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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 September 30, 2021**

**OR**

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

**For the transition period from _____ to _____ .**

**Commission File Number 001-33451**

# Albireo Pharma, Inc.

**(Exact name of registrant as specified in its charter)**

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

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

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

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

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

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

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

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

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

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

As of October 28, 2021, there were 19,278,634 shares of Common Stock, $0.01 par value per share, outstanding.

**Albireo Pharma, Inc.**


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## 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 globally;
- the progress, number, scope, cost, duration or results of our development activities, nonclinical studies and clinical trials of Bylvay™ (odevixibat), 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:

- 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 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 initiation or 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 and the pivotal trial of Bylvay in ALGS;
- 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 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, future revenues, uses of cash and capital requirements;
- our ability to obtain additional financing on reasonable terms, or at all;
- our ability to establish additional licensing, collaboration or similar arrangements on favorable terms and our ability to attract collaborators with development, regulatory and commercialization expertise;
- the success of competing third-party products or product candidates;
- our ability to successfully commercialize any approved product candidates, including their rate and degree of market acceptance;

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

These and other risks and uncertainties are described in greater detail under the caption “Risk Factors” in Item 1A of Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, in Item 1A of Part II of this quarterly report, and in other filings that we make with the Securities and Exchange Commission, or SEC. As a result of the risks and uncertainties, the results or events indicated by the forward-looking statements may not occur. We caution you not to place undue reliance on any forward-looking statement.

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

## PART I — FINANCIAL INFORMATION

### Item 1. Financial Statements

**Albireo Pharma, Inc.**

**Condensed Consolidated Balance Sheets**

**(in thousands, except share data)**

**(unaudited)**

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 262,612 | $ 251,272 |
| Accounts receivable, net | 1,307 | — |
| Inventory | 196 | — |
| Prepaid expenses and other current assets | 7,779 | 10,593 |
| Total current assets | 271,894 | 261,865 |
| Property and equipment, net | 775 | 478 |
| Goodwill | 17,260 | 17,260 |
| Other assets | 6,516 | 6,004 |
| Total assets | $ 296,445 | $ 285,607 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 7,222 | $ 5,283 |
| Accrued expenses | 20,884 | 19,051 |
| Other current liabilities | 5,043 | 948 |
| Total current liabilities | 33,149 | 25,282 |
| Liability related to sale of future royalties | 68,513 | 65,894 |
| Note payable, net of discount | 9,929 | 9,621 |
| Other long-term liabilities | 3,138 | 3,579 |
| Total liabilities | 114,729 | 104,376 |
| Stockholders' Equity: | | |
| Preferred stock, $0.01 par value per share — 50,000,000 shares authorized at September 30, 2021 and December 31, 2020; 0 and 0 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively | — | — |
| Common stock, $0.01 par value per share — 60,000,000 and 30,000,000 shares authorized at September 30, 2021 and December 31, 2020, respectively; 19,283,269 and 19,275,509 shares issued and outstanding at September 30, 2021, respectively, and 19,107,040 shares issued and outstanding at December 31, 2020 | 193 | 191 |
| Additional paid-in capital | 472,363 | 456,472 |
| Accumulated other comprehensive loss | (722) | (8,612) |
| Accumulated deficit | (289,888) | (266,820) |
| Treasury stock at cost, 7,760 shares and 0 shares at September 30, 2021 and December 31, 2020, respectively | (230) | — |
| Total stockholders' equity | 181,716 | 181,231 |
| Total liabilities and stockholders' equity | $ 296,445 | $ 285,607 |

**See accompanying notes to Condensed Consolidated Financial Statements.**

**Albireo Pharma, Inc.**

**Condensed Consolidated Statements of Operations**

**(in thousands, except share and per share data)**

**(unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| **Revenue:** | | | | |
| Product revenue, net | $ 1,060 | $ — | $ 1,060 | $ — |
| Royalty revenue | 2,604 | 2,131 | 6,998 | 5,592 |
| Total revenue | 3,664 | 2,131 | 8,058 | 5,592 |
| Cost of product revenue | 431 | — | 431 | — |
| Gross profit | 3,233 | 2,131 | 7,627 | 5,592 |
| **Operating expenses:** | | | | |
| Research and development | 21,083 | 22,200 | 61,920 | 56,727 |
| Selling, general and administrative | 17,612 | 11,663 | 49,825 | 28,290 |
| Other operating expense (income), net | 3,719 | (4,628) | 7,873 | (4,556) |
| Total operating expenses | 42,414 | 29,235 | 119,618 | 80,461 |
| Operating loss | (39,181) | (27,104) | (111,991) | (74,869) |
| **Other income (loss):** | | | | |
| Gain from sale of priority review voucher, net of transaction costs | 103,387 | — | 103,387 | — |
| Interest expense, net | (3,331) | (3,639) | (10,675) | (7,965) |
| Net income (loss) before income taxes | 60,875 | (30,743) | (19,279) | (82,834) |
| Provision for income taxes | 3,789 | — | 3,789 | — |
| Net income (loss) | $ 57,086 | $ (30,743) | $ (23,068) | $ (82,834) |
| Net income (loss) per share attributable to holders of common stock: | | | | |
| Basic | $ 2.96 | $ (1.96) | $ (1.20) | $ (5.54) |
| Diluted | $ 2.90 | $ (1.96) | $ (1.20) | $ (5.54) |
| Weighted-average common shares outstanding: | | | | |
| Basic | 19,258,905 | 15,704,293 | 19,197,536 | 14,942,213 |
| Diluted | 19,651,243 | 15,704,293 | 19,197,536 | 14,942,213 |

**See accompanying notes to Condensed Consolidated Financial Statements.**

**Albireo Pharma, Inc.**

**Condensed Consolidated Statements of Comprehensive Income (Loss)**

**(in thousands)**

**(unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Net income (loss) | $ 57,086 | $ (30,743) | $ (23,068) | $ (82,834) |
| Other comprehensive income (loss): | | | | |
| Foreign currency translation adjustment | 3,657 | (4,031) | 7,890 | (4,309) |
| Total other comprehensive income (loss) | 3,657 | (4,031) | 7,890 | (4,309) |
| Total comprehensive income (loss) | $ 60,743 | $ (34,774) | $ (15,178) | $ (87,143) |

**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 (loss) | 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 |
| Stock-based compensation expense | — | — | 6,706 | — | — | — | — | 6,706 |
| Exercise of options and vesting of RSUs | 35,466 | 1 | 751 | — | — | — | — | 752 |
| Issuance of common stock under the at-the-market sales agreement, net of costs | 7,508 | — | 241 | — | — | — | — | 241 |
| Other comprehensive income | — | — | — | 3,657 | — | — | — | 3,657 |
| Purchases of treasury stock, at cost | — | — | — | — | — | (7,760) | (230) | (230) |
| Net income | — | — | — | — | 57,086 | — | — | 57,086 |
| Balance--September 30, 2021 | 19,283,269 | $ 193 | $ 472,363 | $ (722) | $ (289,888) | (7,760) | $ (230) | $ 181,716 |

| | Common Stock | | Additional Paid-In Capital | Accumulated Other Comprehensive Income (loss) | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| Balance--December 31, 2019 | 12,749,443 | $ 127 | $ 245,769 | $ 6,452 | $ (159,187) | $ 93,161 |
| Stock-based compensation expense | — | — | 2,381 | — | — | 2,381 |
| Exercise of options and vesting of RSUs | 37,662 | — | 94 | — | — | 94 |
| Issuance of common stock, net of costs | 2,190,750 | 22 | 42,977 | — | — | 42,999 |
| Other comprehensive income | — | — | — | 6,287 | — | 6,287 |
| Net loss | — | — | — | — | (31,488) | (31,488) |
| Balance--March 31, 2020 | 14,977,855 | $ 149 | $ 291,221 | $ 12,739 | $ (190,675) | $ 113,434 |
| Stock-based compensation expense | — | — | 2,603 | — | — | 2,603 |
| Exercise of options and vesting of RSUs | 11,166 | — | 138 | — | — | 138 |
| Issuance of warrants | — | — | 113 | — | — | 113 |
| Other comprehensive loss | — | — | — | (6,565) | — | (6,565) |
| Net loss | — | — | — | — | (20,603) | (20,603) |
| Balance--June 30, 2020 | 14,989,021 | $ 149 | $ 294,075 | $ 6,174 | $ (211,278) | $ 89,120 |
| Stock-based compensation expense | — | — | 5,089 | — | — | 5,089 |
| Exercise of options and vesting of RSUs | 84,477 | 1 | 1,924 | — | — | 1,925 |
| Issuance of common stock, net of costs | 4,000,000 | 40 | 150,360 | — | — | 150,400 |
| Other comprehensive loss | — | — | — | (4,031) | — | (4,031) |
| Net loss | — | — | — | — | (30,743) | (30,743) |
| Balance--September 30, 2020 | 19,073,498 | $ 190 | $ 451,448 | $ 2,143 | $ (242,021) | $ 211,760 |

**See accompanying notes to Condensed Consolidated Financial Statements.**

**Albireo Pharma, Inc.**

**Condensed Consolidated Statements of Cash Flows**

**(in thousands)**

**(unaudited)**

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2021 | 2020 |
| Cash flows from operating activities: | | |
| Net loss | $ (23,068) | $ (82,834) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Gain from sale of priority review voucher, net of transaction costs | (103,387) | — |
| Accretion of liability related to sale of future royalties | 9,428 | 7,670 |
| Accretion of debt discount and amortization of issuance costs | 308 | 135 |
| Depreciation and amortization | 167 | 119 |
| Share based compensation expense | 13,272 | 10,073 |
| Foreign currency adjustments | 7,776 | (3,968) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | (1,307) | — |
| Inventory | (196) | — |
| Prepaid expenses and other current assets | 2,765 | 1,770 |
| Other assets | 293 | 425 |
| Accounts payable | 2,023 | (1,221) |
| Accrued expenses | 2,068 | (3,213) |
| Other current and long-term liabilities | (3,810) | (1,790) |
| Net cash used in operating activities | (93,668) | (72,834) |
| Cash flows from investing activities: | | |
| Purchase of property and equipment | (465) | (78) |
| Proceeds from sale of priority review voucher, net of transaction costs | 103,387 | — |
| Net cash provided by (used in) investing activities | 102,922 | (78) |
| Cash flows from financing activities: | | |
| Proceeds from issuance of note payable, net of issuance costs | — | 9,521 |
| Proceeds from issuance of common stock, net of issuance costs | 241 | 193,399 |
| Proceeds from royalty agreement, net of issuance costs | — | 14,750 |
| Proceeds from exercise of options | 2,378 | 2,156 |
| Payments related to repurchases of common stock | (230) | — |
| Net cash provided by financing activities | 2,389 | 219,826 |
| Effect of exchange rate changes on cash and cash equivalents | (303) | (66) |
| Net increase in cash and cash equivalents | 11,340 | 146,848 |
| Cash and cash equivalents—beginning of period | 251,272 | 131,843 |
| Cash and cash equivalents—end of period | $ 262,612 | $ 278,691 |
| Supplemental disclosures of cash and non-cash activities | | |
| Warrants issued with long-term debt | $ — | $ 113 |
| Deferred issuance costs included in accrued expenses | $ — | $ 34 |

**See accompanying notes to Condensed Consolidated Financial Statements.**

**Albireo Pharma, Inc.**

**Notes to Condensed Consolidated Financial Statements**

**(unaudited)**

## 1. Summary of significant accounting policies and basis of presentation

***Organization***

Albireo Pharma, Inc. (the Company), is a 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 US and Europe, elobixibat, approved in Japan for the treatment of chronic constipation, a Phase 1 product candidate and multiple preclinical candidates. Bylvay (odevixibat) was approved by the U.S. Food and Drug Administration on July 20, 2021 for the treatment of pruritis 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, prepare for potential commercialization of Bylvay in PFIC in 2021 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 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 September 30, 2021, 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, 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 launch 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 September 30, 2021, the Company had cash and cash equivalents of $262.6 million. Management believes that its cash and cash equivalent resources at September 30, 2021 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, 2020. 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 nine months ended September 30, 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 currency*

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

*Transactions and balances*

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

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

a. assets and liabilities presented are translated at the closing exchange rate as of September 30, 2021 and December 31, 2020;

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

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

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

***Use of estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts of assets, liabilities, revenues and expenses reported in the financial statements and accompanying notes. Management must apply significant judgment in this process. On an ongoing basis, the Company evaluates its estimates and assumptions, including but not limited to accruals, 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 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 our 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, and (iii) trade allowances, such as invoice discounts for prompt payment and customer fees. Product revenue, net in the U.S. was $0.8 million and $0.3 million in Europe for

the three months and nine months ended September 30, 2021. There was no product revenue for the three and nine months ended September 30, 2020.

*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 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 $0.1 million and $0.0 million in such estimates as of September 30, 2021 and December 31, 2020, respectively, in accounts receivable, net of allowance for credit losses and other 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 less than $0.1 million and $0.0 million in such estimates as of September 30, 2021 and December 31, 2020, respectively, in other 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 which included a $0.1 million dollar payment in the quarter ended September 30, 2021. The Company recorded less than $0.1 million and $0.0 million in such estimates as of September 30, 2021 and December 31, 2020, respectively, in prepaid expenses and other current assets on the consolidated balance sheets.

*Trade Allowances*

The Company provides invoice discounts on Bylvay sales 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. Trade allowances are recorded in accounts receivable, net of allowance for credit losses on the consolidated balance sheets and were $0.1 million.

*Trade Receivables, net*

Accounts receivable, net related to product sales are recorded in accounts receivable, net of allowance for credit losses on the consolidated balance sheets were approximately $1.3 million and $0 million as of September 30, 2021 and December 31, 2020, respectively. As of September 30, 2021 and December 31, 2020, 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 our 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.

*Milestone Payments*

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

*Royalties*

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

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

As of September 30, 2021, the Company is eligible to receive an additional regulatory-based milestone payment under the Agreement of $5.0 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 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 nine-month period ended September 30, 2021:

| | September 30, 2021 (in thousands) |
|---|---|
| Liability related to sale of future royalties—beginning balance | $ 68,594 |
| Accretion of interest expense on liability related to royalty monetization | 9,428 |
| Repayment of the liability | (6,956) |
| Liability related to sale of future royalties—ending balance | $ 71,066 |
| Less current portion classified within accrued expenses | (2,553) |
| Long-term liability related to sale of future royalties | $ 68,513 |

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, as noted above. The sum of these amounts less the $59.3 million proceeds the Company received will be recorded as interest expense over the life of the royalty obligation. At September 30, 2021, the Company's estimate of its total interest expense resulted in an annual effective interest rate of approximately 18.7%.

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.

***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 of the Company's active pharmaceutical ingredient (API) and drug product occurred prior to FDA approval. As a result, manufacturing costs, which totaled approximately $1.6 million, were not capitalized, and instead were expensed as research and development expenses from 2020 to 2021. All packaging of the Company's drug product occurred after FDA approval and is included as capitalized inventory within Finished goods.

***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):

| | September 30, 2021 | | |
|---|---|---|---|
| | Level 1 | Level 2 | Level 3 |
| **Cash Equivalents:** | | | |
| Money market funds | $ 256,451 | $ — | $ — |
| Total | $ 256,451 | $ — | $ — |

| | December 31, 2020 | | |
|---|---|---|---|
| | Level 1 | Level 2 | Level 3 |
| **Cash Equivalents:** | | | |
| Money market funds | $ 242,854 | $ — | $ — |
| Total | $ 242,854 | $ — | $ — |

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 liabilities, accounts payable, accrued expenses, and other current liabilities approximate their estimated fair value due to their short-term maturities. At September 30, 2021, the Company believes the carrying value of the Loan and Security Agreement with Hercules Capital, Inc., approximates the fair value of the note payable.

**3. Commitments and contingencies**

***Agreements with CROs and CMOs***

As of September 30, 2021, 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 $11.8 million upon the completion of contracted work.

**4. Net income (loss) per share**

Basic net income (loss) per share, is calculated by dividing the net income (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. 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 income (loss) per share (in thousands, except for share and per share data):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Basic and Diluted net loss per share: | | | | |
| Numerator | | | | |
| Net income (loss) | $ 57,086 | $ (30,743) | $ (23,068) | $ (82,834) |
| Denominator | | | | |
| Weighted average number of shares outstanding | | | | |
| Number of shares used for basic EPS computation | 19,258,905 | 15,704,293 | 19,197,536 | 14,942,213 |
| Effect of dilutive securities | | | | |
| Dilutive options | 380,934 | — | — | — |
| Dilutive stock units | 11,404 | — | — | — |
| Number of shares used for diluted EPS computation | 19,651,243 | 15,704,293 | 19,197,536 | 14,942,213 |
| Basic net income (loss) per share | $ 2.96 | $ (1.96) | $ (1.20) | $ (5.54) |
| Diluted net income (loss) per share | $ 2.90 | $ (1.96) | $ (1.20) | $ (5.54) |

For purposes of a dilutive net loss per share calculation, stock options, 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 income (loss) per share for the three and nine months ended September 30, 2021 and 2020 because including them would have been anti-dilutive:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Options to purchase common stock, RSUs and warrants | 2,779,257 | 2,403,090 | 3,171,596 | 2,403,090 |

**5. Income taxes**

The Company recorded a tax provision of $3.8 million for the three and nine months ended September 30, 2021, related to the sale of the PRV as it was considered a discrete event pursuant to ASC 740-270, offset by a tax benefit from the Company's ordinary losses. The Company expects to have sufficient tax losses in the current year to offset the

income from the sale and thus no current year liability is expected. 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:

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| Raw materials | $ — | $ — |
| Work-in-process | — | — |
| Finished goods | 196 | — |
| Total inventory | $ 196 | $ — |

There were no write downs for excess and obsolete inventory during the three and nine months ended September 30, 2021 or 2020 based on the finish 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 September 30, 2021.

**7. Note Payable**

*2020 Loan and Security Agreement*

On June 8, 2020, the Company entered into a Loan and Security Agreement with the several banks and other financial institutions or entities from time to time parties to the Loan and Security Agreement, as lenders, or collectively referred to as the Lender, and Hercules Capital, Inc., in its capacity as administrative agent and collateral agent for itself and Lender (in such capacity, the Agent or Hercules). The Loan and Security Agreement provides for term loans in an aggregate principal amount of up to $80.0 million to be delivered in multiple tranches (the Term Loans). The tranches consist of (i) a term loan advance to the Company in an aggregate principal amount of up to $15.0 million, of which (A) the Company 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 the Company did not request that the Lender make an additional term loan advance to the Company in an aggregate principal amount of $5.0 million prior to December 15, 2020 as permitted under the agreement, (ii) subject to the achievement of certain initial performance milestones, or Performance Milestone I, the Company has 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, and (iii) subject to the Lender's investment committee's sole discretion, the Company has 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. As of September 30, 2021, the Company borrowed an aggregate principal amount of $10.0 million. An aggregate principal amount of up to $20.0 million remains available for future borrowings upon request and an aggregate principal amount of up to $45.0 million remains available for future borrowing subject to approval from the Lender. 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 is extendable to June 1, 2024 upon achievement of Performance Milestone I (the Maturity Date).

The Term Loan bears interest at an annual rate equal to the greater of 9.15% and 9.15% plus the prime rate of interest minus 3.25%. Borrowings under the Loan and Security Agreement are repayable in monthly interest-only payments through January 1, 2022 and extendable to (i) July 1, 2022 upon achievement of Performance Milestone I and (ii) July 1, 2023 upon achievement of certain additional performance milestones. After the interest-only payment period, borrowings under the Loan and Security Agreement are repayable in equal monthly payments of principal and accrued interest until the Maturity Date. At the Company's option, the Company may elect to prepay all, but not less than all, of the outstanding term loan by paying the entire principal balance and all accrued and unpaid interest thereon

plus a prepayment charge equal to the following percentage of the principal amount being prepaid: 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 is approximately 13.0%.

As of September 30, 2021 the carrying value of the note payable consists of the following:

| | September 30, 2021 (in thousands) |
|---|---|
| Note payable, including End of Term Charge | 10,695 |
| Debt discount, net of accretion | (766) |
| Note payable net of discount, long-term | $ 9,929 |

During the three and nine months ended September 30, 2021, the Company recognized $0.3 million and $1.0 million, respectively, of interest expense related to the Loan and Security Agreement. During the three and nine months ended September 30, 2020, the Company recognized $0.3 million and $0.4 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 September 30, 2021:

| | Note Principal Payments (in thousands) |
|---|---|
| Remainder of 2021 | $ — |
| 2022 | — |
| 2023 | 5,254 |
| 2024 | 5,441 |

As of September 30, 2021, 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**

*2020 Underwritten Public Offerings*

In February 2020, the Company completed an underwritten public offering of 2,190,750 shares of its common stock under a universal shelf registration statement for net proceeds of approximately $43.0 million, after deducting underwriting discounts and commissions and offering expenses.

On September 9, 2020, the Company completed an underwritten public offering of 4,000,000 shares of its common stock. The Company received net proceeds from this offering of approximately $150.4 million, after deducting underwriting discounts and, commissions but before deducting offering expenses.

*2021 At-the-Market Offering Program Sales Agreement*

On February 25, 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 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.

**9. Stock-based Compensation**

For the nine months ended September 30, 2021, the Company granted 824,450 options at a weighted average exercise price per share of $34.82. For the nine months ended September 30, 2021, the Company granted 187,450 RSUs.

The Company recorded the following stock-based compensation expense:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| | (in thousands) | | | |
| Employee awards: | | | | |
| Research and development expense | $ 2,817 | $ 2,044 | $ 5,330 | $ 3,966 |
| General and administrative expense | 3,889 | 3,045 | 7,942 | 6,107 |
| Total stock-based compensation expense | $ 6,706 | $ 5,089 | $ 13,272 | $ 10,073 |

**10. Gain from Sale of Priority Review Voucher, net of transaction costs**

On August 31, 2021, the Company entered into a definitive agreement to sell the rare pediatric disease PRV that it 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, the Company completed its 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 within other income (loss).

**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, 2020, 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, 2020, 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 pruritis 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 FDA granted the Company orphan drug exclusivity for Bylvay for the treatment of pruritis in patients ages 3 months or older with PFIC. In July 2021, the EMA granted the Company orphan drug exclusivity for Bylvay for the treatment of patients 6 months or older with PFIC. 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, and continue to enroll 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 and have dosed the first patients in the trial. We expect topline results from the ASSERT trial in 2022. Our most advanced product candidate in addition to Bylvay is elobixibat, which is approved in Japan and Thailand for the treatment of chronic constipation. 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 oralbioavailability 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. We initiated a Phase 1 clinical trial, with the first patient dosed in the first quarter of 2021, and we expect topline results from that trial by year end 2021. If the Phase 1 trial supports continued development, we expect to initiate a Phase 2 trial for A3907 in adult liver disease in 2022. A U.S. composition of matter and method of use patent for A3907 was issued with an expiration date between 2039 and 2040, not including patent term extension. 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 allowed, and IND enabling studies are being completed. Preclinical efforts with other bile acid modulator approaches continue.

**Bylvay — Our Lead Product for PFIC.**

Bylvay (odevixibat) was approved by the FDA on July 20, 2021 for the treatment of pruritis in patients ages 3 months or older with PFIC, and authorized by the European Medicines Agency 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 million. We further announced in September 2021 that Bylvay became available by prescription to patients in Germany. 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 pruritis 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. We hold global rights to Bylvay unencumbered. Our current plan is to commercialize Bylvay ourselves in the United States and Europe. We have entered into a Co-Promotion Agreement with Travere Therapeutics, Inc. for the co-promotion of Bylvay in the United States. The initial term of the arrangement is two years from launch of Bylvay, terminable at will by either party after one year following launch. 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 Ltd. for Israel, Gen İlaç ve Sağlık Ürünleri 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 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 Bylvay for the treatment of biliary atresia, and in January 2019, the FDA granted orphan drug designation to Bylvay 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. We continue to enroll patients in the trial and 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 Bylvay 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 18,100 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 expected to enroll approximately 45 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 2022, before the announcement of the topline results from the BOLD trial. 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 11,700 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. There are currently no drugs approved for the treatment of ALGS. Current treatment for ALGS is generally in line with current treatments for PFIC as described above. In August 2012, the European Commission granted orphan designation to Bylvay for the treatment of ALGS. In October 2018, the FDA granted orphan drug designation to Bylvay 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 September 30, 2021, we had an accumulated deficit of $289.9 million. We expect to continue to incur significant expenses and increasing operating losses as we continue our development of, and seek marketing approvals for, our product candidates, prepare for and begin the commercialization of any approved products, and add infrastructure and personnel to support our product development efforts and operations as a public company in the United States.

As a 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 September 30, 2021, we had approximately $262.6 million in cash and cash equivalents.

**Financial Operations Overview**

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

***Revenue***

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

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.

*Product Revenue, Net*

We recognize revenue upon delivery of Bylvay to our customers. 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, and (iii) trade allowances, such as invoice discounts for prompt payment and customer fees.

We recognized net sales of Bylvay of $1.1 million and $1.1 million for the three and nine months ended September 30, 2021, respectively. No revenue was recognized for the three and nine months ended September 20, 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).

***Cost of Product Revenue***

Cost of product revenue consists of manufacturing costs for sales of Bylvay. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval on July 20, 2021, certain of the Bylvay costs during the nine months ended September 30, 2021 were expensed prior to July 20, 2021 and, therefore, are not included in costs of sales during the current period. These costs expensed prior to regulatory approval were determined to be immaterial after estimating the cost of sales, with or without such costs, compared to the net sales of Bylvay as a whole. Cost of product revenues for the next 24 months, when pre-approval inventory will be depleted, will reflect a lower average per unit cost of sales. Manufacturing costs, which totaled approximately $1.6 million, were not capitalized, and instead were expensed as research and development expenses from 2020 to 2021.

***Operating Expenses***

*Research and Development Expenses*

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

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

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

*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 allocated overhead, marketing expenses related to the commercial launch of Bylvay, as well as other corporate expenses.

*Other Operating Expense (income), net*

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

*Gain from sale of priority review voucher, net of transaction costs*

Gain from sale of priority review voucher, net of transaction costs consists of cash proceeds recorded in connection with the sale of the rare pediatric disease priority review voucher received from the FDA in connection with the approval of the Company’s product Bylvay (odevixibat).

*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 and Thailand 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.

*Provision for Income Taxes*

Provision for income taxes consists of taxes related to the sale of the PRV, offset by a tax benefit from our ordinary losses. We expect to have sufficient tax losses in the current year to offset the income from the sale and thus no current year liability is expected. We expect to maintain a full valuation allowance against its net deferred tax assets for the year.

**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 February 25, 2021, the date we filed our Annual Report on Form 10-K for the year ended December 31, 2020. 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, 2020.

Results of Operations

***Three Months Ended September 30, 2021 and September 30, 2020***

*Result of Operations*

| | Three Months Ended September 30, | | Change |
|---|---|---|---|
| | 2021 | 2020 | $ |
| | | (in thousands) | |
| Revenue | | | |
| Product revenue, net | $ 1,060 | $ — | $ 1,060 |
| Royalty revenue | 2,604 | 2,131 | 473 |
| Total revenue | 3,664 | 2,131 | 1,533 |
| Cost of product revenue | 431 | — | 431 |
| Gross profit | 3,233 | 2,131 | 1,102 |
| Operating Expenses | | | |
| Research and development | 21,083 | 22,200 | (1,117) |
| Selling, general and administrative | 17,612 | 11,663 | 5,949 |
| Other operating expense (income), net | 3,719 | (4,628) | 8,347 |
| Total operating expenses | 42,414 | 29,235 | 13,179 |
| Operating loss | (39,181) | (27,104) | (12,077) |
| Other income (loss) | | | |
| Gain from sale of priority review voucher, net of transaction costs | 103,387 | — | 103,387 |
| Interest expense, net | (3,331) | (3,639) | 308 |
| Net income (loss) before income taxes | 60,875 | (30,743) | 91,618 |
| Provision for income taxes | 3,789 | — | 3,789 |
| Net income (loss) | $ 57,086 | $ (30,743) | $ 87,829 |

*Revenue*

| | Three Months Ended September 30, 2021 | 2020 | Change $ |
|---|---|---|---|
| | (in thousands) | | |
| Product revenue, net | $ 1,060 | $ — | $ 1,060 |
| Royalty revenue | 2,604 | 2,131 | 473 |
| Total revenue | $ 3,664 | $ 2,131 | $ 1,533 |

Product revenue, net was $1.1 million for the three months ended September 30, 2021 due to net revenue recognized upon Bylvay sales. There was no product revenue for the three months ended September 30, 2020.

Royalty revenue was $2.6 million for the three months ended September 30, 2021 compared with $2.1 million for the three months ended September 30, 2020, an increase of $0.5 million. The increase 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 September 30, 2021 | 2020 | Change $ |
|---|---|---|---|
| | (in thousands) | | |
| Cost of product revenue | $ 431 | $ — | $ 431 |

Cost of product revenue was $0.4 million for the three months ended September 30, 2021. 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, was expensed prior to approval. Bylvay was approved during this quarter, therefore there was no cost of product revenue for the three months ended September 30, 2020.

*Research and development expenses*

| | Three Months Ended September 30, 2021 | 2020 | Change $ |
|---|---|---|---|
| | (in thousands) | | |
| Research and development expenses | $ 21,083 | $ 22,200 | $ (1,117) |

Research and development expenses were $21.1 million for the three months ended September 30, 2021 compared with $22.2 million for the three months ended September 30, 2020, a decrease of $1.1 million. The decrease in research and development expenses for the 2021 period was principally due to program activities related to Bylvay, elobixibat, and preclinical programs and were offset by the increase in program activities related to odevixibat in biliary atresia and Alagille syndrome and A3907.

The following table summarizes our principal product development programs and the out-of-pocket third-party expenses incurred with respect to each clinical-stage product candidate and our preclinical programs for the three months ended September 30, 2021 and 2020.

| | Three Months Ended September 30, 2021 | 2020 | Change $ |
|---|---|---|---|
| | (in thousands) | | |
| Direct third-party project costs: | | | |
| Bylvay | $ 3,697 | $ 9,463 | $ (5,766) |
| Odevixibat | 7,254 | 2,579 | 4,675 |
| Elobixibat | — | 1,077 | (1,077) |
| A3907 | 1,423 | — | 1,423 |
| Preclinical | 915 | 1,717 | (802) |
| Total | $ 13,289 | $ 14,836 | $ (1,547) |
| Other project costs[1]: | | | |
| Personnel costs | $ 7,741 | $ 7,179 | $ 562 |
| Other costs[2] | 53 | 185 | (132) |
| Total | $ 7,794 | $ 7,364 | $ 430 |
| Total research and development costs | $ 21,083 | $ 22,200 | $ (1,117) |

(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 September 30, 2021 | 2020 | Change $ |
|---|---|---|---|
| | (in thousands) | | |
| Selling, general and administrative | $ 17,612 | $ 11,663 | $ 5,949 |

Selling, general and administrative expenses were $17.6 million for the three months ended September 30, 2021 compared with $11.7 million for the three months ended September 30, 2020, an increase of $5.9 million. The increase is attributable to personnel and related expenses as we continue to increase our headcount, and commercial expenses to launch Bylvay.

*Other operating expense (income), net*

| | Three Months Ended September 30, 2021 | 2020 | Change $ |
|---|---|---|---|
| | (in thousands) | | |
| Other operating expense (income), net | $ 3,719 | $ (4,628) | $ 8,347 |

Other operating expense, net totaled $3.7 million for the three months ended September 30, 2021 compared with income of $4.6 million for the three months ended September 30, 2020. The difference primarily relates to changes in foreign currency exchange rates in the two periods.

*Gain from sale of priority review voucher, net of transaction costs*

| | Three Months Ended September 30, 2021 | 2020 | Change $ |
|---|---|---|---|
| | (in thousands) | | |
| Gain from sale of priority review voucher, net of transaction costs | $ 103,387 | $ — | $ 103,387 |

Gain from sale of priority review voucher, net of transaction costs totaled $103.4 million for the three months ended September 30, 2021. There was no gain from the sale of priority review voucher, net for the three months ended September 30, 2020.

*Interest expense, net*

| | Three Months Ended September 30, 2021 | 2020 | Change $ |
|---|---|---|---|
| | (in thousands) | | |
| Interest expense, net | $ (3,331) | $ (3,639) | $ 308 |

Interest expense, net totaled $3.3 million for the three months ended September 30, 2021 compared with $3.6 million for the three months ended September 30, 2020. 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, in addition to interest expense associated with our note payable.

*Provision for income taxes*

| | Three Months Ended September 30, 2021 | 2020 | Change $ |
|---|---|---|---|
| | In thousands | | |
| Provision for income taxes | $ 3,789 | $ — | $ 3,789 |

We recorded a tax provision of $3.8 million for the three months ended September 30, 2021, primarily related to the sale of the PRV, offset by a tax benefit from our ordinary losses. We expect to have sufficient tax losses in the current year to offset the income from the sale and thus no current year liability is expected. We expect to maintain a full valuation allowance against its net deferred tax assets for the year.

***Nine Months Ended September 30, 2021 and September 30, 2020***

*Result of Operations*

| | Nine Months Ended September 30, 2021 | 2020 | Change $ |
|---|---|---|---|
| | | (in thousands) | |
| Revenue | | | |
| Product revenue, net | $ 1,060 | $ — | $ 1,060 |
| Royalty revenue | 6,998 | 5,592 | 1,406 |
| Total revenue | 8,058 | 5,592 | 2,466 |
| Cost of product revenue | 431 | — | 431 |
| Gross profit | 7,627 | 5,592 | 2,035 |
| Operating Expenses | | | |
| Research and development | 61,920 | 56,727 | 5,193 |
| Selling, general and administrative | 49,825 | 28,290 | 21,535 |
| Other operating expense (income), net | 7,873 | (4,556) | 12,429 |
| Total operating expenses | 119,618 | 80,461 | 39,157 |
| Operating loss | (111,991) | (74,869) | (37,122) |
| Other income (loss) | | | |
| Gain from sale of priority review voucher, net of transaction costs | 103,387 | — | 103,387 |
| Interest expense, net | (10,675) | (7,965) | (2,710) |
| Net loss before income taxes | (19,279) | (82,834) | 63,555 |
| Provision for income taxes | 3,789 | — | 3,789 |
| Net loss | $ (23,068) | $ (82,834) | $ 59,766 |

*Revenue*

| | Nine Months Ended September 30, 2021 | 2020 | Change $ |
|---|---|---|---|
| | (in thousands) | | |
| Product revenue, net | $ 1,060 | $ — | $ 1,060 |
| Royalty revenue | 6,998 | 5,592 | 1,406 |
| Total revenue | $ 8,058 | $ 5,592 | $ 2,466 |

Product revenue, net was $1.1 million for the nine months ended September 30, 2021 due to revenue recognized upon Bylvay sales. There was no product revenue for the nine months ended September 30, 2020.

Royalty revenue was $7.0 million for the nine months ended September 30, 2021 compared with $5.6 million for the nine months ended September 30, 2020, an increase of $1.4 million. The increase relates to estimated royalty revenue to be received from EA Pharma for elobixibat for the treatment of chronic constipation.

*Cost of product revenue*

| | Nine Months Ended September 30, 2021 | 2020 | Change $ |
|---|---|---|---|
| | (in thousands) | | |
| Cost of product revenue | $ 431 | $ — | $ 431 |

Cost of product revenue was $0.4 million for the nine months ended September 30, 2021 due to the approval of Bylvay in July 2021. 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, was expensed prior to approval. Bylvay was approved during this quarter, therefore there was no cost of product revenue for the nine months ended September 30, 2020.

*Research and development expenses*

| | Nine Months Ended September 30, 2021 | 2020 | Change $ |
|---|---|---|---|
| | (in thousands) | | |
| Research and development expenses | $ 61,920 | $ 56,727 | $ 5,193 |

Research and development expenses were $61.9 million for the nine months ended September 30, 2021 compared with $56.7 million for the nine months ended September 30, 2020, an increase of $5.2 million. The increased research and development expenses for the 2021 period were principally due to clinical programs and personnel expenses, including stock-based compensation as we continue to increase our headcount and program activities. The increase in program activities related to odevixibat in biliary atresia and Alagille syndrome and A3907 and were partially offset by Bylvay PFIC expenses, elobixibat and preclinical programs.

The following table summarizes our principal product development programs and the out-of-pocket third-party expenses incurred with respect to each clinical-stage product candidate and our preclinical programs for the nine months ended September 30, 2021 and 2020.

| | Nine Months Ended September 30, 2021 | 2020 | Change $ |
|---|---|---|---|
| | | (in thousands) | |
| Direct third-party project costs: | | | |
| Bylvay | $ 15,181 | $ 26,119 | $ (10,938) |
| Odevixibat | 18,008 | 5,616 | 12,392 |
| Elobixibat | — | 2,834 | (2,834) |
| A3384 | — | 93 | (93) |
| A3907 | 5,241 | — | 5,241 |
| Preclinical | 2,873 | 4,200 | (1,327) |
| Total | $ 41,303 | $ 38,862 | $ 2,441 |
| Other project costs[1]: | | | |
| Personnel costs | $ 19,668 | $ 15,774 | $ 3,894 |
| Other costs[2] | 949 | 2,091 | (1,142) |
| Total | $ 20,617 | $ 17,865 | $ 2,752 |
| Total research and development costs | $ 61,920 | $ 56,727 | $ 5,193 |

(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*

| | Nine Months Ended September 30, 2021 | 2020 | Change $ |
|---|---|---|---|
| | | (in thousands) | |
| Selling, general and administrative | $ 49,825 | $ 28,290 | $ 21,535 |

Selling, general and administrative expenses were $49.8 million for the nine months ended September 30, 2021 compared with $28.3 million for the nine months ended September 30, 2020, an increase of $21.5 million. The increase is attributable to personnel and related expenses as we continue to increase our headcount, and commercialization readiness activities related to Bylvay.

*Other operating expense (income), net*

| | Nine Months Ended September 30, 2021 | 2020 | Change $ |
|---|---|---|---|
| | | (in thousands) | |
| Other operating expense (income), net | $ 7,873 | $ (4,556) | $ 12,429 |

Other operating expense, net totaled $7.9 million for the nine months ended September 30, 2021 compared with income of $4.6 million for the nine months ended September 30, 2020. The difference primarily relates to changes in foreign currency exchange rates in the two periods.

*Gain from sale of priority review voucher, net of transaction costs*

| | Nine Months Ended September 30, 2021 | 2020 | Change $ |
|---|---|---|---|
| | | (in thousands) | |
| Gain from sale of priority review voucher, net of transaction costs | $ 103,387 | $ — | $ 103,387 |

Gain from sale of priority review voucher, net of transaction costs totaled $103.4 million for the three months ended September 30, 2021. There was no gain from the sale of priority review voucher, net for the three months ended September 30, 2020.

*Interest expense, net*

| | Nine Months Ended September 30, 2021 | 2020 | Change $ |
|---|---|---|---|
| | | (in thousands) | |
| Interest expense, net | $ (10,675) | $ (7,965) | $ (2,710) |

Interest expense, net totaled $10.7 million for the nine months ended September 30, 2021 compared with $8.0 million for the nine months ended September 30, 2020. The difference was principally attributable to higher non-cash interest expense recorded in connection with the sale of future royalties related to sales of elobixibat in Japan, in addition to interest expense associated with our note payable.

*Provision for income taxes*

| | Nine Months Ended September 30, 2020 | 2019 | Change $ |
|---|---|---|---|
| | | In thousands | |
| Provision for income taxes | $ 3,789 | $ — | $ 3,789 |

We recorded a tax provision of $3.8 million for the nine months ended September 30, 2021, primarily related to the sale of the PRV, offset by a tax benefit from our ordinary losses. We expect to have sufficient tax losses in the current year to offset the income from the sale and thus no current year liability is expected. We expect to maintain a full valuation allowance against its net deferred tax assets for the year.

**Liquidity and Capital Resources**

*Sources of Liquidity*

We anticipate generating low single digit U.S. $ million revenue from sales of Bylvay in 2021. 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 our other product candidates. We are subject to all of the risks applicable to the development of new pharmaceutical products and may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may harm our business. We expect that we will need substantial additional funding to complete development of and potentially commercialize our other product candidates.

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

As of September 30, 2021, our cash and cash equivalents were approximately $262.6 million.

During the first quarter of 2018, following the Japanese MHLW's approval of elobixibat for the treatment of chronic constipation in January 2018, we received a $44.5 million payment, net of certain transaction expenses, from HCR under our RIAA. Additionally, this approval triggered a milestone payment to us from EA Pharma of $11.2 million. 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 September 30, 2021, 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 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 September 30, 2021, $40.0 million of securities remain available for issuance under the 2020 Form S-3.

On May 7, 2020, we also entered into a sales agreement, with respect to an at-the-market offering program under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $50.0 million. This agreement terminated on September 9, 2020.

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 provides for term loans in an aggregate principal amount of up to $80.0 million to be delivered in multiple tranches, (the Term Loans). The tranches consist of (i) a term loan advance to 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 have 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, and (iii) subject to the Lender's investment committee's sole discretion, we have 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. As of September 30, 2021, we borrowed an aggregate principal amount of $10.0 million. An aggregate principal amount of up to $20.0 million remains available for future borrowing upon request and an aggregate principal amount of up to $45.0 million remains available for future borrowing subject to approval from the Lender.

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 continue to satisfy the requirements of a "well-known seasoned issuer" under SEC rules, which we refer to as the 2021 Form S-3. This registration statement will remain in effect for up to three years from the date it became effective. On February 25, 2021, we also entered into a new sales agreement, 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 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. We make no assurances as to the continued effectiveness of the 2021 Form S-3.

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*

*Nine months ended September 30, 2021 and September 30, 2020*

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2021 | 2020 |
| | (in thousands) | |
| Net cash (used in) provided by: | | |
| Operating activities | $ (93,668) | (72,834) |
| Investing activities | 102,922 | (78) |
| Financing activities | 2,389 | 219,826 |
| Total | $ 11,643 | $ 146,914 |
| Effect of exchange rate changes on cash and cash equivalents | (303) | (66) |
| Net increase in cash and cash equivalents | 11,340 | 146,848 |

*Operating activities*

Cash used in operating activities of $93.7 million during the nine months ended September 30, 2021 was primarily a result of our $23.1 million net loss from operations, $103.4 million net gain from sale of PRV, and a net increase in assets and liabilities of $1.8 million. The net increase in operating assets and liabilities during the nine months ended September 30, 2021 was primarily driven by increases in accrued expenses, accounts payables, accounts receivable, other assets and inventory, offset by decreases in other current and long-term liabilities and prepaid expenses and other current assets. This increase was offset by non-cash items, including $13.3 million of stock-based compensation expense, $9.4 million of accretion of liability related to sale of future royalties, and $7.8 million of foreign currency adjustments. Cash used in operating activities of $72.8 million during the nine months ended September 30, 2020 was primarily a result of our $82.8 million net loss from operations and a net decrease in assets and liabilities of $4.0 million. The net decrease in operating assets and liabilities during the nine months ended September 30, 2020 was primarily driven by decreases in accrued expenses, other current and long-term liabilities, prepaid expenses and other current assets, and accounts payable. This decrease was offset by non-cash items, including $10.1 million of stock-based compensation expense, $7.7 million of accretion of liability related to sale of future royalties, and $4.0 million of foreign currency adjustments.

*Investing activities*

Cash provided by investing activities of $102.9 million during the nine months ended September 30, 2021 was primarily related to net proceeds from the sale of the PRV offset by purchases of property and equipment. Cash used in investing activities of $0.1 million during the nine months ended September 30, 2020 was primarily related to the purchase of property and equipment.

*Financing activities*

Cash provided by financing activities of $2.4 million during the nine months ended September 30, 2021 was primarily related to proceeds from exercise of options. Cash provided by financing activities of $219.8 million during the nine months ended September 30, 2020 was primarily related to proceeds from the issuance of common stock, net of issuance costs of $193.4 million, proceeds from royalty agreement of $14.8 million, and proceeds from issuance of debt, net of issuance costs of $9.5 million.

*Funding Requirements*

Cash used to fund operating expenses is affected by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. The 2021 operating cash burn guidance has been $130-$135 million and is expected to be closer to $130 million. During the third quarter of 2021 an additional $103.4 million of net proceeds were received after deducting fees from the recently completed sale of the PRV. An additional $15 million cash upfront fee from the recently announced Japan licensing agreement due to be received in the fourth quarter of 2021. 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. 2021 revenue from Bylvay is anticipated to be $3-4 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 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 September 30, 2021, $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 continue 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 million of our common stock pursuant to the sales agreement with respect to an at-the-market offering program. As of September 30, 2021, there remained $99.7 million of our common stock available for sale pursuant to the sales agreement. We make no assurances as to the continued effectiveness of the 2021 Form S-3.

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 September 30, 2021, 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 controls over financial reporting identified in connection with the evaluation of such internal controls that occurred during the three months ended September 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting other than the implementation of controls designed to address risks related to product revenue recognition and inventory.

We engaged in the process of design and implementation of internal control over financial reporting in a manner commensurate with the scale of our commercial operations, including the review of inventory held by third party providers.

## PART II — OTHER INFORMATION

### Item 1. Legal Proceedings

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

### Item 1A. Risk Factors

Except as set forth below, 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, 2020, filed with the Securities and Exchange Commission, or SEC, on February 25, 2021.

***We depend heavily on the commercial success of Bylvay, which was only recently approved for commercial sale. There is no assurance that our commercialization efforts in the U.S. and Europe with respect to Bylvay will be successful or that we will be able to generate revenues at the levels or within the timing we expect, or at the levels or within the timing necessary to support our goals.***

Bylvay was approved by the FDA and authorized by the EMA in July 2021. Bylvay was also granted marketing authorization by the MHRA in September 2021. We may still encounter delays or hurdles related to our product launch that affect timing of commercial availability.

Our business currently depends heavily on our ability to successfully commercialize Bylvay in the U.S. and Europe in its approved indications. We may never be able to successfully commercialize Bylvay or meet our expectations with respect to revenues. There is no guarantee that the infrastructure, systems, processes, policies, personnel, relationships and materials we have built in preparation for the launch and commercialization of Bylvay in the U.S. and Europe will be sufficient for us to achieve success at the levels we expect. Additionally, healthcare providers may not accept a new treatment paradigm for patients with PFIC. We may also encounter challenges related to reimbursement of Bylvay, even if we have positive early indications from payors, including potential limitations in the scope, breadth, availability, or amount of reimbursement covering Bylvay. Similarly, healthcare settings or patients may determine that the financial burdens of treatment are not acceptable. Our results may also be negatively impacted if we have not adequately sized our field teams or our physician segmentation and targeting strategy is inadequate or if we encounter deficiencies or inefficiencies in our infrastructure or processes. Any of these issues could impair our ability to successfully commercialize Bylvay or to generate substantial revenues or profits or to meet our expectations with respect to the amount or timing of revenue or profits. Any issues or hurdles related to our commercialization efforts may materially adversely affect our business, results of operations, financial condition and prospects. There is no guarantee that we will be successful in our launch or commercialization efforts with respect to Bylvay.

### Item 5. Other Information

On November 3, 2021 our Board of Directors (the “Board”) adopted the Incentive Compensation Recoupment Policy (the “Clawback Policy”). The Clawback Policy, which is administered by the Compensation Committee of the Board (the “Committee”), permits the Committee to seek to recoup incentive compensation granted or awarded to or earned by our employees who are “officers” under the reporting requirements of Section 16 of the Exchange Act (the “Executives”), in the event the Committee determines that an Executive engaged in serious misconduct, or failed to supervise a subordinate employee who engaged in serious misconduct which the Executive knew, or was reckless in not knowing, was occurring, and such misconduct resulted in a material violation of law or a written Company policy that caused significant financial or reputational harm to the Company. For purposes of the Clawback Policy, incentive compensation means (i) any equity or equity-based award granted on or after January 1, 2022, and (ii) any cash-based performance or incentive award (i.e., bonus or cash incentive plan payment, including any amounts deferred with respect thereto) approved, awarded or granted to an Executive on or after January 1, 2022. The Clawback Policy provides that the Committee may not seek recoupment of incentive compensation following a change of control or that was awarded

more than three years prior to the first event giving rise to the recoupment. Notwithstanding the Policy, we may recoup compensation to the extent required by law or the requirements of the exchange on which the Company's stock is listed for trading.

The foregoing is only a brief description of the terms of the Clawback Policy, does not purport to be complete and is qualified in its entirety by reference to the Clawback Policy that has been filed as an exhibit to this Quarterly Report on Form 10-Q.

**Item 6. Exhibits**

| Exhibit No. | Description | Filed Herewith | Incorporated by Reference Herein from Form or Schedule | Filing Date | SEC File/ Req. Number |
|---|---|---|---|---|---|
| 10.1+@ | Asset Purchase Agreement, dated as of August 31, 2021, by and among the Registrant, Albireo AB and Ares Trading SA. | X | | | |
| 10.2* | Albireo Pharma, Inc. Incentive Compensation Recoupment Policy. | X | | | |
| 31.1 | Certification of the Registrant's Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | X | | | |
| 31.2 | Certification of the Registrant's Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | X | | | |
| 32.1 | Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | X | | | |
| 101 | The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets (unaudited) at September 30, 2021 and December 31, 2020, (ii) Condensed Consolidated Statements of Operations (unaudited) for the three and nine months ended September 30, 2021 and 2020, (iii) Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three and nine months ended September 30, 2021 and 2020, (iv) Condensed Consolidated Statement of Stockholders' Equity (unaudited) for the three and nine months ended September 30, 2021 and 2020, (v) Condensed Consolidated Statements of Cash Flows (unaudited) for the nine months ended September 30, 2021 and 2020, 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.
+ Certain of the exhibits and schedules to this Exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5). The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.
@ Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets ("[***]") because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

**SIGNATURES**

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

ALBIREO PHARMA, INC.

Dated: November 4, 2021

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

EXECUTION VERSION

**Exhibit 10.1**

# ASSET PURCHASE AGREEMENT

**BY AND AMONG**

**ALBIREO AB,**

**ALBIREO PHARMA, INC.**

**AND**

**ARES TRADING SA**

**August 31, 2021**

**[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.**

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**ASSET PURCHASE AGREEMENT**

This ASSET PURCHASE AGREEMENT (this "***Agreement***") is made and entered into as of August 31, 2021 (the "***Effective Date***"), by and among Ares Trading SA, a corporation organized under the laws of Switzerland ("***Buyer***"), Albireo AB, a corporation organized under the laws of Sweden ("***Seller***"), and Albireo Pharma, Inc., a corporation organized under the laws of Delaware ("***Albireo Pharma***"), for the limited purposes of ARTICLES VII, VIII, X and XI. Buyer, Seller and Albireo Pharma may hereinafter be referred to individually as a "***Party***" and collectively as the "***Parties***."

RECITALS

**WHEREAS**, Seller is the sole beneficial and record holder of all right, title and interest in and to the Priority Review Voucher (as defined below).

**WHEREAS**, Seller and Buyer each (i) desire that Buyer purchase from Seller, and Seller sell, transfer and assign to Buyer, the Purchased Assets (as defined below), all on the terms set forth herein (such transaction, the "***Asset Purchase***"), and (ii) in furtherance thereof, have duly authorized, approved and executed this Agreement and the other transactions contemplated by this Agreement in accordance with all applicable Legal Requirements (as defined below).

**WHEREAS**, Seller and Buyer desire to make certain representations, warranties, covenants and other agreements in connection with the Asset Purchase as set forth herein.

**NOW, THEREFORE**, in consideration of the foregoing and their mutual undertakings hereinafter set forth, and intending to be legally bound, the Parties hereby agree as follows:

ARTICLE I
DEFINITIONS

1.1 Certain Definitions. As used in this Agreement, the following terms shall have the meanings indicated below:

(a) "***Affiliate***" means any Person which, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with, a Party to this Agreement, for so long as such control exists, whether such Person is or becomes an Affiliate on or after the Effective Date. A Person shall be deemed to "control" another Person if it: (i) with respect to such other Person that is a corporation, owns, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by such Person in a particular jurisdiction) of such other Person, or, with respect to such other Person that is not a corporation, has other comparable ownership interest; or (ii) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of such other Person.

(b) "***Alternative Transaction***" means, other than the transactions contemplated by this Agreement, any sale, assignment, transfer or encumbrance, whether by option, agreement, understanding or other arrangement, of any right, title or interest in and to the Purchased Assets;

provided, that for the avoidance of doubt, "***Alternative Transaction***" shall not include (i) a transaction for the sale, assignment, transfer or encumbrance of any or all of the equity interests of Seller (whether through a stock purchase, merger or otherwise), or (ii) any acquisition or sale of substantially all of Seller's assets so long as such acquisition or sale provides that this Agreement continues to be binding, enforceable and in full force and effect on the same terms in effect as of the Effective Date.

(c) "***Business Day***" means a day (i) other than Saturday or Sunday, and (ii) on which commercial banks are open for business in New York, New York.

(d) "***Buyer Fundamental Representations***" means those representations and warranties contained in Sections 5.1, 5.2, 5.3, 5.4 and 5.6.

(e) "***Contract***" means any written or oral legally binding contract, agreement, instrument, commitment or undertaking (including leases, licenses, mortgages, notes, guarantees, sublicenses, subcontracts and purchase orders).

(f) "***Encumbrance***" means any lien, pledge, charge, mortgage, easement, encroachment, imperfection of title, title exception, title defect, right of possession, lease, security interest, encumbrance, adverse claim, interference or restriction on use or transfer.

(g) "***FDA***" means the United States Food and Drug Administration.

(h) "***FDCA***" means the United States Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 *et seq.*), as amended, and including any rules and regulations promulgated thereunder.

(i) "***Governmental Entity***" means any supranational, national, state, municipal, local or foreign government, any court, tribunal, arbitrator, administrative agency, commission or other governmental official, authority or instrumentality, in each case whether domestic or foreign, any stock exchange or similar self-regulatory organization or any quasi-governmental or private body exercising any regulatory, taxing or other governmental or quasi-governmental authority.

(j) "***HSR Act***" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder.

(k) "***Knowledge***" means, with respect to Seller, the actual knowledge of the facts and information of any director or officer of Seller, after performing a reasonable inquiry with respect to such facts and information.

(l) "***Legal Requirements***" means any federal, state, foreign, local, municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, rule, regulation, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Entity and any Orders applicable to a Party or to any of its assets, properties or businesses. Legal Requirements shall include, with respect to Seller, any responsibilities, obligations, requirements, parameters and conditions

relating to the Priority Review Voucher set forth in (i) the NDA Approval Letter, (ii) Section 529 of the FDCA (21 U.S.C. § 360ff), or (iii) any other correspondence received by Seller or its Affiliates from the FDA.

(m) "***Lender Notice***" means that the notice under the Loan and Security Agreement, a form of which is attached hereto as Exhibit A.

(n) "***Liabilities***" means all debts, liabilities and obligations, whether presently in existence or arising hereafter, accrued or fixed, absolute or contingent, matured or unmatured, determined or determinable, asserted or unasserted, known or unknown, including those arising under any law, action or governmental order and those arising under any Contract.

(o) ***"Loan and Security Agreement"*** means that certain Loan and Security Agreement by and among Seller, the Borrowers and Lenders identified therein and Hercules Capital, Inc., dated June 8, 2020.

(p) "***Mutual Confidentiality Agreement***" means that certain Mutual Confidentially Agreement by and between the Parties, dated July 27, 2021.

(q) "***NDA Approval Letter***" means the NDA approval letter dated July 20, 2021 from the FDA to Seller, Reference ID 4828760, regarding approval of the Subject NDA and granting the Priority Review Voucher, attached hereto as Exhibit B.

(r) "***Order***" means any order, decree, edict, injunction, writ, award or judgment of any Governmental Entity.

(s) "***Person***" means any natural person, company, corporation, limited liability company, general partnership, limited partnership, trust, proprietorship, joint venture, business organization or Governmental Entity.

(t) "***Priority Review***" means a priority review of and action by the FDA upon a human drug application not later than six (6) months after receipt by the FDA of such application, as defined and provided in Section 529(a)(1) the FDCA (21 U.S.C. § 360ff(a)(1)).

(u) "***Priority Review Voucher***" means the priority review voucher issued by the FDA to Seller pursuant to section 529(b)(1) of the FDCA (21 U.S.C. § 360ff(b)(1)), that entitles the holder of such voucher to Priority Review, as evidenced by the NDA Approval Letter, and assigned tracking number PRV NDA 215498.

(v) "***Proceeding***" means any action, arbitration, audit, claim, hearing, investigation, proceeding, litigation or suit (whether civil, criminal, administrative, judicial or investigative, whether formal or informal, whether public or private) commenced, brought, conducted or heard by or before, or otherwise involving, any Governmental Entity or arbitrator.

(w) "***Purchased Assets***" means (i) the Priority Review Voucher, and (ii) any and all rights, benefits and entitlements afforded to the holder of the Priority Review Voucher.

(x) "***Regulatory Change***" means any (i) changed or additional Legal Requirement, amendment, supplement or interpretation to any then-existing Legal Requirement, or (ii) additional, amended or supplemented term or condition that is not set forth in the Approval Letter or on a party seeking to use or transfer the Priority Review Voucher, that in either case of (i) or (ii) has been enacted, adopted, approved, or imposed by a Governmental Entity with appropriate jurisdiction over the matter between the Effective Date and the Closing Date and materially adversely impacts or limits the manner in which Buyer may use, receive, hold, transfer or otherwise exploit the Priority Review Voucher.

(y) "***Representative***" means, with respect to a particular Person, any director, officer, manager, employee, agent, consultant, advisor, accountant, financial advisor, legal counsel or other representative of that Person.

(z) "***Seller Fundamental Representations***" means those representations and warranties contained in Sections 4.1, 4.2, 4.3, 4.4, 4.5, 4.10, 4.11, 4.12 and 4.13.

(aa) "***Subject NDA***" means New Drug Application ("***NDA***") Number 215498, approved by the FDA on July 20, 2021 for BYLVAY (odevixibat) capsules and oral pellets for the treatment of pruritus in patients three months of age and older with progressive familial intrahepatic cholestasis (PFIC).

(bb) "***Tax***" or "***Taxes***" means any federal, state, local or foreign income, gross receipts, branch profits, license, payroll, employment, excise, severance, stamp, occupation, premium, windfall profits, environmental, customs duties, capital stock, franchise, profits, withholding, social security, unemployment, disability, real property, personal property, sales, use, transfer, registration, ad valorem, value added, alternative or add-on minimum or estimated tax or other tax of any kind whatsoever, including any interest, penalty or addition thereto.

(cc) "***Tax Authority***" shall mean any Governmental Entity, having or purporting to exercise jurisdiction with respect to any Tax.

(dd) "***Tax Return***" shall mean any return, declaration, report, claim for refund or information return or statement of any kind relating to Taxes, including any schedule or attachment thereto, and including any amendment thereof, filed or required to be filed with any Tax Authority.

(ee) "***Third Party***" means any Person other than a Party and such Party's Affiliates.

Other capitalized terms defined elsewhere in this Agreement and not defined in this Section 1.1 shall have the meanings assigned to such terms in this Agreement.

## ARTICLE II
## PURCHASE AND SALE

2.1 Purchase and Sale; No Assumed Liabilities.

(a) Upon the terms and subject to the conditions of this Agreement, Buyer agrees to purchase from Seller, and Seller agrees to sell, transfer, convey, assign and deliver to Buyer, at the Closing all of Seller's right, title and interest in, to and under the Purchased Assets, in each case free and clear of all Encumbrances.

(b) Buyer shall not assume, nor shall it be liable for, or otherwise be obligated to pay, perform or discharge, any Liabilities of any nature of Seller or its Affiliates, including any Liabilities arising from or related to Seller's ownership prior to the Closing of any rights with respect to the Purchased Assets (other than such obligations as are imposed generally by applicable Legal Requirements solely on the holder of the Priority Review Voucher in respect of its use or transfer following the Closing pursuant to this Agreement) (all of such excluded Liabilities, "***Excluded Liabilities***").

2.2 Purchase Price. The total consideration (the "***Purchase Price***") to be paid by Buyer to Seller for all of the Purchased Assets shall be One Hundred Five Million Dollars (U.S. $105,000,000) due and payable on the Closing Date. Buyer shall pay the Purchase Price to Seller on the Closing Date in United States dollars by wire transfer of immediately available funds to a bank account of Seller in accordance with the wire instructions provided by Seller to Buyer at least five (5) days prior to the Closing Date.

2.3 Indirect Tax. All amounts due under, and consideration given in respect of the subject matter of, this Agreement from or by Buyer, including the Purchase Price, are exclusive of value added taxes ("***VAT***"), goods and services tax ("***GST***") or sales tax (all of such taxes together, "***Indirect Tax***"). If any Indirect Tax is chargeable in respect of any supply made by Seller or any Affiliate of Seller to Buyer or any Affiliate of Buyer, Buyer shall on demand pay or reimburse (or procure that the relevant Affiliate of Buyer shall pay or reimburse) such Indirect Tax in addition to the amounts or consideration otherwise due or payable, at the rate in force at the time of the relevant supply or such other time as is stipulated under the relevant legislation. Seller shall (and shall procure that each relevant Affiliate of Seller shall) promptly provide to Buyer or relevant Affiliate of Buyer a valid invoice (including a VAT invoice or GST invoice) in respect of any such Indirect Tax. Each of Seller and Buyer shall use (and procure that their respective Affiliates shall use) commercially reasonable efforts to minimize (to the extent permissible at Law) obligations relating to Indirect Tax as a result of the transactions contemplated by this Agreement. Seller shall remit such Indirect Tax to the competent Tax authorities and shall cooperate with Buyer in any way reasonably requested to obtain legally permitted reductions, credits or refunds of any invoiced Tax amount. Seller shall deliver to Buyer the wiring instructions as provided under Section 2.2, and shall cooperate with Buyer in order to enable Buyer to make any required Tax payments in connection therewith.

## ARTICLE III
## CLOSING

3.1 Closing. The consummation of the Asset Purchase contemplated by this Agreement (the "***Closing***") shall be conducted telephonically or via email, facsimile transfer or other similar means of correspondence on such date to be mutually agreed upon by Buyer and

Seller, which date shall be no later than the third (3rd) Business Day after all of the conditions set forth in ARTICLE VI have been satisfied or waived (other than those conditions which, by their terms, are intended to be satisfied at the Closing, but subject to satisfaction or waiver of such conditions). The date on which the Closing actually takes place is referred to in this Agreement as the "***Closing Date***."

3.2 Transactions to be Effected at Closing. At the Closing:

(a) Seller shall deliver, or cause to be delivered, to Buyer a duly executed Bill of Sale substantially in the form attached hereto as Exhibit C;

(b) Seller shall deliver, or cause to be delivered, to Buyer a duly executed certificate from an authorized officer of Seller certifying as to the matters set forth in Section 6.2(c);

(c) Buyer shall deliver, or cause to be delivered, to Seller a duly executed certificate from an authorized officer of the Buyer certifying as to the matters set forth in Section 6.3(c);

(d) Seller shall deliver, or cause to be delivered, to Buyer an executed certificate of the secretary or an assistant secretary (or equivalent duly authorized officer or other representative) of Seller certifying (i) that attached thereto are true and complete copies of all resolutions adopted by the board of directors of Seller authorizing the execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby, and (ii) as to the incumbency of each person executing this Agreement and any other document delivered in connection herewith on behalf of Seller and that the signature of each such person on this Agreement and such other document is such person's genuine signature;

(e) Buyer shall pay the Purchase Price to Seller in accordance with Section 2.2;

(f) Seller shall deliver, or cause to be delivered, to Buyer a copy of the notification of the purchase and sale of the Priority Review Voucher pursuant to this Agreement to be submitted to the FDA pursuant to Section 3.3(b), which notification shall be substantially in the form attached hereto as Exhibit D or such other form as the FDA may require as of the Closing Date; and

(g) Buyer shall deliver, or cause to be delivered, to Seller a copy of the notification of the purchase and sale of the Priority Review Voucher pursuant to this Agreement to be submitted to the FDA pursuant to Section 3.3(b), which notification shall be substantially in the form attached hereto as Exhibit E or such other form as the FDA may require as of the Closing Date.

3.3 Title Passage; Notification.

(a) Title Passage. Upon the Closing, all of the right, title and interest of Seller in and to the Purchased Assets shall pass to Buyer.

(b) Method of Delivery of Assets. On the Closing Date, each of Buyer and Seller will submit to the FDA the separate notifications referred to in Section 3.2(f) and Section 3.2(g), respectively, as a submission to the Subject NDA, in each case under the cover letter substantially in the form attached hereto as Exhibit F. Each Party shall provide to the other Party confirmation from the FDA of successful submission and a complete copy of such submission. Notwithstanding anything to the contrary set forth herein, the Parties acknowledge and agree that Seller is not making any representation or warranty regarding, and shall not be liable to Buyer or any other Buyer Indemnitee hereunder with respect to, the adequacy of the requirements set forth in this Section 3.3(b) to comply with Legal Requirements applicable to the transfer of the Priority Review Voucher as contemplated by this Agreement.

(c) Filings; Notifications. Buyer and Seller agree to reasonably cooperate and assist each other with respect to all filings or notifications to any Governmental Entity related to the transfer and assignment of the Purchased Assets.

## ARTICLE IV
## REPRESENTATIONS AND WARRANTIES OF SELLER

Seller represents and warrants to Buyer, as of the Effective Date, as follows:

4.1 Organization, Standing and Power. Seller is a corporation duly organized and validly existing under the laws of Sweden, and Albireo Pharma is a corporation duly organized and validly existing under the laws of the State of Delaware. Seller has the corporate power and authority to own, operate and lease its properties and to carry on its business as presently conducted and is duly qualified or licensed to do business and is in good standing in each jurisdiction where the character of its properties owned or leased or the nature of its activities make such qualification or licensing necessary, except where the failure to be so qualified or licensed would not, individually or in the aggregate, reasonably be expected to adversely affect any of the Purchased Assets or Seller's ability to consummate the Asset Purchase contemplated by this Agreement.

4.2 Authority. Each of Seller and Albireo Pharma has the requisite corporate power and authority to enter into and perform its respective obligations under this Agreement. The execution, delivery and performance of this Agreement, and the consummation of the Asset Purchase, have been duly and validly approved and authorized by all necessary corporate action on the part of each of Seller and Albireo Pharma, and this Agreement has been duly executed and delivered by each of Seller and Albireo Pharma. This Agreement, upon execution by all Parties, will constitute a valid and binding obligation of each of Seller and Albireo Pharma, enforceable against each of Seller and Albireo Pharma in accordance with its terms, subject only to the effect, if any, of (a) applicable bankruptcy and other similar laws affecting the rights of creditors generally, and (b) Legal Requirements governing specific performance, injunctive relief and other equitable remedies.

4.3 Noncontravention. The execution and delivery by each of Seller and Albireo Pharma of this Agreement does not, and the consummation of the Asset Purchase contemplated hereby, including the transfer by Seller of title to, ownership in, and possession of the Purchased Assets, will not, (a) result in the creation of any Encumbrance on any of the Purchased Assets, or

(b) conflict with, or result in any violation of or default under (with or without notice or lapse of time, or both), or give rise to a right of termination, cancellation or acceleration of any obligation or loss of any benefit under, or require any consent, approval or waiver (other than the Lender Notice) from any Person pursuant to, (i) any provision of the certificate of incorporation or bylaws or other charter documents of each of Seller and Albireo Pharma, in each case as amended to date, (ii) the Priority Review Voucher or the NDA Approval Letter, (iii) any Contract to which either of Seller or Albireo Pharma is a party or by which either of Seller or Albireo Pharma is bound which involves or affects in any way any of the Purchased Assets, or (iv) except as may be required to comply with the HSR Act, any Legal Requirements applicable to Seller, Albireo Pharma or any of the Purchased Assets.

4.4 No Consents. Except for the letters referenced in Sections 3.2(f) and 3.2(g), the Lender Notice, and the filing of a Premerger Notification and Report Form under the HSR Act, no filing, authorization, consent, approval, permit, order, registration or declaration, governmental or otherwise, is necessary to enable or authorize Seller or Albireo Pharma to enter into, perform its respective obligations under, and consummate the Asset Purchase contemplated by this Agreement.

4.5 Title to Purchased Assets. Seller is the sole and exclusive owner of all right, title and interest in and to the Purchased Assets (subject, prior to the Closing, to the Encumbrances pursuant to the credit documents described in the Lender Notice, which Encumbrances will be released at or prior to Closing), and owns and at the Closing will transfer to Buyer good and transferable title to the Purchased Assets free and clear of any Encumbrances. Seller has performed all actions, if any, necessary to perfect its ownership of, and its ability to transfer, the Purchased Assets to Buyer pursuant to this Agreement.

4.6 Contracts. Except for this Agreement and the credit documents described in the Lender Notice, there is no Contract to which Seller, Albireo Pharma or any Affiliate of Seller or Albireo Pharma is a party that involves or affects, or is reasonably likely to involve or affect, the issuance of, ownership of, licensing of, title to, or use of any of the Purchased Assets.

4.7 Compliance with Legal Requirements. Each of Seller, Albireo Pharma and their respective Affiliates are, and at all times have been, in full compliance with each Legal Requirement that is or was applicable to (a) each of Seller's, Albireo Pharma's and their respective Affiliates' conduct, acts or omissions with respect to any of the Purchased Assets, or (b) any of the Purchased Assets. Neither Seller nor Albireo Pharma has received any written notice or other written communication from any Person, including the FDA, regarding any actual or alleged violation of, or failure to comply with, any such Legal Requirement applicable to clauses (a) and (b) above.

4.8 Legal Proceedings. There is no pending, or to the Knowledge of Seller, threatened, Proceeding, and to the Knowledge of Seller, there are no facts or circumstances applicable to Seller that could reasonably be expected to serve as a basis for a Proceeding involving Seller, Albireo Pharma or their respective Affiliates, in any such case (a) that involves or affects (or may involve or affect) the ownership of, licensing of, title to, ability to transfer, or use of any of the Purchased Assets (including by Buyer), or (b) challenging the Asset Purchase contemplated by this

Agreement. None of the Purchased Assets are subject to any Order of any Governmental Entity or arbitrator.

4.9 Governmental Authorizations. Neither Seller nor Albireo Pharma is required to hold any license, registration or permit issued by any Governmental Entity to own, use or transfer the Purchased Assets, other than such licenses, registrations or permits that have already been obtained.

4.10 Revocation; Use of Transferred Rights. The Priority Review Voucher has not been terminated, cancelled, revoked or used, and none of Seller, Albireo Pharma or any of their respective Affiliates has not done or omitted to do any act which act or omission would reasonably be expected to result in the termination, cancellation, revocation or use of the Priority Review Voucher. There is no term or condition imposed by the FDA on the Priority Review Voucher that is not set forth in the NDA Approval Letter or in Section 529 of the FDCA (21 U.S.C. § 360ff), as interpreted by the FDA in the *Rare Pediatric Disease Priority Review Vouchers Guidance for Industry – Draft Guidance* issued in July 2019. To the Knowledge of Seller, there are no facts or circumstances that could reasonably be expected to preclude or interfere with (a) the transfer of the Purchased Assets to Buyer, or (b) Buyer's ability to use the Purchased Assets to obtain Priority Review. Seller has provided to Buyer true and complete copies of the NDA Approval Letter and any other material communications between Seller, Albireo Pharma or any of their respective Affiliates and the FDA regarding the Priority Review Voucher.

4.11 Intent to Use. None of Seller, Albireo Pharma or any of their respective Affiliates has filed or submitted to the FDA a notification of intent to use the Priority Review Voucher to obtain a Priority Review for any human drug or biologic application.

4.12 No Broker. Except for Jefferies LLC, the fees and expenses of which shall be paid by Seller at the Closing, there is no investment banker, broker, finder or other intermediary which has been authorized to act on behalf of Seller or Albireo Pharma who might be entitled to any fee or commission in connection with the Asset Purchase contemplated by this Agreement.

4.13 Marketing. Seller and/or Albireo Pharma has begun marketing in the United States the rare pediatric disease product for which the Priority Review Voucher was awarded, BYLVAY (odevixibat), within the 365-day period beginning on the date of the FDA approval of such rare pediatric disease product to ensure the continued use of, or right to transfer, the Priority Review Voucher in the United States, and has continuously marketed such rare pediatric disease product in the United States since Seller initiated marketing of such product. Each of Seller and Albireo Pharma and their respective Affiliates is complying, and since the date of the FDA approval of the rare pediatric disease product for which the Priority Review Voucher was awarded has complied, with any obligations or requirements set forth in the NDA Approval Letter as they relate solely to the Priority Review Voucher.

4.14 No Other Representations and Warranties. None of Seller, Albireo Pharma or any of their respective Affiliates or their respective Representatives is making any representation or warranty of any kind or nature whatsoever, oral or written, express or implied, including with respect to merchantability or fitness for any particular purpose or in connection with the Purchased

Assets or the accuracy or completeness of any information provided in connection with the Asset Purchase contemplated by this Agreement, except as otherwise expressly set forth in this ARTICLE IV.

## ARTICLE V
## REPRESENTATIONS AND WARRANTIES OF BUYER

Buyer represents and warrants to Seller, as of the Effective Date, as follows:

5.1 Organization, Standing and Power. Buyer is a corporation duly organized and validly existing under the laws of Switzerland. Buyer has the corporate power and authority to own, operate and lease its properties and to carry on its business as presently conducted and is duly qualified or licensed to do business and is in good standing in each jurisdiction where the character of its properties owned or leased or the nature of its activities make such qualification or licensing necessary, except where the failure to be so qualified or licensed would not, individually or in the aggregate, reasonably be expected to adversely affect Buyer's ability to consummate the Asset Purchase contemplated by this Agreement.

5.2 Authority. Buyer has the requisite corporate power and authority to enter into and perform its obligations under this Agreement. The execution, delivery and performance of this Agreement, and the consummation of the Asset Purchase, have been duly and validly approved and authorized by all necessary corporate action on the part of Buyer, and this Agreement has been duly executed and delivered by Buyer. This Agreement, upon execution by all Parties, will constitute a valid and binding obligation of Buyer enforceable against Buyer in accordance with its terms, subject only to the effect, if any, of (a) applicable bankruptcy and other similar laws affecting the rights of creditors generally, and (b) rules of law governing specific performance, injunctive relief and other equitable remedies.

5.3 Noncontravention. The execution and delivery by Buyer of this Agreement does not, and the consummation of the Asset Purchase contemplated hereby will not, conflict with, or result in any violation of or default under (with or without notice or lapse of time, or both), or give rise to a right of termination, cancellation or acceleration of any obligation or loss of any benefit under, or require any consent, approval or waiver from any Person pursuant to, (a) any provision of the certificate of incorporation or bylaws of Buyer, in each case as amended to date, (b) any Contract to which Buyer is a party or by which it is bound which involves or affects in any way the Asset Purchase or (c) except as may be required to comply with the HSR Act, any Legal Requirements applicable to Buyer.

5.4 No Consents. Except for the letters referenced in Sections 3.2(f) and 3.2(g) and the filing of a Premerger Notification and Report Form required under the HSR Act, no filing, authorization, consent, approval, permit, order, registration or declaration, governmental or otherwise, is necessary to enable or authorize Buyer to enter into, and to perform its obligations under, this Agreement.

5.5 Financing. Buyer has, on the Effective Date, the financial capability and all sufficient cash on hand necessary to consummate the Asset Purchase contemplated by this

Agreement on the terms and subject to the conditions set forth herein, and will have all such capability as of the Closing Date.

5.6 No Broker. Buyer has not engaged, retained or entered into an agreement with any investment banker, broker, finder or other intermediary who has been authorized to act on behalf of Buyer who would be entitled to any fee or commission payable by Seller in connection with the Asset Purchase contemplated by this Agreement.

5.7 Non-Reliance. Except for the representations and warranties expressly set forth in ARTICLE IV or in any other certificate or document delivered by or on behalf of Seller or any of its Affiliates pursuant to this Agreement, neither Seller nor any of its Affiliates or their respective Representatives makes, or has made, any representation or warranty, oral or written, express or implied, relating to Seller, the Purchased Assets or otherwise in connection with the Asset Purchase. Except for the representations and warranties expressly set forth in ARTICLE IV or in any other certificate or document delivered by or on behalf of Seller or any of its Affiliates pursuant to this Agreement, Buyer has not relied, and is not relying, on any representation or warranty of Seller or any of its Affiliates relating to Seller, the Purchased Assets or otherwise in connection with the Asset Purchase. Buyer acknowledges that it is relying on its own independent investigation and analysis in entering into the Asset Purchase contemplated by this Agreement, and that it is capable of evaluating the merits and risks of the Asset Purchase contemplated by this Agreement.

## ARTICLE VI
## CONDITIONS TO CLOSING

6.1 Conditions Precedent of Buyer and Seller. Each Party's obligations to consummate the Asset Purchase contemplated by this Agreement are subject to the satisfaction or waiver, at or prior to the Closing Date, of each of the following conditions precedent:

(a) HSR Act. The applicable waiting period under the HSR Act relating to the Asset Purchase contemplated by this Agreement shall have expired or been terminated.

(b) No Injunctions or Restraints. No temporary restraining order, preliminary or permanent injunction or other legal restraint or prohibition issued or promulgated by a Governmental Entity preventing, prohibiting or materially restraining the consummation of the Asset Purchase contemplated by this Agreement shall be in effect, and there shall not be any applicable Legal Requirement that makes consummation of the Asset Purchase contemplated by this Agreement illegal.

(c) No Governmental Litigation. There shall not be any Proceeding commenced or pending by a Governmental Entity seeking to prohibit, limit, delay, or otherwise restrain the consummation of this Agreement and/or the Asset Purchase contemplated hereby.

6.2 Buyer's Conditions Precedent. The obligations of Buyer to consummate the Asset Purchase contemplated by this Agreement are subject to the satisfaction or waiver, at or prior to the Closing Date, of each of the following conditions precedent:

(a) Accuracy of Representations. Each of the representations and warranties made by Seller in this Agreement (other than the Seller Fundamental Representations) shall be true and correct in all material respects at and as of the Effective Date and at and as of the Closing Date. Each of the Seller Fundamental Representations shall be true and correct in all respects at and as of the Effective Date and at and as of the Closing Date.

(b) Performance of Covenants. All of the covenants and obligations that Seller is required to comply with or to perform hereunder at or prior to the Closing Date shall have been complied with and performed in all material respects.

(c) Closing Certificate. Seller shall have delivered to Buyer a certificate, dated the Closing Date and duly executed by Seller, certifying that the conditions set forth in Sections 6.2(a) and 6.2(b) have been satisfied.

(d) No Regulatory Change. There shall not have occurred and remain in effect any Regulatory Change.

(e) Deliverables. Seller shall have made the applicable deliveries contemplated to be made by it pursuant to Section 3.2.

6.3 Seller's Conditions Precedent. The obligations of Seller to consummate the Asset Purchase contemplated by this Agreement are subject to the satisfaction or waiver, at or prior to the Closing Date, of each of the following conditions precedent:

(a) Accuracy of Representations. Each of the representations and warranties made by Buyer in this Agreement (other than the Buyer Representations and Warranties) shall be true and correct in all material respects at and as of the Effective Date and at and as of the Closing Date. Each of the Buyer Fundamental Representations shall be true and correct in all respects at and as of the Effective Date and at and as of the Closing Date.

(b) Performance of Covenants. All of the covenants and obligations that Buyer is required to comply with or to perform hereunder at or prior to the Closing Date shall have been complied with and performed in all material respects.

(c) Closing Certificate. Buyer shall have delivered to Seller a certificate, dated the Closing Date and duly executed by Buyer, certifying that the conditions set forth in Sections 6.3(a) and 6.3(b) have been satisfied.

(d) Deliverables. Buyer shall have made the applicable deliveries contemplated to be made by it pursuant to Section 3.2.

## ARTICLE VII
## PRE-CLOSING COVENANTS AND AGREEMENTS

7.1 Efforts; Antitrust. The Parties shall use their commercially reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary or desirable under applicable Legal Requirements to consummate the transactions contemplated by this

Agreement as promptly as reasonably practicable. Without limiting the generality of the foregoing, prior to the Effective Date, Seller and Buyer shall have filed, or caused their "ultimate parent entities" (as defined in the HSR Act) to have filed, the notifications required under the HSR Act, and shall respond as promptly as practicable to all inquiries or requests received from the Federal Trade Commission, the Antitrust Division of the Department of Justice or any other Governmental Entity for additional information or documentation. In connection therewith, the Parties shall, or shall cause their respective Affiliates to, (a) continue to furnish to the other Party such necessary information and reasonable assistance as the other Party may reasonably request in connection with such filing or submission that is necessary under the HSR Act, and (b) keep the other Party reasonably apprised of the status of any communications with, and any inquiries or requests for additional information from, the applicable Governmental Entity. The Parties shall have requested early termination of the waiting period under the HSR Act.

7.2 Notification; Consultation. Subject to applicable confidentiality restrictions or restrictions required by applicable Legal Requirements, each Party will notify the other promptly upon the receipt of (a) any comments or questions from any Governmental Entity in connection with any filings made pursuant to Section 7.1 or the transactions contemplated by this Agreement, and (b) any request by any Governmental Entity for information or documents relating to an investigation of the transactions contemplated by this Agreement. Without limiting the generality of the foregoing, each Party shall provide to the other (or the other's respective advisors) upon request copies of all correspondence between such Party and any Governmental Entity relating to the transactions contemplated by this Agreement. The Parties may, as they deem advisable and necessary, designate any competitively sensitive materials provided to the other under this Section 7.2 as "outside counsel only." Such materials and the information contained therein shall be given only to outside counsel of the recipient and will not be disclosed by such outside counsel to employees, officers, or directors of the recipient without the advance written consent of the Party providing such materials. In addition, to the extent reasonably practicable, all discussions, telephone calls, and meetings with a Governmental Entity regarding the transactions contemplated by this Agreement shall include representatives of both Parties. Subject to applicable Legal Requirements, the Parties will consult and cooperate with each other in connection with any analyses, appearances, presentations, memoranda, briefs, arguments, and proposals made or submitted to any Governmental Entity regarding the transactions contemplated by this Agreement by or on behalf of any Party. Nothing contained in this Agreement shall require any Party to disclose to the other Party or its outside counsel (i) documents filed pursuant to Item 4(c) and 4(d) of the Notification and Report Form under the HSR Act or communications regarding the same documents, (ii) information submitted in response to any request for additional information, documents which reveal such Party's negotiating objectives or strategies regarding the transactions contemplated hereunder, (iii) information relating to businesses and investments of Buyer or its Affiliates, (iv) any information for which disclosure is prohibited by any Governmental Entity or applicable Legal Requirements or (v) any information for which disclosure would waive applicable legal privilege.

7.3 No Divestiture. Notwithstanding anything to the contrary set forth in Sections 7.1 and 7.2, nothing in this Agreement shall require, or be construed to require, the Parties or any of their respective Affiliates to offer or agree to (a) (i) sell, hold, hold separate, divest, license, discontinue or limit, before or after the Closing Date, any assets, businesses, equity holdings,

intellectual property, or other interests, or (ii) any conditions relating to, or changes or restrictions in, the operations of any such assets, businesses, equity holdings, intellectual property or interests (including, but not limited to, any requirements to enter into new Contracts or modify or terminate existing Contracts), or (b) any material modification or waiver of the terms and conditions of this Agreement.

7.4 No Solicitation. During the period from the Effective Date and continuing until the earlier of (a) the termination of this Agreement in accordance with ARTICLE IX, and (b) the Closing Date, neither Seller nor Albireo Pharma shall, nor shall either Seller or Albireo Pharma authorize, instruct, or permit any of their respecive Affiliates or any of their respective Representatives to, (i) solicit, initiate or encourage the submission of any proposal or indication of interest relating to an Alternative Transaction, (ii) participate in any discussions or negotiations regarding, or furnish to any Person any information with respect to, or take any other action to facilitate any inquiries or the making of any proposal that constitutes, or may reasonably be expected to lead to, any Alternative Transaction, (iii) accept any proposal or offer from any Person in respect of an Alternative Transaction or (iv) resolve to propose, propose or agree to do any of the foregoing. Upon the execution of this Agreement, Seller, Albireo Pharma and their respective Affiliates shall immediately cease and cause to be terminated any existing discussions with any Person that are in respect of an Alternative Transaction.

7.5 Other Covenants. From the Effective Date until the earlier of (a) the termination of this Agreement in accordance with ARTICLE IX, and (b) the Closing Date, each of Seller and Albireo Pharma shall, and shall cause their respective Affiliates to (i) provide Buyer with prompt written notification of it becoming aware of the occurrence of any Regulatory Change, (ii) not surrender or voluntarily forfeit the Priority Review Voucher, and (iii) not file or submit to the FDA a notification of intent to use the Priority Review Voucher, as described in Section 529(b)(4)(B)(i) of the FDCA (21 U.S.C. § 360ff(b)(4)(B)(i)).

## ARTICLE VIII
## INDEMNIFICATION

8.1 Indemnification.

(a) Indemnification by Seller. From and after the Closing, Seller and Albireo Pharma, jointly and severally, will indemnify, defend and hold Buyer and its Affiliates, and their respective directors, officers, employees and agents harmless for, from and against any and all Liabilities, claims, losses, damages, claims, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "***Damages***") arising out of or resulting from (i) any breach of Seller's or Albireo Pharma's representations, warranties, covenants or obligations under this Agreement or any certificate delivered by Seller hereunder, and (iii) any Excluded Liabilities.

(b) Indemnification by Buyer. From and after the Closing, Buyer will indemnify, defend and hold Seller and its Affiliates, and their respective directors, officers, employees and agents harmless for, from and against any and all Damages arising out of or resulting from (i) any breach of Buyer's representations, warranties, covenants or obligations

under this Agreement or any certificate delivered by Buyer hereunder, and (ii) Buyer's, its Affiliates', or any subsequent transferee's use or ownership of the Purchased Assets.

(c) Survival. The representations and warranties of Seller and Buyer under this Agreement, and liability for the breach thereof, shall survive the Closing and shall remain in full force and effect and terminate on the date that is twelve (12) months following the Closing Date, except that the Seller Fundamental Representations and the Buyer Fundamental Representations shall remain in full force and effect for a period of three (3) years following the Closing Date. All covenants and agreements of Seller, Albireo Pharma and Buyer required to be performed prior to the Closing shall terminate at Closing, and all covenants and agreements required to be performed by Seller, Albireo Pharma and Buyer after the Closing shall survive the Closing until performed or as specified in such covenant or agreement. No claim for breach of any representation, warranty, covenant or agreement may be brought after expiration of the applicable survival periods set forth in this Section 8.1. Notwithstanding the foregoing, if written notice of a Claim has been asserted in good faith and been given in the manner required by Section 8.2 prior to the expiration of the applicable survival period by the Party seeking indemnification for such Claim, then the relevant covenants, representations and warranties of the other Party shall survive as to such Claim until such Claim has been finally resolved pursuant to this ARTICLE VIII.

(d) Limits on Indemnification. Notwithstanding anything to the contrary contained in this Agreement, the maximum aggregate amount of indemnifiable Losses that may be recovered from (a) Seller and Albireo Pharma by Buyer Indemnitees pursuant to Section 8.1(a) shall equal the Purchase Price, and (b) Buyer by Seller Indemnitees pursuant to Section 8.1(b) shall equal the Purchase Price. Notwithstanding anything to the contrary set forth herein, except to the extent actually awarded against an Indemnified Party pursuant to a judgment with respect to a Third Party Claim (as defined in Section 8.2(b)), no Party hereto shall have any liability under any provision of this Agreement (including this ARTICLE VIII) for any punitive, incidental, special or indirect damages or damages for or otherwise based on business interruption, diminution of value, loss of future revenue, profits or income, or loss of business reputation or opportunity relating to the breach or alleged breach of this Agreement. Each Person entitled to indemnification hereunder will take commercially reasonable steps to mitigate all Damages after becoming aware of any event that could reasonably be expected to give rise to any Damages that are indemnifiable or recoverable hereunder or in connection herewith. Notwithstanding any other provision of this Agreement to the contrary, (i) Damages claimed hereunder will be reasonable and in good faith in light of the facts then known regarding such Damages, and (ii) if on the Closing Date the Indemnitee knows of any information that would cause one or more of the representations, warranties or covenants made by the Indemnitor to be inaccurate as of the date made, the Indemnitee will have no right or remedy after the Closing with respect to such inaccuracy and will be deemed to have waived its rights to indemnification in respect thereof.

8.2 Indemnification Procedures.

(a) A Person entitled to indemnification pursuant to Section 8.1 will hereinafter be referred to as an "***Indemnitee***." A Party obligated to indemnify an Indemnitee hereunder will hereinafter be referred to as an "***Indemnitor***." Indemnitee shall provide written notice to the Indemnitor of any claim for indemnification hereunder (a "***Claim***") as soon as reasonably practicable after the Claim arises which notice shall include the facts constituting the basis for such claim for indemnification, the provisions of this Agreement upon which such claim for indemnification is then based and an estimate, if possible, of the amount of Damages suffered or reasonably expected to be suffered by the Indemnitee; provided, that the failure to give such notice will not relieve the Indemnitor of its indemnification obligation under this Agreement except and only to the extent that such Indemnitor is materially prejudiced as a result of such failure to give notice.

(b) With respect to any Claim instituted or asserted by any Third Party ("***Third Party Claim***"), if the Indemnitor has acknowledged in writing to the Indemnitee the Indemnitor's responsibility for defending such Third Party Claim and liability in respect thereof, the Indemnitor shall have the right to defend, at its sole cost and expense, such Third Party Claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnitor to a final conclusion or settled at the discretion of the Indemnitor; provided, that the Indemnitor may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnitee of a release from all liability in respect of such Third Party Claim; and (ii) the Indemnitee consents to such compromise or settlement, which consent shall not be withheld or delayed unless such compromise or settlement involves (A) any admission of legal wrongdoing by the Indemnitee, (B) any payment by the Indemnitee that is not indemnified hereunder or (C) the imposition of any equitable relief against the Indemnitee. If the Indemnitor does not elect to assume control of the defense of a Third Party Claim or if a diligent defense is not being or ceases to be materially conducted by the Indemnitor, the Indemnitee shall have the right, at the sole cost and expense of the Indemnitor, upon at least ten (10) Business Days' prior written notice to the Indemnitor of its intent to do so, to undertake the defense of such Third Party Claim for the account of the Indemnitor (with counsel selected by the Indemnitee and approved by the Indemnitor, such approval not to be unreasonably withheld or delayed). The Party defending such Third Party Claim shall keep the other Party apprised of all material developments with respect to such Third Party Claim and promptly provide the other Party with copies of all correspondence and documents exchanged by the Party defending the Third Party Claim and the opposing party(ies) to such litigation. If the Indemnitor has elected to defend such Third Party Claim or if the Indemnitor has otherwise acknowledged in writing its responsibility for indemnifying a Third Party Claim, the Indemnitee may not compromise or settle such litigation without the prior written consent of the Indemnitor, such consent not to be unreasonably withheld or delayed.

(c) The Indemnitee may participate in, but not control, any defense or settlement of any Third Party Claim controlled by the Indemnitor pursuant to this Section 8.2 and shall bear its own costs and expenses with respect to such participation.

8.3 Direct Claims. A claim for indemnification for any matter not involving a Third Party Claim may be asserted by written notice from the Indemnitee to the Indemnitor. Such notice shall include the facts constituting the basis for such claim for indemnification, the Sections of this Agreement upon which such claim for indemnification is based, and an estimate, if possible, of the amount of Damages suffered or reasonably expected to be suffered by the Indemnitee.

8.4 Exclusive Remedy. From and after the Closing, except in the case of fraud, the sole and exclusive remedy of any Indemnitee for any Damages (including any Damages from Liabilities or claims for breach of contract, warranty, or otherwise and whether predicated on common law, statute, strict liability or otherwise) that such Indemnitee may at any time suffer or incur, or become subject to, as a result of, or in connection with this Agreement, including any inaccuracy, violation or breach of any representation and warranty contained in this Agreement by any Party, or any failure by any Party to perform or comply with any covenant or agreement that, by its terms, was to have been performed, or complied with, under this Agreement, shall be indemnification in accordance with this ARTICLE VIII (subject to the applicable qualifications and limitations set forth in this Agreement).

8.5 Adjustments. Any amount paid under this ARTICLE VIII shall be treated as an adjustment to the Purchase Price for all Tax purposes unless otherwise required by applicable Legal Requirements.

## ARTICLE IX
## TERMINATION

9.1 Termination Prior to Closing. Notwithstanding any contrary provisions of this Agreement, the respective obligations of the Parties to consummate the transactions contemplated by this Agreement may be terminated and abandoned at any time before the Closing only as follows:

(a) Upon the mutual written consent of Buyer and Seller; or

(b) By either Party, by written notice to the other Party, if the Closing has not occurred on or before 11:59 p.m., Eastern Standard Time, on the date that is forty-five (45) days following the Effective Date (such date, the "***Outside Date***"); provided, that the right to terminate this Agreement under this Section 9.1(b) shall not be available to any Party whose material breach of any provision set forth in this Agreement has resulted in the failure of the Closing to occur on or before such date; and, provided further, that if the failure of the Closing to occur by the Outside Date is due to any condition precedent to the Parties' obligations to consummate the transactions contemplated by this Agreement set forth in Section 6.1 not being satisfied, then the Outside Date shall be automatically extended by twenty-five (25) days.

9.2 Effect of Termination. In the event of the termination of this Agreement as provided in Section 9.1, this Agreement shall become void and of no further force or effect and there shall be no liability on the part of Buyer or Seller, except for Damages resulting from any willful and intentional breach prior to termination of this Agreement by Buyer or Seller, as applicable, except that (a) the provisions of this Section 9.2, ARTICLE I and ARTICLE XI shall

survive the termination of this Agreement and shall remain in full force and effect, and (b) the Mutual Confidentiality Agreement shall survive termination in accordance with its terms.

## ARTICLE X
## ADDITIONAL COVENANTS

10.1 Further Assurances.

(a) The Parties shall cooperate reasonably with each other in connection with any steps required to be taken as part of their respective obligations under this Agreement, including, without limitation, any notifications or filings required to be made to the FDA in connection with the transfer of the Purchased Assets, and shall (i) furnish upon request to each other such further information, (ii) execute and deliver to each other such other documents, and (iii) do such other acts and things, all as the other Party may reasonably request for the purpose of carrying out the intent of this Agreement and the transactions contemplated by this Agreement, including the use by Buyer, its Affiliates or their respective successors and assigns, of the Priority Review Voucher to obtain Priority Review in accordance with its terms and applicable Legal Requirements.

(b) Without limiting the foregoing, Buyer, on the one hand, and Seller and Albireo Pharma, on the other hand, agree to cooperate and assist each other with respect to all filings or notifications to any Governmental Entity related to the transfer and assignment from Seller to Buyer of the Purchased Assets.

10.2 Compliance with Legal Requirements. Seller, Albireo Pharma and their respective Affiliates shall materially comply with all Legal Requirements applicable to such Persons (as the sponsor of the rare pediatric disease product and, through the Closing, as the owner of the Priority Review Voucher) pertaining to the use or transfer of the Priority Review Voucher. Each of Seller and Albireo Pharma shall forward to Buyer any communications or notices it or its Affiliates receive from any Governmental Entity to the extent relating to or otherwise materially impacting the Priority Review Voucher; provided that Seller may redact any portion of such written communications or other notices that is not relevant to the Priority Review Voucher.

10.3 Marketing. Each of Seller and Albireo Pharma and their respective Affiliates shall continue to comply with any obligations or requirements set forth in the NDA Approval Letter as they relate solely to the Priority Review Voucher.

10.4 Nondisclosure. The Parties acknowledges that they remain bound by the Mutual Confidentiality Agreement.

10.5 Disclosures Concerning this Agreement. The press release with respect to the execution of this Agreement that is attached as Exhibit G hereto shall be issued by Seller on September 7, 2021. Buyer and Seller agree not to (and to ensure that their respective Affiliates do not) issue any other press releases or public announcements concerning this Agreement without the prior written consent of the other Party (which shall not be unreasonably withheld or delayed), except as required by a Governmental Entity or applicable Legal Requirement (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's)

securities are traded); provided, that the Party intending to disclose such information shall use reasonable efforts to provide the other Party with advance notice of such required disclosure, and an opportunity to review and comment on such proposed disclosure (which comments shall be considered in good faith by the disclosing Party); and, provided further, that except as required by applicable Legal Requirement, in no event shall any public announcements or other public disclosures concerning this Agreement or the Asset Purchase include the identity of Buyer or any of its Affiliates. Notwithstanding the foregoing, but subject in all events to the foregoing proviso with respect to the prohibition on disclosing the identity of Buyer or any of its Affiliates, without the prior submission to or approval of the other Party, either Party may issue press releases or public announcements which incorporate information concerning this Agreement which information was included in a press release or public disclosure which was previously disclosed under the terms of this Agreement. Each Party acknowledges that the other Party, or the other Party's parent entity, as a publicly-traded company, is legally obligated to make timely disclosures of material events relating to its business. The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with the United States Securities and Exchange Commission; provided, that if a Party is obligated to so file a copy of this Agreement, such Party shall prepare a proposed redacted version thereof and request confidential treatment thereof.

## ARTICLE XI
## GENERAL PROVISIONS

11.1 Transfer Taxes and Fees. Any and all transfer Taxes assessed or incurred by reason of the sale by Seller and the purchase by Buyer of the Purchased Assets hereunder ("***Transfer Taxes***," which, for the avoidance of doubt, does not include any Indirect Taxes), shall be shared equally by the Parties, regardless of which Party such Transfer Taxes are assessed against. For the avoidance of doubt, any income Taxes of Seller due as a result of the Asset Purchase shall be the sole liability of Seller, and the agreement with respect to value added Taxes is set forth in Section 2.3.

11.2 Priority Review Fee. The priority review fee described in section 529(c) of the FDCA (21 U.S.C § 360ff(c)) (the "***Priority Review Fee***") and all other user fees under the FDCA applicable to the human drug application for which the Priority Review Voucher is redeemed following the Closing shall be borne exclusively by Buyer, its Affiliates or any subsequent transferee of the Priority Review Voucher. In any event, following the Closing Seller shall have no liability or obligation for any such fees.

11.3 Notices. Any notice or other communication required or permitted to be delivered to any Party shall be in writing and shall be deemed properly delivered, given and received: (a) when delivered by hand; (b) upon such Party's receipt after being sent by registered mail, by courier or express delivery service; or (c) upon confirmation of receipt during normal business hours on a Business Day or, if received after normal business hours, on the next Business Day, after being sent by electronic mail, in any case to the address or electronic mail address set forth beneath the name of such Party below (or to such other address as such Party shall have specified in a written notice given to the other Party in accordance with this Section 11.3):

(i) if to Buyer, to:

Ares Trading SA
Zone industrielle de l'Ouriettaz
1170 Aubonne
Switzerland
Attention: [***]
Email: [***]

with a copy (which shall not constitute notice) to:

[***]
[***]
[***]

And with a copy (which shall not constitute notice) to:

Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004-2541
Attention: [***]
Email: [***]

(ii) if to Seller or Albireo Pharma, to:

Albiero Pharma, Inc.
10 Post Office Square
Boston, MA 02109
Attention: Jason Duncan, Chief Legal Officer & General Counsel
Email: jason.duncan@albireopharma.com

with a copy (which shall not constitute notice) to:

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
One Financial Center
Boston, Massachusetts 02111
Attention: Megan Gates
E-mail: MGates@mintz.com

11.4 Construction.

(a) The Parties agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting Party shall not be applied in the construction or interpretation of this Agreement.

(b) As used in this Agreement, the words "include" and "including," and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words "without limitation."

(c) Except as otherwise indicated, all references in this Agreement to "Articles" and "Sections" are intended to refer to Articles and Sections of this Agreement.

11.5 Counterparts. This Agreement may be executed in two or more counterparts, all of which shall be considered one and the same instrument, and shall become effective when one or more counterparts have been signed by each of the Parties and delivered to the other Party, it being understood that all Parties need not sign the same counterpart. The exchange of a fully executed Agreement (in counterparts or otherwise) by electronic transmission or facsimile (including PDF or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., DocuSign) shall be sufficient to bind the Parties to the terms and conditions of this Agreement.

11.6 Entire Agreement. This Agreement, including all exhibits attached hereto and the Mutual Confidentiality Agreement, sets forth the entire understanding of the Parties relating to the subject matter hereof, and supersedes all prior agreements and understandings among or between the Parties relating to the subject matter hereof.

11.7 Assignment. No Party will have the right to assign this Agreement, in whole or in part, by operation of law or otherwise, without the other Party's express prior written consent. Any attempt to assign this Agreement without such consent will be null and void. Notwithstanding the foregoing, any Party may assign this Agreement, in whole or in part, without the consent of the other Party: (a) to a Third Party that succeeds to all or substantially all of its assets or business related to this Agreement (whether by sale, merger, operation of law or otherwise); or (b) to an Affiliate of such Party. For the avoidance of doubt, no assignment made pursuant to this Section 11.7 shall relieve the assigning Party of any of its obligations under this Agreement. Subject to the foregoing, this Agreement will bind and inure to the benefit of each Party's respective successors and permitted assigns.

11.8 Severability. If any provision of this Agreement, or the application thereof, becomes or is declared by a court of competent jurisdiction to be illegal, void or unenforceable, the remainder of this Agreement shall continue in full force and effect and shall be interpreted so as reasonably to effect the intent of the Parties. The Parties shall use commercially reasonable efforts to replace such void or unenforceable provision of this Agreement with a valid and enforceable provision that shall achieve, to the extent possible, the economic, business and other purposes of such void or unenforceable provision.

11.9 Remedies Cumulative. Except as otherwise provided herein, any and all remedies herein expressly conferred upon a Party shall be deemed cumulative with and not exclusive of any other remedy conferred hereby or by law or equity upon such Party, and the exercise by a Party of any one remedy shall not preclude the exercise of any other remedy and nothing in this Agreement shall be deemed a waiver by any Party of any right to specific performance or injunctive relief.

11.10 Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware, regardless of the laws that might otherwise govern under applicable principles of conflicts of law. The Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the state and federal courts in the State of Delaware solely

and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.

11.11 WAIVER OF JURY TRIAL. TO THE EXTENT NOT PROHIBITED BY APPLICABLE LEGAL REQUIREMENTS THAT CANNOT BE WAIVED, THE PARTIES HEREBY WAIVE, AND COVENANT THAT THEY WILL NOT ASSERT (WHETHER AS PLAINTIFF, DEFENDANT OR OTHERWISE), ANY RIGHT TO TRIAL BY JURY IN ANY ACTION ARISING IN WHOLE OR IN PART UNDER OR IN CONNECTION WITH THIS AGREEMENT OR THE ASSET PURCHASE, WHETHER NOW EXISTING OR HEREAFTER ARISING, AND WHETHER SOUNDING IN CONTRACT, TORT OR OTHERWISE. THE PARTIES AGREE THAT EITHER OF THEM MAY FILE A COPY OF THIS SECTION 11.11 WITH ANY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY AND BARGAINED FOR AGREEMENT BETWEEN THE PARTIES IRREVOCABLY TO WAIVE THEIR RESPECTIVE RIGHTS TO TRIAL BY JURY IN ANY ACTION WHATSOEVER BETWEEN THEM RELATING TO THIS AGREEMENT OR THE ASSET PURCHASE AND THAT SUCH ACTIONS WILL INSTEAD BE TRIED IN A COURT OF COMPETENT JURISDICTION BY A JUDGE SITTING WITHOUT A JURY.

11.12 Amendment; Extension; Waiver. Subject to the provisions of applicable Legal Requirements, the Parties may amend this Agreement at any time pursuant to an instrument in writing signed on behalf of each of the Parties. At any time, any Party may, to the extent legally allowed, (a) extend the time for the performance of any of the obligations or other acts of the other Party, (b) waive any inaccuracies in the representations and warranties made to such Party contained herein or (c) waive compliance with any of the agreements or conditions for the benefit of such Party contained herein. Any agreement on the part of a Party to any such extension or waiver shall be valid only if set forth in an instrument in writing signed on behalf of such Party. Without limiting the generality or effect of the preceding sentence, no delay in exercising any right under this Agreement shall constitute a waiver of such right, and no waiver of any breach or default shall be deemed a waiver of any other breach or default of the same or any other provision in this Agreement.

11.13 Representation by Counsel; Interpretation. Seller and Albireo Pharma, on the one hand, and Buyer, on the other hand, each acknowledge that it has been represented by its own legal counsel in connection with this Agreement and the transactions contemplated by this Agreement. Accordingly, any rule of law, or any legal decision that would require interpretation of any claimed ambiguities in this Agreement against the Party that drafted it, has no application and is expressly waived.

11.14 No Benefit to Third Parties. Except as provided in ARTICLE VIII, the covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other Persons.

11.15 Expenses. Except as otherwise expressly set forth in this Agreement, each of the Parties shall bear its own fees and expenses incurred in connection with this Agreement and the Asset Purchase contemplated by this Agreement.

[Signatures on Following Page]



**[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.**

IN WITNESS WHEREOF, each of Buyer, Seller and Albireo Pharma has caused this Asset Purchase Agreement to be executed and delivered by their respective officers thereunto duly authorized, all as of the date first written above.

**ARES TRADING SA**

By: /s/ Cédric Hyde
Name: Cédric Hyde
Title: Authorized Representative

**ALBIREO AB**

By: /s/ Ronald H.W. Cooper
Name: Ronald H.W. Cooper
Title: Authorized Signatory

**ALBIREO PHARMA, INC.**
**(For the purposes of ARTICLES VI, VIII, X and XI)**

By: /s/ Ronald H.W. Cooper
Name: Ronald H.W. Cooper
Title: President



**[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.**

**Exhibit 10.2**

**ALBIREO PHARMA, INC.**

**INCENTIVE COMPENSATION RECOUPMENT POLICY**

Albireo Pharma, Inc. has adopted this Incentive Compensation Recoupment Policy, which is effective as of November 3, 2021 (the "Effective Date").

1. Certain Definitions.

(a) "Board" means the Board of Directors of the Company.

(b) "Committee" means the Compensation Committee of the Board.

(c) "Company" means Albireo Pharma, Inc., a corporation incorporated under the laws of the State of Delaware.

(d) "Effective Date" shall have the meaning as set forth above.

(e) "Executive" means an employee of the Company or any subsidiary of the Company, who is serving as an "officer" of the Company within the meaning of Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended.

(f) "Incentive Compensation" means (i) any equity or equity-based award granted on or after January 1, 2022, and (ii) any cash-based performance or incentive award (i.e., bonus or cash incentive plan payment, including any amounts deferred with respect thereto) approved, awarded or granted to an Executive on or after January 1, 2022.

(g) "Policy" means this Albireo Pharma, Inc. Incentive Compensation Recoupment Policy.

(h) "Recoupment" (and "Recoup") includes (a) the recovery, in whole or in part, of Incentive Compensation already paid, (b) forfeiture, recapture, reduction or cancellation, in whole or in part, of Incentive Compensation awarded or granted over which the Company retains control, and (c) the reduction, in whole or in part, of current or future Incentive Compensation.

(i) "Recoverable Payment" is the term that is used to describe amounts subject to Recoupment under this Policy, and means any Incentive Compensation after the Effective Date, to the extent granted or awarded to or earned by the Executive in respect of services as an employee, all as determined by the Committee.

2. Administration of this Policy.

This Policy will be administered by the Committee, which will consider the facts and circumstances related to possible Recoupment decisions and make determinations in its discretion regarding seeking Recoupment. Any determination to seek Recoupment under this Policy shall only be made after providing the Executive, upon his or her request, a reasonable opportunity to appear before the Committee to present his or her position regarding the alleged misconduct being considered by the Committee and to present and explain any exculpatory and/or mitigating information and related documents that he or she believes to be relevant.

In administering this Policy, the Committee shall have the following powers, which it may exercise in its discretion, subject to and not inconsistent with the express provisions of this Policy: (i) to exercise all the power and authority either specifically granted to it under this Policy or reasonably necessary or advisable in the administration of this Policy; (ii) to determine whether, to what extent and under what circumstances to pursue Recoupment; (iii) to determine the Executive or Executives from whom to seek Recoupment; (iv) to interpret this Policy; (v) to prescribe, amend and rescind rules and regulations relating to this Policy; and (vi) to make all other determinations deemed reasonably necessary or advisable for the administration of this Policy.

The decisions of the Committee as to all questions of interpretation, application and administration of this Policy shall be presumed to be made in good faith and in the exercise of reasonable business judgment, but nothing contained herein shall prevent an Executive from challenging on legal grounds a Recoupment determination.

3. Recoupment.

On and after the Effective Date of this Policy, the Committee may seek Recoupment of any Recoverable Payment, when in its judgment, after reviewing relevant facts and circumstances, it determines that: (a) an Executive (i) engaged in serious misconduct, or (ii) failed to supervise a subordinate employee who engaged in serious misconduct which the Executive knew, or was reckless in not knowing, was occurring, and (b) such misconduct resulted in a material violation of law or a written Company policy that caused significant financial or reputational harm to the Company. As used in this Policy, "serious misconduct" may be found to have occurred only where an Executive or a supervised employee acted knowingly, intentionally, or recklessly in violating a law or written Company policy. For the avoidance of doubt, an Executive's business judgment made in good faith and in the reasonable belief that such judgments and related actions were in or not opposed to the best interests of the Company shall not subject the Executive's Incentive Compensation to Recoupment.

The determination by the Committee whether and the extent to which to seek Recoupment may be influenced by a variety of factors, including, but not limited to, (i) the elements of the compensation received by the Executive, (ii) retention, promotion, or succession planning considerations, (iii) pay equity factors, (iv) whether the underlying conduct was an isolated occurrence, (v) feasibility and cost of implementation, (vi) legal and compliance factors, (vii) whether other disciplinary actions have been taken against the Executive, and (viii) the objective of administering the Policy in a way that does not discourage settlement of disputes when settlements are in the best long-term interests of the Company and its stockholders.

Based on the facts and circumstances, the Committee may decide on the appropriate Recoupment method, including whether to seek Recoupment of Recoverable Payments already paid or otherwise seek Recoupment (totally or partially) of Recoverable Payments that have not vested or have not been paid. However, the Committee may not seek Recoupment of any Recoverable Payments (a) following a change in control (as defined in the Executive's employment agreement) or (b) that were awarded more than three years prior to the first event giving rise to the Recoupment. Recoupment determinations pursuant to this Policy shall only be made to the extent permitted by law, and this Policy shall be interpreted so as not to violate any law or regulation.

4. Indemnification.

The Company shall not indemnify any Executive against (i) the loss of any incorrectly awarded Incentive Compensation or any Incentive Compensation that is recouped pursuant to the terms of this Policy, or (ii) any claims relating to the Company's enforcement of its rights under this Policy.

5. Miscellaneous.

This Policy shall not be construed to require Recoupment or create a presumption that Recoupment shall be sought in any particular case. Notwithstanding this Policy, the Company may, to the extent required by law (including, without limitation, the Dodd-Frank Wall Street Reform and Consumer Protection Act) or the requirements of an exchange on which the Company's shares are listed for trading, in each case as in effect from time to time, recoup compensation of whatever kind at any time from any applicable employee or former employee of the Company.

Public disclosure concerning Recoupment decisions shall be made in compliance with the rules and regulations of the Securities and Exchange Commission and other applicable laws, including without limitation, Item 402(b) of Regulation S-K, reasonably interpreted and applied. Where the Company deems it appropriate, it may provide disclosure beyond that required by law.

The Recoupment remedies provided herein are not intended to be exclusive. In the event of any misconduct or supervisory failure described in Section 3 above, the Company may take any actions that it deems appropriate to remedy the misconduct or supervisory failure and/or prevent its recurrence, including, but not limited to, dismissing or otherwise disciplining the Executive or authorizing legal action for breach of fiduciary duty.

**OFFICER ACKNOWLEDGEMENT & AGREEMENT**
**PERTAINING TO THE ALBIREO PHARMA, INC. INCENTIVE COMPENSATION RECOUPMENT POLICY**

This Acknowledgement & Agreement (the "Acknowledgement") is delivered by the undersigned officer ("Executive"), as of the date set forth below, to Albireo Pharma, Inc. (the "Company"). Executive is an employee of the Company (or one of its subsidiaries) who is serving as an "officer" of the Company within the meaning of Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended.

Effective November 3, 2021, the Board of Directors (the "Board") of the Company adopted an Incentive Compensation Recoupment Policy, attached as Exhibit A hereto (as amended, restated, supplemented or otherwise modified from time to time by the Board, the "Recoupment Policy"). The Recoupment Policy provides for the recoupment of certain compensation from officers in the event the Compensation Committee of the Board determines that (a) such officer (i) engaged in serious misconduct, or (ii) failed to supervise a subordinate employee who engaged in serious misconduct which the Executive knew, or was reckless in not knowing, was occurring, and (b) such misconduct resulted in a material violation of law or a written Company policy that caused significant financial or reputational harm to the Company.

In consideration of the continued benefits to be received from the Company (and/or any subsidiary of the Company) and Executive's right to participate in, and as a condition to the receipt of, Incentive Compensation (as defined in the Recoupment Policy), Executive hereby acknowledges and agrees to the following:

1. Executive has read and understands the Recoupment Policy and has had an opportunity to ask questions to the Company regarding the Recoupment Policy.

2. Executive agrees to be bound by and to abide by the terms of the Recoupment Policy and intends for the Recoupment Policy to be applied to the fullest extent of the law.

3. The Recoupment Policy shall apply to any and all Incentive Compensation that is approved, awarded or granted to Executive on or after January 1, 2022.

4. In the event of any inconsistency between the provisions of the Recoupment Policy and this Acknowledgement or any applicable incentive-based compensation arrangements, employment agreement, equity agreement, indemnification agreement or similar agreement or arrangement setting forth the terms and conditions of any Incentive Compensation, the terms of the Recoupment Policy shall govern.

No modifications, waivers or amendments of the terms of this Acknowledgement shall be effective unless signed in writing by Executive and the Company. The provisions of this Acknowledgement shall inure to the benefit of the Company, and shall be binding upon, the successors, administrators, heirs, legal representatives and assigns of Executive.

By signing below, Executive agrees to the application of the Recoupment Policy and the other terms of this Acknowledgement.

_____

Name:

**Exhibit 31.1**

CERTIFICATIONS UNDER SECTION 302

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

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

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

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

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

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

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

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

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

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

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

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

Date: November 4, 2021

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

**Exhibit 31.2**

CERTIFICATIONS UNDER SECTION 302

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

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

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

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

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

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

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

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

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

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

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

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

Date: November 4, 2021

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

**Exhibit 32.1**

CERTIFICATIONS UNDER SECTION 906

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

The Quarterly Report for the quarter ended September 30, 2021 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 4, 2021

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

Dated: November 4, 2021

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