4 million for the three months ended June 30, 2021, a decrease of $0.1 million. The decrease relates to estimated royalty revenue to be received from EA Pharma for elobixibat for the treatment of chronic constipation.

Cost of product revenue

	Three Months Ended June 30,		Change
	2022	2021	$
		(in thousands)	
Cost of product revenue	$ 776	$ —	$ 776

Cost of product revenue was $0.8 million for the three months ended June 30, 2022. Following Bylvay approval, certain manufacturing and quality headcount costs are now included in cost of product revenue. There were no material costs, as materials related to current product sold, were expensed prior to approval. Bylvay was not approved until July 2021, therefore there was no cost of product revenue for the three months ended June 30, 2021.

Research and development expenses

	Three Months Ended June 30, 2022	2021	Change $
		(in thousands)	
Research and development expenses	$ 22,888	$ 20,894	$ 1,994

Research and development expenses were $22.9 million for the three months ended June 30, 2022 compared with $20.9 million for the three months ended June 30, 2021, an increase of $2.0 million. The increase in research and development expenses for the 2022 period was principally due to clinical program activities, personnel expenses and other costs as we continue to increase our headcount and program activities. The increase in program activities related to ongoing Phase 3 clinical trials for biliary atresia and Alagille syndrome and Bylvay – PFIC primarily related to medical affairs and clinical costs, and were partially offset by a decrease in preclinical expenses and expenses for A3907 due to the completion of the Phase 1 study.

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, 2022 and 2021.

	Three Months Ended June 30, 2022	2021	Change $
		(in thousands)	
Direct third-party project costs:			
Bylvay - PFIC	$ 6,502	$ 5,491	$ 1,011
Bylvay - biliary atresia and ALGS	6,788	5,010	1,778
A3907	1,926	2,213	(287)
Preclinical	395	1,145	(750)
Total	$ 15,611	$ 13,859	$ 1,752
Other project costs[(1)]:			
Personnel costs	$ 6,385	$ 6,267	$ 118
Other costs[(2)]	892	768	124
Total	$ 7,277	$ 7,035	$ 242
Total research and development costs	$ 22,888	$ 20,894	$ 1,994

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

Selling, general and administrative expenses

	Three Months Ended June 30, 2022	2021	Change $
		(in thousands)	
Selling, general and administrative	$ 21,600	$ 16,940	$ 4,660

Selling, general and administrative expenses were $21.6 million for the three months ended June 30, 2022 compared with $16.9 million for the three months ended June 30, 2021, an increase of $4.7 million. The increase is attributable to personnel and related expenses as we continue to increase our headcount, and commercialization activities related to Bylvay including our sales force and support for global expansion efforts.

Other operating expense (income), net

	Three Months Ended June 30, 2022	2021	Change $
		(in thousands)	
Other operating expense (income), net	$ 145	$ (2,374)	$ 2,519

Other operating expense (income), net totaled $0.1 million of expense for the three months ended June 30, 2022 compared with $2.4 million of income for the three months ended June 30, 2021. The difference primarily relates to changes in foreign currency exchange rates in the two periods.

Interest expense, net

	Three Months Ended June 30, 2022	2021	Change $
		(in thousands)	
Interest expense, net	$ (2,746)	$ (3,389)	$ 643

Interest expense, net totaled $2.7 million for the three months ended June 30, 2022 compared with $3.4 million for the three months ended June 30, 2021. The difference was principally attributable to lower non-cash interest expense recorded in connection with the sale of future royalties related to sales of elobixibat in Japan, partially offset by interest income associated with our interest bearing cash accounts.

Six Months Ended June 30, 2022 and June 30, 2021

Result of Operations

	Six Months Ended June 30, 2022	2021	Change $
		(in thousands)	
Revenue			
Product revenue, net	$ 10,547	$ —	$ 10,547
Royalty revenue	4,491	4,394	97
Total revenue	15,038	4,394	10,644
Cost and operating expenses:			
Cost of product revenue	1,010	—	1,010
Research and development	44,791	40,837	3,954
Selling, general and administrative	38,455	32,213	6,242
Other operating expense, net	7,543	4,154	3,389
Total cost and operating expenses	91,799	77,204	14,595
Operating loss	(76,761)	(72,810)	(3,951)
Other loss			
Interest expense, net	(5,622)	(7,344)	1,722
Net loss	$ (82,383)	$ (80,154)	$ (2,229)

Revenue

	Six Months Ended June 30, 2022	2021	Change $
		(in thousands)	
Product revenue, net	$ 10,547	$ —	$ 10,547
Royalty revenue	4,491	4,394	97
Total revenue	$ 15,038	$ 4,394	$ 10,644

Product revenue, net was $10.5 million for the six months ended June 30, 2022 due to Bylvay product sales. Product revenue, net was $6.3 million in the United States and $4.2 million in international markets. There was no product revenue for the six months ended June 30, 2021.

Royalty revenue was $4.5 million for the six months ended June 30, 2022 compared with $4.4 million for the six months ended June 30, 2021, an increase of $0.1 million. The increase relates to estimated royalty revenue to be received from EA Pharma for elobixibat for the treatment of chronic constipation.

Research and development expenses

	Six Months Ended June 30, 2022	2021	Change $
		(in thousands)	
Research and development expenses	$ 44,791	$ 40,837	$ 3,954

Research and development expenses were $44.8 million for the six months ended June 30, 2022 compared with $40.8 million for the six months ended June 30, 2021, an increase of $4.0 million. The increase in research and development expenses for the 2022 period was principally due to clinical and preclinical program activities, personnel expenses and other costs as we continue to increase our headcount and program activities. The increase in program activities related to ongoing Phase 3 clinical trials for biliary atresia and Alagille syndrome, ongoing preclinical trials, and A3907 and were partially offset by a decrease in Bylvay PFIC expenses related to the completion of the PEDFIC 1 study.

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, 2022 and 2021.

	Six Months Ended June 30, 2022	2021	Change $
		(in thousands)	
Direct third-party project costs:			
Bylvay - PFIC	$ 10,846	$ 11,484	$ (638)
Bylvay - biliary atresia and ALGS	12,379	10,754	1,625
A3907	3,928	3,818	110
Preclinical	3,254	1,958	1,296
Total	$ 30,407	$ 28,014	$ 2,393
Other project costs[(1)]:			
Personnel costs	$ 12,819	$ 11,927	$ 892
Other costs[(2)]	1,565	896	669
Total	$ 14,384	$ 12,823	$ 1,561
Total research and development costs	$ 44,791	$ 40,837	$ 3,954

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

Selling, general and administrative expenses

	Six Months Ended June 30, 2022	2021	Change $
		(in thousands)	
Selling, general and administrative	$ 38,455	$ 32,213	$ 6,242

Selling, general and administrative expenses were $38.4 million for the six months ended June 30, 2022 compared with $32.2 million for the six months ended June 30, 2021, an increase of $6.2 million. The increase is attributable to personnel and related expenses as we continue to increase our headcount, and commercialization activities related to Bylvay including our sales force and support for global expansion efforts.

Other operating expense, net

	Six Months Ended June 30, 2022	2021	Change $
		(in thousands)	
Other operating expense, net	$ 7,543	$ 4,154	$ 3,389

Other operating expense, net totaled $7.5 million for the six months ended June 30, 2022 compared with expense of $4.2 million for the six months ended June 30, 2021. The difference primarily relates to changes in foreign currency exchange rates in the two periods.

Interest expense, net

	Six Months Ended June 30, 2022	2021	Change $
		(in thousands)	
Interest expense, net	$ (5,622)	$ (7,344)	$ 1,722

Interest expense, net totaled $5.6 million for the six months ended June 30, 2022 compared with $7.3 million for the six months ended June 30, 2021. The difference was principally attributable to lower non-cash interest expense recorded in connection with the sale of future royalties related to sales of elobixibat in Japan and interest income associated with our interest bearing cash accounts.

Liquidity and Capital Resources

Sources of Liquidity

We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we commercialize Bylvay and continue the development of and seek regulatory approvals for Bylvay in other indications and for our other product candidates. We are subject to all of the risks applicable to the development and commercialization 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 other 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 HealthCare Royalty Partners III, L.P. (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 other product candidates as well as commercialization and pre-commercialization efforts.

As of June 30, 2022, our cash and cash equivalents were approximately $181.0 million.

During the first quarter of 2018, following the Japanese Ministry of Health, Labour and Welfare'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 royalty interest acquisition agreement (RIAA). Additionally, this approval triggered a milestone payment to us from EA Pharma of $11.2 million. In June 2020, we entered into an amendment to the RIAA with HCR pursuant to which HCR agreed to pay us an additional $14.8 million, net of certain transaction 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) $15.0 million payable to us if a specified sales milestone is achieved for elobixibat in Japan. As of June 30, 2022, we have received approximately $59.3 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 $5.0 million under the amended agreement, if a specified regulatory event is achieved for elobixibat. To the extent we receive future Japanese royalties, sales milestones or other specified payments from EA Pharma, we are obligated to pay those amounts as royalty interest payments to HCR under the RIAA.

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 statement on Form S-3, or the 2020 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 7, 2020, we also entered into a sales agreement with Cowen and Company, LLC, or Cowen, with respect to an at-the-market offering program providing for us to 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. This agreement terminated on September 9, 2020.

On September 14, 2020, we completed an underwritten public offering of 4,000,000 shares of our common stock under this registration statement. We received net proceeds from this offering of approximately $150.4 million, after deducting underwriting discounts and commissions, but before deducting offering expenses. As of June 30, 2022, $40.0 million of securities remain available for issuance under the 2020 Form S-3.

On June 8, 2020, we entered into a Loan and Security Agreement with 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 provided 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 consisted of (i) a term loan advance to us 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), but we did not 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 as permitted under the agreement, (ii) subject to the achievement of certain initial performance milestones, or Performance Milestone I, we had the right 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, which we did not exercise, and (iii) subject to the Lender's investment committee's sole discretion, we had the right 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, which we did

not exercise. As of June 30, 2022, we borrowed an aggregate principal amount of $10.0 million and there were no term loans available to us for advance under the Loan and Security Agreement. On July 27, 2022, the Loan and Security Agreement was terminated upon the receipt by Hercules of a payoff amount of $10.9 million from the Company; provided that we continue to be bound by certain indemnification obligations under the Hercules Loan Agreement.

Under the Loan and Security Agreement, we also agreed to issue to Hercules warrants to purchase a number of shares of our 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, we issued a warrant for 5,311 shares of our 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. The shares of common stock underlying the warrants were subsequently registered on Form S-3 with the SEC, which was declared effective on August 18, 2020.

On February 25, 2021, we filed an automatic shelf registration statement on Form S-3 with the SEC, which became effective upon filing, pursuant to which we registered for sale an unlimited amount 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, so long as we continued to satisfy the requirements of a "well-known seasoned issuer" under SEC rules, which we refer to as the 2021 Form S-3. Because we are no longer a well-known seasoned issuer, the 2021 Form S-3 is no longer available for us to offer and sell securities pursuant to the 2021 Form S-3 following the filing of our Annual Report on Form 10-K for the year ended December 31, 2021 on March 1, 2022. On February 25, 2021, we also entered into a new sales agreement with Cowen, which we refer to as the 2021 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 $100.0 million. Subsequently in July 2021, we sold 7,508 shares of our common stock for net proceeds of approximately $0.2 million pursuant to the 2021 Sales Agreement. Since the 2021 Form S-3 is no longer available, unless and until we register the offer and sale of securities pursuant to the 2021 Sales Agreement in the future, we will not be able to make any further sales of securities under the 2021 Sales Agreement.

On August 31, 2021, we entered into a definitive agreement to sell the rare pediatric disease priority review voucher ("PRV") that we received from the FDA in connection with the approval of the Company's product Bylvay (odevixibat), for cash proceeds of $105.0 million. On September 28, 2021, we completed our sale of the PRV and received net proceeds of $103.4 million, after deducting commission costs, which was recorded as a gain from sale of priority review voucher, net of transaction costs.

Cash Flows

Six months ended June 30, 2022 and June 30, 2021

	Six Months Ended June 30,	
	2022	2021
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (71,801)	(66,185)
Investing activities	(920)	(279)
Financing activities	6,181	1,627
Total	$ (66,540)	$ (64,837)
Effect of exchange rate changes on cash and cash equivalents	(596)	(149)
Net decrease in cash and cash equivalents	(67,136)	(64,986)

Operating activities

Cash used in operating activities of $71.8 million during the six months ended June 30, 2022 was primarily a result of our $82.4 million net loss from operations and a net decrease in assets and liabilities of $9.5 million. The net decrease

in operating assets and liabilities during the six months ended June 30, 2022 was primarily driven by decreases in accrued expenses, inventory, accounts payable and other current and long-term liabilities, offset by increases in prepaid expenses and other current assets and accounts receivable, net and other assets. This decrease was offset by non-cash items, including $7.1 million of foreign currency adjustments, $7.1 million of share-based compensation expense and $5.5 million of accretion of liability related to sale of future royalties. Cash used in operating activities of $66.2 million during the six months ended June 30, 2021 was primarily a result of our $80.2 million net loss from operations and a net decrease in assets and liabilities of $3.3 million. The net decrease in operating assets and liabilities during the six months ended June 30, 2021 was primarily driven by increases in accrued expenses, prepaid expenses and other current assets, and accounts payable, offset by decreases in other current and long-term liabilities and other assets. This decrease was offset by non-cash items, including $6.6 million of stock-based compensation expense, $6.2 million of accretion of liability related to sale of future royalties, and $4.1 million of foreign currency adjustments.

Investing activities

Cash used in investing activities of $0.9 million during the six months ended June 30, 2022 was primarily related to purchases of property and equipment. Cash used in investing activities of $0.3 million during the six months ended June 30, 2021 was primarily related to the purchase of property and equipment.

Financing activities

Cash provided by financing activities of $6.2 million during the six months ended June 30, 2022 was primarily related to proceeds from the exercise of options. Cash provided by financing activities of $1.6 million during the six months ended June 30, 2021 was primarily related to proceeds from the exercise of options.

Funding Requirements

Cash used to fund operating expenses is affected by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. As a result, cash and cash equivalents are anticipated to be sufficient to fully fund the launches of Bylvay and the next stages of the early asset portfolio into 2024 based on current revenue and expense projections. Bylvay 2022 sales are now expected to be $24.0 million.

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

- Future revenue from commercial sales of Bylvay for patients with PFIC;
- the costs, design, duration and any potential delays of the pivotal clinical trial of Bylvay in biliary atresia and the pivotal clinical trial of Bylvay 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 build and maintain 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 current and 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 and maintain 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 be certain that we will be able to successfully commercialize Bylvay or that we will be able to establish and maintain distribution arrangements. Our failure or the failure of our distributors to successfully commercialize Bylvay could have a material adverse effect on our financial position or results of operations. In addition, we cannot be certain that we will be able to successfully complete our pre-commercialization activities or 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 products and 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 $200.0 million of any combination of our common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that we may determine. As of June 30, 2022, $40.0 million of securities remain available for issuance under the shelf registration statement, which we refer to as the 2020 Form S-3. On February 25, 2021, we filed an automatic shelf registration statement on Form S-3 with the SEC, pursuant to which we registered for sale an unlimited amount 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, so long as we continued to satisfy the requirements of a “well-known seasoned issuer” under SEC rules, which we refer to as the 2021 Form S-3, including up to $100.0 million of our common stock pursuant to the sales agreement with respect to an at-the-market offering program. As of June 30, 2022, there remained $99.7 million of our common stock available for sale pursuant to the sales agreement. Because we are no longer a well-known seasoned issuer, the 2021 Form S-3 is no longer available for us to offer and sell securities pursuant to the 2021 Form S-3 following the filing of our Annual Report on Form 10-K for the year ended December 31, 2021 on March 1, 2022. Since the 2021 Form S-3 is no longer

available, unless and until we register the offer and sale of securities pursuant to the 2021 Sales Agreement in the future, we will not be able to make any further sales of securities under our at-the-market offering program.

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.

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, 2022, 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

There were no changes in our internal control over financial reporting identified in connection with the evaluation of such internal control that occurred during the three months ended June 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting other than the implementation of controls designed to address risks related to product revenue recognition and inventory.

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, 2021, filed with the Securities and Exchange Commission on March 1, 2022.

Item 6. Exhibits

Exhibit No.	Description	Filed Herewith	Incorporated by Reference Herein from Form or Schedule	Filing Date	SEC File/ Req. Number
10.1*	Nonemployee Director Compensation Policy.		Form 8-K (Exhibit 10.1)	8/10/2022	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, 2022, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets (unaudited) at June 30, 2022 and December 31, 2021, (ii) Condensed Consolidated Statements of Operations (unaudited) for the three and six months ended June 30, 2022 and 2021, (iii) Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three and six months ended June 30, 2022 and 2021, (iv) Condensed Consolidated Statement of Stockholders' Equity (unaudited) for the three and six months ended June 30, 2022 and 2021, (v) Condensed Consolidated Statements of Cash Flows (unaudited) for the six months ended June 30, 2022 and 2021, 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			

* Management contract or compensatory plan or arrangement.

SIGNATURES

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

ALBIREO PHARMA, INC.

Dated: August 15, 2022

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

Dated: August 15, 2022

By: /s/ Simon N.R. Harford
Simon N.R. Harford
Chief Financial Officer and Treasurer
(principal financial officer and principal accounting 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 15, 2022

/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 15, 2022

/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, 2022 (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 15, 2022

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

Dated: August 15, 2022

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