

SECURITIES AND EXCHANGE COMMISSION

FORM 10-Q

Quarterly report pursuant to sections 13 or 15(d)

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FILER

ALBIRO PHARMA, INC.

CIK: **1322505** | IRS No.: **000000000** | State of Incorporation: **DE** | Fiscal Year End: **1231**
Type: **10-Q** | Act: **34** | File No.: **001-33451** | Film No.: **221369400**
SIC: **2834** Pharmaceutical preparations

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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, 2022

OR

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

For the transition period from _____ to _____.

Commission File Number 001-33451

Albireo Pharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or
organization)

90-0136863
(IRS Employer Identification No.)

53 State Street, 19th Floor, Boston, MA
(Address of principal executive offices)

02109
(Zip code)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.01 per share	ALBO	The Nasdaq Capital Market

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 November 1, 2022, there were 20,701,283 shares of Common Stock, \$0.01 par value per share, outstanding.

Albireo Pharma, Inc.

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- our commercialization plans and expectations for commercializing Bylvay™ (odevixibat) globally;
- the progress, number, scope, cost, duration or results of our development activities, nonclinical studies and clinical trials of Bylvay, elobixibat, A3907, A2342 or any of our other product candidates or programs, such as the target indication(s) for development or approval, the size, design, population, conduct, cost, objective or endpoints of any clinical trial, or the timing for initiation or completion of or availability of results from any clinical trial (including BOLD, our pivotal clinical trial of Bylvay in patients with biliary atresia, 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;
- any royalty payments we may make to Sagard Healthcare Partners (Delaware) LP (“Sagard”) for revenues generated from Bylvay (odevixibat);
- the potential impacts of the COVID-19 pandemic, inflation and rising interest rates on our business operations or financial condition;
- our future operations, financial position, revenues, costs, expenses, uses of cash, capital requirements, our need for additional financing or the period for which our existing cash resources will be sufficient to meet our operating requirements; or
- our strategies, prospects, plans, expectations, forecasts or objectives.

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

any forward-looking statement as a result of various important factors, including our critical accounting policies and risks and uncertainties relating, among other things, to:

- our ability to effectively commercialize Bylvay for its approved indications;

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- the design, size, duration and endpoints for, and results from BOLD, our pivotal trial of Bylvay in biliary atresia or any other trials that will be required to obtain marketing approval for Bylvay to treat patients with progressive familial intrahepatic cholestasis, or PFIC, biliary atresia, Alagille syndrome, or 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, findings in our completed pivotal trial in ALGS and findings in indications other than PFIC and ALGS, will be predictive of results from future clinical trials, including our pivotal trial of Bylvay in biliary atresia;
- the outcome and interpretation by regulatory authorities of an ongoing third-party study pooling and analyzing long-term PFIC patient data;
- the timing for completion of, or for availability of data from, our pivotal trial of Bylvay in biliary atresia, and the outcome of the trial;
- delays or other challenges in the recruitment of patients for the pivotal trial of Bylvay in biliary atresia;
- the COVID-19 pandemic, which may negatively impact the conduct of, and the timing of initiation, enrollment, completion and reporting with respect to, our clinical trials; negatively impact the supply of drug product for our clinical and preclinical programs; and/or result in other adverse impacts on our business;
- the competitive environment and commercial opportunity for a treatment for PFIC, ALGS or other pediatric cholestatic liver diseases, if approved in the future;
- 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 and, if approved, in patients with ALGS or other pediatric cholestatic liver diseases;
- our ability to fulfill our obligations under the Purchase Agreement with Sagard, including our ability to make royalty payments and our ability to buy or Sagard's interest or at Sagard's request, in certain circumstances, repurchase Sagard's interest in the royalty interest payments;
- the significant control or influence that EA Pharma has over the commercialization of elobixibat in Japan, and through its sublicensee in Thailand, and the development and commercialization of elobixibat in EA Pharma's other licensed territories;
- whether we elect to seek and, if so, our ability to establish a license or other partnering transaction with a third party for elobixibat in the United States or Europe;

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

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- our ability to obtain additional financing on reasonable terms, or at all;
- our ability to establish and maintain additional licensing, collaboration or similar arrangements on favorable terms and our ability to attract collaborators with development, regulatory and commercialization expertise;
- the success of competing third-party products or product candidates;
- our ability to successfully commercialize any approved product candidates, including their rate and degree of market acceptance;
- our ability to expand and protect our intellectual property estate;
- regulatory developments in the United States and other countries;
- the effectiveness of our internal control over financial reporting;
- the performance of our third-party suppliers, manufacturers and contract research organizations and our ability to obtain alternative sources of raw materials;
- our ability to attract and retain key personnel;
- 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; and
- global economic uncertainty, rising inflation, rising interest rates, market disruptions and volatility in commodity prices.

These and other risks and uncertainties are described in greater detail under the caption “Risk Factors” in Item 1A of Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, in Item 1A of Part II of this quarterly report, and in other filings that we make with the Securities and Exchange Commission, or SEC. As a result of the risks and uncertainties, the results or events indicated by the forward-looking statements may not occur. We caution you not to place undue reliance on any forward-looking statement.

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

PART I — FINANCIAL INFORMATION**Item 1. Financial Statements****Albireo Pharma, Inc.****Condensed Consolidated Balance Sheets****(in thousands, except share data)**

	<u>September 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 222,476	\$ 248,107
Accounts receivable, net	2,029	3,272
Inventory	3,149	194
Prepaid expenses	8,516	5,261
Other current assets	2,666	12,096
Total current assets	238,836	268,930
Restricted cash	50,000	—
Property and equipment, net	1,303	668
Goodwill	17,260	17,260
Other assets	13,823	15,193
Total assets	<u>\$ 321,222</u>	<u>\$ 302,051</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 6,950	\$ 6,516
Accrued expenses	25,365	35,951
Other current liabilities	5,504	2,880
Total current liabilities	37,819	45,347
Liability related to sale of future royalties	62,053	60,132
Revenue interest liability, net	111,644	—
Note payable, net of discount	—	10,004
Other long-term liabilities	9,635	10,960
Total liabilities	221,151	126,443
Stockholders' Equity:		
Preferred stock, \$0.01 par value per share — 50,000,000 shares authorized at September 30, 2022 and December 31, 2021; 0 and 0 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	—	—
Common stock, \$0.01 par value per share — 60,000,000 shares authorized at September 30, 2022 and December 31, 2021; 20,700,458 and 20,692,698 shares issued and outstanding at September 30, 2022, respectively, and 19,304,312 and 19,296,552 shares issued and outstanding at December 31, 2021, respectively	207	193
Additional paid-in capital	512,915	475,390
Accumulated other comprehensive income	8,212	1,105
Accumulated deficit	(421,033)	(300,850)
Treasury stock at cost, 7,760 shares at September 30, 2022 and December 31 2021, respectively	(230)	(230)
Total stockholders' equity	<u>100,071</u>	<u>175,608</u>

Total liabilities and stockholders' equity	<u>\$ 321,222</u>	<u>\$ 302,051</u>
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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)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Revenue:				
Product revenue, net	\$ 7,543	\$ 1,060	\$ 18,090	\$ 1,060
Royalty revenue	2,289	2,604	6,780	6,998
Total revenue	<u>9,832</u>	<u>3,664</u>	<u>24,870</u>	<u>8,058</u>
Cost and operating expenses:				
Cost of product revenue	612	431	1,622	431
Research and development	23,312	21,083	68,103	61,920
Selling, general and administrative	20,564	17,612	59,019	49,825
Other operating expense, net	1	3,719	7,544	7,873
Total cost and operating expenses	<u>44,489</u>	<u>42,845</u>	<u>136,288</u>	<u>120,049</u>
Operating loss	<u>(34,657)</u>	<u>(39,181)</u>	<u>(111,418)</u>	<u>(111,991)</u>
Other (loss) income:				
Gain from sale of priority review voucher, net of transaction costs	—	103,387	—	103,387
Loss on extinguishment of note payable, net of discount	(613)	—	(613)	—
Interest expense, net	(2,530)	(3,331)	(8,152)	(10,675)
Net (loss) income before income taxes	<u>(37,800)</u>	<u>60,875</u>	<u>(120,183)</u>	<u>(19,279)</u>
Provision for income taxes	—	3,789	—	3,789
Net (loss) income	<u>\$ (37,800)</u>	<u>\$ 57,086</u>	<u>\$ (120,183)</u>	<u>\$ (23,068)</u>
Net (loss) income per share attributable to holders of common stock:				
Basic	<u>\$ (1.92)</u>	<u>\$ 2.96</u>	<u>\$ (6.15)</u>	<u>\$ (1.20)</u>
Diluted	<u>\$ (1.92)</u>	<u>\$ 2.90</u>	<u>\$ (6.15)</u>	<u>\$ (1.20)</u>
Weighted-average common shares outstanding:				
Basic	<u>19,655,350</u>	<u>19,258,905</u>	<u>19,541,044</u>	<u>19,197,536</u>
Diluted	<u>19,655,350</u>	<u>19,651,243</u>	<u>19,541,044</u>	<u>19,197,536</u>

See accompanying notes to Condensed Consolidated Financial Statements.

Albireo Pharma, Inc.

Condensed Consolidated Statements of Comprehensive (Loss) Income

(in thousands)

(Unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Net (loss) income	\$ (37,800)	\$ 57,086	\$ (120,183)	\$ (23,068)
Other comprehensive (loss) income:				
Foreign currency translation adjustment	(40)	3,657	7,107	7,890
Total other comprehensive (loss) income	(40)	3,657	7,107	7,890
Total comprehensive (loss) income	<u>\$ (37,840)</u>	<u>\$ 60,743</u>	<u>\$ (113,076)</u>	<u>\$ (15,178)</u>

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)		Treasury Stock At Cost		Total Stockholders' Equity
	Shares	Amount		Accumulated Deficit	Shares	Amount		
	Balance--December 31, 2021	19,304,312	\$ 193	\$ 475,390	\$ 1,105	\$ (300,850)	(7,760)	\$ (230)
Stock-based compensation expense	—	—	3,508	—	—	—	—	3,508
Exercise of options and vesting of RSUs	223,683	2	4,378	—	—	—	—	4,380
Other comprehensive income	—	—	—	7,124	—	—	—	7,124
Net loss	—	—	—	—	(42,434)	—	—	(42,434)
Balance--March 31, 2022	19,527,995	\$ 195	\$ 483,276	\$ 8,229	\$ (343,284)	(7,760)	\$ (230)	\$ 148,186
Stock-based compensation expense	—	—	3,616	—	—	—	—	3,616
Exercise of options and vesting of RSUs	82,565	1	1,800	—	—	—	—	1,801
Other comprehensive income	—	—	—	23	—	—	—	23
Net loss	—	—	—	—	(39,949)	—	—	(39,949)
Balance--June 30, 2022	19,610,560	\$ 196	\$ 488,692	\$ 8,252	\$ (383,233)	(7,760)	\$ (230)	\$ 113,677
Stock-based compensation expense	—	—	3,547	—	—	—	—	3,547
Exercise of options and vesting of RSUs	17,872	—	70	—	—	—	—	70
Issuance of common stock under the at-the-market sales agreement, net of costs	1,072,310	11	20,606	—	—	—	—	20,617
Other comprehensive loss	—	—	—	(40)	—	—	—	(40)
Net loss	—	—	—	—	(37,800)	—	—	(37,800)
Balance--September 30, 2022	20,700,742	\$ 207	\$ 512,915	\$ 8,212	\$ (421,033)	(7,760)	\$ (230)	\$ 100,071

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)		Treasury Stock At Cost		Total Stockholders' Equity
	Shares	Amount		Accumulated Deficit	Shares	Amount		
	Balance--December 31, 2020	19,107,040	\$ 191	\$ 456,472	\$ (8,612)	\$ (266,820)	—	\$ —
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	<u>19,240,295</u>	<u>\$ 192</u>	<u>\$ 464,665</u>	<u>\$ (4,379)</u>	<u>\$ (346,974)</u>	<u>—</u>	<u>\$ —</u>	<u>\$ 113,504</u>
Stock-based compensation expense	—	—	6,706	—	—	—	—	6,706
Exercise of options and vesting of RSUs	35,466	1	751	—	—	—	—	752
Issuance of common stock, net of costs	7,508	—	241	—	—	—	—	241
Other comprehensive income	—	—	—	3,657	—	—	—	3,657
Purchase of treasury stock, at cost	—	—	—	—	—	(7,760)	(230)	(230)
Net income	—	—	—	—	57,086	—	—	57,086
Balance--September 30, 2021	<u>19,283,269</u>	<u>\$ 193</u>	<u>\$ 472,363</u>	<u>\$ (722)</u>	<u>\$ (289,888)</u>	<u>(7,760)</u>	<u>\$ (230)</u>	<u>\$ 181,716</u>

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,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (120,183)	\$ (23,068)
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	8,250	9,428
Accretion of revenue interest liability, net	403	—
Accretion of debt discount and amortization of issuance costs	178	308
Depreciation and amortization	322	167
Extinguishment of note payable, net of discount	613	—
Share based compensation expense	10,671	13,272
Foreign currency adjustments	7,010	7,776
Changes in operating assets and liabilities:		
Accounts receivable, net	1,018	(1,307)
Inventory	(3,103)	(196)
Prepaid expenses and other current assets	5,946	2,765
Other assets	93	293
Accounts payable	654	2,023
Accrued expenses	(9,832)	2,068
Other current and long-term liabilities	(3,471)	(3,810)
Net cash used in operating activities	<u>(101,431)</u>	<u>(93,668)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(960)	(465)
Proceeds from sale of priority review voucher, net of transaction costs	—	103,387
Net cash (used in) provided by investing activities	<u>(960)</u>	<u>102,922</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	20,633	241
Proceeds from revenue interest liability, net of issuance costs	111,577	—
Payment of principal on borrowings	(10,795)	—
Proceeds from exercise of options	6,251	2,378
Payments related to repurchases of common stock	—	(230)
Net cash provided by financing activities	<u>127,666</u>	<u>2,389</u>
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(906)	(303)
Net increase in cash, cash equivalents and restricted cash	24,369	11,340
Cash, cash equivalents and restricted cash—beginning of period	248,107	251,272
Cash, cash equivalents and restricted cash—end of period	<u>\$ 272,476</u>	<u>\$ 262,612</u>
Supplemental disclosures of cash and non-cash activities		
Unpaid transaction cost of revenue interest agreement	\$ 250	\$ —
Unpaid royalty interest included in accrued expenses	\$ 87	\$ —
Unpaid issuance costs related to common stock	\$ 16	\$ —

See accompanying notes to Condensed Consolidated Financial Statements.

Albireo Pharma, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Summary of significant accounting policies and basis of presentation

Organization

Albireo Pharma, Inc. (the Company), is a commercial-stage biopharmaceutical company focused on the development and commercialization of novel bile acid modulators to treat orphan pediatric liver diseases and other liver and gastrointestinal diseases and disorders. The Company's product pipeline includes Bylvay (odevixibat) approved in the United States and Europe, elobixibat, approved in Japan and Thailand for the treatment of chronic constipation, A3907, our Phase 1 lead candidate for the treatment of adult liver diseases, A2342, our lead preclinical candidate for the treatment of adult viral and liver diseases, and multiple other preclinical candidates. Bylvay was approved by the U.S. Food and Drug Administration (FDA) on July 20, 2021 for the treatment of pruritus in patients with progressive familial intrahepatic cholestasis (PFIC) ages 3 months or older, and authorized by the European Medicines Agency on July 16, 2021 for the treatment of PFIC in patients 6 months or older. Bylvay was also granted marketing authorization by the UK Medicines and Healthcare Products Regulatory Agency (MHRA) in September 2021 for the treatment of PFIC in patients 6 months or older. In October 2022 the Company announced positive results from its Phase 3 trial of Bylvay for the treatment of patients with Alagille syndrome (ALGS), and Bylvay is also in Phase 3 development for the treatment of biliary atresia. ALGS and biliary atresia are each a rare, life-threatening disorder affecting young children.

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

The Company has primarily funded its operations with proceeds from the sales of common stock, the sale of future royalties, upfront and milestone payments for regional agreements, proceeds from the issuance of debt, and the sale of a Priority Review Voucher (PRV). As of September 30, 2022, the Company has raised an aggregate of \$377.5 million through the issuance of common stock, net of issuance costs, \$59.3 million from the sale of its future royalties, net of issuance costs, \$111.3 million from the revenue interest liability, net of issuance costs, and net proceeds of \$103.4 million, after deducting commission costs, from the sale of the PRV.

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

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As of September 30, 2022, the Company had cash, cash equivalents and restricted cash of \$272.5 million. Management believes that its unrestricted cash and cash equivalents at September 30, 2022 will be sufficient to allow the Company to fund its current operating plan through at least the next twelve months from the issuance of these financial statements.

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

Basis of presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information, and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the audited consolidated financial statements and accompanying notes included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021. In the opinion of management, all adjustments (including normal recurring adjustments) considered necessary for fair presentation have been included in the Condensed Consolidated Financial Statements. The results of operations for the three and nine months ended September 30, 2022 and 2021 are not necessarily indicative of the results that may be expected for the full fiscal year, any other interim period or any future fiscal year. The Condensed Consolidated Financial Statements are prepared on a basis consistent with prior periods.

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

Principles of consolidation

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

Foreign currency translation

Functional and presentation currency

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

Transactions and balances

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

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

- a. assets and liabilities presented are translated at the closing exchange rate as of September 30, 2022 and December 31, 2021;
- b. income and expenses for the statement of operations and comprehensive loss are translated at the average exchange rates that are relevant for the respective periods for which the income and expenses occur; and
- c. significant transactions use the exchange rate on the date of the transaction.

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

Use of estimates

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

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments that are readily convertible into cash without penalty and with original maturities of 90 days or less at the date of purchase to be cash equivalents.

Restricted cash consists of deposits placed in a segregated bank account required under the terms of the Company's Purchase Agreement with Sagard Healthcare Partners (Delaware) LP ("Sagard").

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the unaudited condensed consolidated balance sheets that together reflect the same amounts shown in the unaudited condensed consolidated statements of cash flows (in thousands):

	September 30, 2022	December 31, 2021
Cash and cash equivalents	\$ 222,476	\$ 248,107
Restricted cash	50,000	—
Total cash, cash equivalents and restricted cash	<u>\$ 272,476</u>	<u>\$ 248,107</u>

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

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assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Revenue, net

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

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

The Company has written contracts with each of its customers that have a single performance obligation to deliver products upon receipt of a customer order and these obligations are satisfied when delivery occurs and the customer receives Bylvay. The Company evaluates creditworthiness of each of its customers to determine whether collection is reasonably assured. The wholesale acquisition cost that the Company charges its customers for Bylvay is adjusted to arrive at the Company's estimated net product revenues by deducting components of variable consideration which include (i) estimated government rebates and discounts related to Medicaid and other government programs, (ii) estimated costs of incentives offered to certain indirect customers including patients, (iii) trade allowances, such as invoice discounts for prompt payment and customer fees, and (iv) allowance for sales returns. Product revenue, net was \$4.1 million in the United States and \$3.4 million in international markets for the three months ended September 30, 2022. Product revenue, net was \$10.4 million in the United States and \$7.7 million in international markets for the nine months ended September 30, 2022. Product revenue, net was \$0.8 million in the United States and \$0.3 million in international markets for the three and nine months ended September 30, 2021.

Rebates and Discounts

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

The Company contracts with national authorities in Europe to make Bylvay available to eligible patients. In jurisdictions in which final pricing is subject to ongoing negotiations with the government, the Company estimates the rebate expected to be due and deducts these estimated amounts from its gross product revenues at the time the revenues are recognized. The Company's estimates of such liabilities are based on current invoice pricing and total prior units sold and assumptions developed using benchmarks of Bylvay pricing approved in other relevant European jurisdictions. The Company recorded \$0.6 million and \$0.2 million in such estimates as of September 30, 2022 and December 31, 2021, respectively, in other current liabilities on the consolidated balance sheets.

Other Incentives

Other incentives that the Company offers to indirect customers include co-pay assistance cards provided by the Company for patients who reside in states that permit co-pay assistance programs. The

Company's co-pay assistance program is intended to reduce each participating patient's portion of the financial responsibility for Bylvay's purchase

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price to a specified dollar amount. The Company estimates the amount of co-pay assistance provided to eligible patients based on the terms of the program when product is dispensed by the specialty pharmacies to the patients. These estimates are based on redemption information provided by third-party claims processing organizations. The Company funds this incentive program through upfront payments. There were no upfront payments made during the quarter ended September 30, 2022. The Company recorded less than \$0.1 million in such estimates as of September 30, 2022 and December 31, 2021 in prepaid expenses on the consolidated balance sheets.

Trade Allowances

The Company provides invoice discounts on Bylvay sales to its customers for prompt payment and records these discounts as a reduction to gross product revenues. These discounts are based on contractual terms. The Company also pays fees to its distributors for their services as well as data that they provide to the Company. Prompt payment allowances are recorded in accounts receivable, net on the consolidated balance sheets. Prompt payment allowances were less than \$0.1 million at September 30, 2022 and December 31, 2021. The other distributor fees are recorded as other current liabilities on the consolidated balance sheets and was \$0.1 million as of September 30, 2022 and December 31, 2021.

Milestone Payments

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

Royalties

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

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

As of September 30, 2022, the Company is eligible to receive an additional regulatory-based milestone payment under the Agreement of \$4.2 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.

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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

Royalty Interest Acquisition Agreement with HCR

In December 2017, the Company entered into a royalty interest acquisition agreement (RIAA) with HealthCare Royalty Partners III, L.P. (HCR) pursuant to which it sold to HCR the right to receive all royalties from sales in Japan and sales milestones achieved from any covered territory potentially payable to the Company under the Agreement, up to a specified maximum "cap" amount of \$78.8 million, based on the funds the Company received from HCR. In January 2018, the Company received \$44.5 million from HCR, net of certain transaction expenses, under the RIAA. On June 8, 2020, the parties entered into an amendment to the RIAA pursuant to which HCR agreed to pay the Company an additional \$14.8 million, net of certain transaction expenses, in exchange for the elimination of (i) the \$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, 2022:

	September 30, 2022	
	(in thousands)	
Liability related to sale of future royalties—beginning balance	\$	71,667
Accretion of interest expense on liability related to royalty monetization		8,250
Repayment of the liability		<u>(15,595)</u>
Liability related to sale of future royalties—ending balance	\$	64,322
Less current portion classified within accrued expenses		<u>(2,269)</u>
Long-term liability related to sale of future royalties	\$	62,053

The Company records estimated royalties due for the current period in accrued expenses until the payment is received from EA Pharma at which time the Company then remits payment to HCR. As royalties are remitted to HCR, the balance of the royalty obligation will be effectively repaid over the life of the RIAA. In order to determine the accretion of the royalty obligation, the Company is required to estimate the total amount of future royalty payments to be received and submitted to HCR. The sum of these amounts less the \$59.3 million proceeds the Company received will be recorded as interest expense over the life of the royalty obligation. At September 30, 2022, the Company's estimate of its total interest expense resulted in an annual effective interest rate of approximately 18.0%.

The Company periodically assesses the estimated royalty payments to HCR and to the extent such payments are greater or less than its initial estimates or the timing of such payments is materially different than its original estimates, the Company will prospectively adjust the accretion of interest on the royalty

obligation. There are a number of factors that could materially affect the amount and the timing of royalty payments, most of which are not within the Company's control. Such factors include, but are not limited to, the rate of elobixibat prescriptions, the number of doses administered, the introduction of competing products, manufacturing or other delays, patent protection, adverse events that result in governmental health authority imposed restrictions on the use of the drug products, significant changes in

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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.

Purchase Agreement with Sagard

In September 2022, the Company and Albireo AB entered into a purchase and sale agreement with Sagard Healthcare Partners (Delaware) LP (Sagard) for the sale of a revenue interest generated from Bylvay (odevixibat) (the Purchase Agreement) for an aggregate purchase price of \$115.0 million payable upon the closing of the transaction, which occurred on September 22, 2022. In consideration for the payment of such purchase price, the Company is obligated to pay to Sagard a revenue interest on the worldwide annual consolidated net revenues of Bylvay (the Included Product Revenue) at a rate of (A) 12.5% for Included Product Revenue up to and including \$250.0 million, (B) 5% for Included Product Revenue in excess of \$250.0 million but less than or equal to \$350.0 million, and (C) prior to approval of a New Drug Application by the U.S. Food and Drug Administration of Bylvay for the treatment of biliary atresia (the Marketing Approval), 5% for Included Product Revenue in excess of \$350.0 million and, from and after Marketing Approval, the rate is decreased to 1% for Included Product Revenue in excess of \$350.0 million (such payments, collectively, the Revenue Interest Payments). These obligations payable to Sagard are capped at \$184.0 million, but the cap will be increased to \$230.0 million if Sagard has not received aggregate Revenue Interest Payments of \$184.0 million by December 31, 2028 (the applicable cap, the Revenue Interest Cap). In addition, if the aggregate amount of Revenue Interest Payments received by Sagard as of December 31, 2036 is less than \$230.0 million, the Company has agreed to pay Sagard the difference between the Revenue Interest Cap and the aggregate amount of all Revenue Interest Payments received by Sagard as of December 31, 2036 (such difference, the True-Up Payment).

In addition, the Company has the right, but not the obligation (the Call Option), to buy out Sagard's interest in the Revenue Interest Payments at a repurchase price (the Put/Call Payment) equal to the difference between (a) a specified amount ranging from \$149.5 million up to \$230.0 million, based on the period of time between the Closing and the exercise of the Call Option, and (b) the aggregate amount of Revenue Interest Payments that have been received by Sagard. Further, Sagard has the right, but not the obligation, to require the Company to make the Put/Call Payment at any time during the 180 days following the occurrence of certain specified events, including, but not limited to, a sale or merger of the Company resulting in a change of control, certain uncured material breaches of the Purchase Agreement by the Company, the withdrawal or suspension of marketing approval for Bylvay, or any sale or other disposition of Bylvay by the Company within the United States. The Company has also agreed that the Put/Call Payment will be automatically payable upon the occurrence of a bankruptcy event.

As of September 30, 2022 \$111.6 million, was recorded as a revenue interest liability, net of issuance costs on the accompanying unaudited condensed consolidated balance sheet. The Company imputes interest expense associated with this liability using the effective interest rate method. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including changes in the estimated level of forecasted product sales and the amount of product sales, net. The Company evaluates the interest rate quarterly based on its current product sales, net forecasts utilizing the prospective method. A significant increase or decrease in product sales, net will materially impact the revenue interest liability, interest expense and the time period for repayment. The Company recorded interest expense related to this arrangement of \$0.4 million for three months ended September 30, 2022.

The Company incurred \$3.4 million of issuance costs in connection with the purchase and sale agreement with Sagard, which reduced the carrying amount of the revenue interest liability and will be amortized to interest expense over the estimated term of the debt.

Revenue Interest Payments made as a result of the Company's product sales, net reduce the revenue interest liability.

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The following table shows the activity within the revenue interest liability account for the nine-month period ended September 30, 2022:

	<u>September 30, 2022</u>	
	(in thousands)	
Revenue interest liability—beginning balance	\$	111,327
Interest expense recognized		403
Revenue interest liability—ending balance	\$	111,730
Less current portion classified within accrued expenses		(86)
Long-term revenue interest liability	\$	111,644

Trade Receivables, net

Accounts receivable, net related to product sales, which are recorded in accounts receivable, net on the consolidated balance sheets, were approximately \$2.0 million and \$3.3 million as of September 30, 2022 and December 31, 2021, respectively. As of September 30, 2022 and December 31, 2021, we had no allowance for doubtful accounts. An allowance for doubtful accounts is determined based on the Company's assessment of the credit worthiness and financial condition of its customers, aging of receivables, as well as the general economic environment. Any allowance would reduce the net receivables to the amount that is expected to be collected. Payment terms for U.S. customers are typically 31 - 36 days from receipt of invoice and for European customers are typically 45 days from receipt of invoice.

Inventory

The Company commenced capitalizing inventory for Bylway upon FDA approval on July 20, 2021. All commercial manufacturing expenses were expensed as research and development expenses prior to FDA approval. Manufacturing costs incurred prior to FDA approval totaled approximately \$1.6 million and were not capitalized, and instead were expensed as research and development expenses from 2020 to 2021. All manufacturing subsequent to FDA approval is capitalized in inventory.

Recent accounting pronouncements

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

2. Fair Value of financial instruments

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

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

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

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

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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, 2022		
	Level 1	Level 2	Level 3
Cash Equivalents:			
Money market funds	\$214,999	\$ —	\$ —
Total	<u>\$214,999</u>	<u>\$ —</u>	<u>\$ —</u>

	December 31, 2021		
	Level 1	Level 2	Level 3
Cash Equivalents:			
Money market funds	\$243,180	\$ —	\$ —
Total	<u>\$243,180</u>	<u>\$ —</u>	<u>\$ —</u>

The Company’s financial instruments consist mainly of cash, cash equivalents and restricted cash, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities. The carrying amounts of cash, cash equivalents, prepaid expenses and other current assets, accounts payable, accrued expenses, and other current liabilities approximate their estimated fair value due to their short-term maturities. The carrying amount of restricted cash as of September 30, 2022 approximates its fair value based on the contractual terms of the purchase and sale agreement with Sagard. The carrying amount of the revenue interest liability, net as of September 30, 2022 approximates its fair value and is based on the Company’s contractual repayment obligation based on the current estimates of future revenues, over the life of the purchase and sale agreement with Sagard. The carrying amount of liability related to sale of future royalties as of September 30, 2022 and December 31, 2021 approximates its fair value and is based on the Company’s contractual repayment obligation based on the current estimates of future revenues, over the life of the RIAA.

3. Commitments and contingencies

Agreements with CROs and CMOs

As of September 30, 2022, the Company had various agreements with CROs and CMOs for the conduct of specified research and development activities and based on the terms of the respective agreements, the Company is contractually obligated to make future payments of up to \$13.0 million upon the completion of contracted work.

4. Net (loss) income per share

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



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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Basic and Diluted net (loss) income per share:				
Numerator				
Net (loss) income	\$ (37,800)	\$ 57,086	\$ (120,183)	\$ (23,068)
Denominator				
Number of shares used for basic EPS computation	19,655,350	19,258,905	19,541,044	19,197,536
Effect of dilutive securities				
Dilutive options	—	380,934	—	—
Dilutive stock units	—	11,404	—	—
Number of shares used for diluted EPS computation	19,655,350	19,651,243	19,541,044	19,197,536
Basic net (loss) income per share	<u>\$ (1.92)</u>	<u>\$ 2.96</u>	<u>\$ (6.15)</u>	<u>\$ (1.20)</u>
Basic and Diluted net loss (income) per share	<u>\$ (1.92)</u>	<u>\$ 2.90</u>	<u>\$ (6.15)</u>	<u>\$ (1.20)</u>

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

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Options to purchase common stock, RSUs and warrants	3,593,074	2,779,257	3,593,074	3,171,596

5. Income taxes

The Company did not record a tax provision or benefit for the three and nine months ended September 30, 2022. 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

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Company's ordinary losses. The Company expects to maintain a full valuation allowance against its net deferred tax assets for the year.

6. Inventory

Inventory consists of the following (in thousands):

	<u>September 30, 2022</u>	<u>December 31, 2021</u>
Raw materials	\$ 953	\$ —
Work-in-process	147	—
Finished goods	2,049	194
Total inventory	<u>\$ 3,149</u>	<u>\$ 194</u>

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

7. Note Payable

2020 Loan and Security Agreement

On June 8, 2020, the Company entered into a Loan and Security Agreement with several banks and other financial institutions or entities from time to time parties to the Loan and Security Agreement (the Loan and Security Agreement), as lenders, (collectively, referred to as the Lender), and Hercules Capital, Inc., in its capacity as administrative agent and collateral agent for itself and Lender (in such capacity, the Agent or Hercules), which provided for term loans up to an aggregate principal amount of \$80.0 million (the Term Loans) to the Company. The Loan and Security Agreement provided for (i) an initial term loan advance of \$10.0 million, which closed on June 8, 2020, (ii) subject to the achievement of certain initial performance milestones (Performance Milestone I), the Company had the right to request that the Lender make additional term loan advances to the Company in an aggregate principal amount of up to \$20.0 million from January 1, 2021 through December 15, 2021 in minimum increments of \$10.0 million, which Company did not exercise, and (iii) subject to the Lender's investment committee's sole discretion, the Company had the right to request that the Lender make additional term loan advances to the Company in an aggregate principal amount of up to \$45.0 million through March 31, 2022 in minimum increments of \$5.0 million, which the Company did not exercise. During the term of the Loan and Security Agreement, the Company had borrowed an aggregate principal amount of \$10.0 million. The Company was 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 had a maturity date of January 1, 2024, which was extended to July 1, 2024 upon achievement of Performance Milestone I (the Maturity Date).

The Term Loan bore interest at an annual rate equal to the greater of 10.65% and 10.65% plus the prime rate of interest minus 4.75%. Borrowings under the Loan and Security Agreement were repayable in monthly interest-only payments through January 1, 2022, which was extended to (i) July 1, 2022 upon the Company's achievement of Performance Milestone I and (ii) July 1, 2023 upon the Company's achievement of certain additional performance milestones. After the interest-only payment period, borrowings under the Loan and Security Agreement were repayable in equal monthly payments of principal and accrued interest until the Maturity Date. At the Company's option, the Company could 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 occurred 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 (the Prepayment Charge).

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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.

On July 27, 2022, the Loan and Security Agreement was terminated upon the receipt by Hercules of a payoff amount of \$10.9 million from the Company; provided that the Company continues to be bound by certain indemnification obligations under the Loan and Security Agreement. The payoff amount paid by the Company in connection with the termination of the Loan and Security Agreement was pursuant to a payoff letter with Hercules and included payment of (a) \$0.7 million as an End of Term Charge and (b) \$0.1 million as a Prepayment Charge. As a result of this payoff we recognized a loss on extinguishment on the note payable, net of discount of \$0.6 million for the three and nine months ended September 30, 2022 within the condensed consolidated statements of operations.

During the three months ended September 30, 2022 and 2021, the Company recognized \$0.1 million and \$0.3 million, respectively, of interest expense related to the Loan and Security Agreement. During the nine months ended September 30, 2022 and 2021, the Company recognized \$0.7 million and \$1.0 million, respectively, of interest expense related to the Loan and Security Agreement.

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 agreed to use its commercially reasonable efforts to (i) file registration statements with the U.S. Securities and Exchange Commission within 60 days following the date of the issuance of each Warrant for purposes of registering the shares of common stock issuable upon exercise of the Warrants for resale by Hercules, and (ii) cause the registration statement to be declared effective as soon as practicable after filing, and in any event no later than 180 days after the date of the issuance of each Warrant.

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

8. Equity Financings

2021 At-the-Market Offering Program Sales Agreement

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

In February 2021, the Company entered into a sales agreement with Cowen and Company, LLC (Cowen) with respect to an at-the-market offering program under which the Company may offer and sell, from time to time at the Company's sole discretion, shares of common stock having an aggregate offering price of up to \$100.0 million (the 2021 Sales Agreement). Subsequently in July 2021, the Company sold 7,508 shares of common stock for net proceeds of approximately \$0.2 million pursuant to the 2021 Sales Agreement. Because the Company no longer qualified as a well-

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known seasoned issuer following the filing of the Annual Report on Form 10-K for the year ended December 31, 2021, the 2021 Form S-3 was no longer available for the Company to offer and sell securities pursuant to the 2021 Form S-3. The 2021 Sales Agreement was terminated in August 2022 in connection with the Company entering into the 2022 Sales Agreement (as defined below) with Cowen.

In August 2022, the Company filed a new universal shelf registration on Form S-3 with the SEC, which was declared effective on August 25, 2022 (the 2022 Form S-3), pursuant to which the Company registered for sale up to \$400.0 million of any combination of its common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that the Company may determine.

In August 2022, the Company entered into a new sales agreement with Cowen with respect to an at-the-market offering program under which the Company may offer and sell, from time to time at the Company's sole discretion, shares of common stock having an aggregate offering price of up to \$100.0 million (the 2022 Sales Agreement). Subsequently in the third quarter of 2022, the Company sold 1,072,310 shares of common stock for net proceeds of approximately \$20.8 million pursuant to the 2022 Sales Agreement.

9. Stock-based Compensation

For the nine months ended September 30, 2022, the Company granted 329,700 options at a weighted average exercise price per share of \$25.89. For the nine months ended September 30, 2021, the Company granted 688,300 RSUs.

The Company recorded the following stock-based compensation expense:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
	(in thousands)			
Employee awards:				
Cost of product revenue	\$ 88	\$ —	\$ 265	\$ —
Research and development expense	1,179	2,817	4,154	5,330
Selling, general and administrative expense	2,280	3,889	6,252	7,942
Total stock-based compensation expense	<u>\$ 3,547</u>	<u>\$ 6,706</u>	<u>\$ 10,671</u>	<u>\$ 13,272</u>

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

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and the related notes included elsewhere in this quarterly report and our audited financial statements and Management’s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results, performance or experience could differ materially from what is indicated by any forward-looking statement due to various important factors, risks and uncertainties, including, but not limited to, those set forth under “Cautionary Note Regarding Forward-Looking Statements” included elsewhere in this quarterly report or under “Risk Factors” in Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2021, in Item 1A of Part II of this Quarterly Report on Form 10-Q, or in other filings that we make with the SEC.

Overview

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

We are also pursuing the development of Bylvay in biliary atresia and in Alagille syndrome, or ALGS, each of which is a rare, life threatening disease that affects the liver and for which there is no approved pharmacologic treatment option. We initiated a pivotal clinical trial of Bylvay in biliary atresia, the BOLD trial, in the first half of 2020. In November 2022, we announced completion of enrollment in the BOLD trial. We expect topline results from the BOLD trial in 2024. In October 2022, we announced topline results from our pivotal trial of Bylvay in ALGS, the ASSERT trial, and we intend to complete regulatory submissions for Bylvay in patients with ALGS in the United States and Europe no later than the first quarter of 2023, in anticipation of potential regulatory approval and commercial launch in the second half of 2023.

We are expanding development to compounds that are intended for adult liver and viral diseases. Our lead candidate for adult liver diseases, A3907, is a selective inhibitor of the apical sodium-dependent bile acid transporter (ASBT) that has, based on animal studies, high predicted oral bioavailability and systemic exposures in man. As a result, A3907 has the potential to not only affect the bile acid pool by increased bile acid excretion in the stools but also through other pathways, including increased urinary bile acid excretion. This unique approach may yield greater dosing flexibility, greater efficacy and lower rates of adverse events, such as diarrhea, associated with the non-systemic IBAT inhibitors acting locally in the intestine. In December 2021, we announced topline results from our Phase 1 clinical trial in healthy adult subjects to investigate the safety, tolerability, pharmacokinetics of orally administered A3907. In the topline results the trial achieved both primary and secondary objectives. A3907 demonstrated a positive safety profile and was well tolerated in the Phase 1 clinical trial at systemic exposures that demonstrated

therapeutic benefits in preclinical models. With the potential to inhibit ileal, renal and hepatic ASBT, we hope A3907 will provide the optimal balance of efficacy and tolerability in patients in multiple liver diseases. A composition of matter patent for A3907 has been granted, with expiration in 2040 without patent term extension. We expect to initiate a Phase 2 trial for A3907 in adult liver disease by the end of 2022.

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

Bylvay — Our Lead Product for PFIC.

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

The precise prevalence of PFIC is unknown, and we are not aware of any patient registries or other method of establishing with precision the actual number of patients with PFIC in any geography. PFIC has been estimated to affect between one in every 75,000 children born worldwide. Based on the published incidence, published regional populations, and estimated median life expectancies, we estimate the prevalence of PFIC across the spectrum of the disease to be approximately 15,000 patients worldwide, not including China and India, but we are not able to estimate the prevalence of PFIC with precision. Apart from rights we granted to third parties in the below agreements and our royalty obligation under our agreement with Sagard, we hold global rights to Bylvay unencumbered. Our current plan is to commercialize Bylvay ourselves in the United States and Europe. We entered into a co-promotion agreement with Travele Therapeutics, Inc. to promote Bylvay in the United States. The initial term of the co-promotion was two years from the July 2021 launch of Bylvay, terminable at will by either party after one year following launch. In June 2022, the parties mutually agreed to terminate the agreement upon the one year anniversary of the launch, with such termination effective July 20, 2022. We are continuing to commercialize Bylvay ourselves in the United States. We have also entered into license agreements with third parties to commercialize Bylvay in certain other jurisdictions, subject to regulatory approval in those jurisdictions including Medison Pharma Canada Inc. for Canada, Medison Pharma Ltd. for Israel, Gen İlaç ve Sağlık 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 patients with PFIC. Ursodeoxycholic acid, or UDCA, is approved in France only for PFIC type 3, and in the United States and elsewhere for the treatment of primary biliary cholangitis, or PBC. However, many PFIC patients do not respond well to UDCA, undergo partial external bile diversion, or PEBD, surgery and often require liver transplantation. PEBD surgery is a life-altering and undesirable procedure in which bile is drained outside the body to a stoma bag that must be worn by the patient 24 hours a day.

Other Indications Under Development for Bylvay.

We are also pursuing the development of Bylvay in patients with biliary atresia, another rare, life-threatening disease that affects the liver and for which there is no approved pharmacologic treatment option. In December 2018,

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the European Commission granted orphan designation to odevixibat for the treatment of biliary atresia, and in January 2019, the FDA granted orphan drug designation to odevixibat for the treatment of biliary atresia. We initiated the BOLD clinical trial, a global pivotal trial and the largest prospective intervention trial ever conducted in biliary atresia, in the first half of 2020. In October 2022 we announced completion of enrollment in the trial and we expect topline results in 2024. We believe biliary atresia is one of the most common rare pediatric liver diseases, and is the leading cause of liver transplants in children. Our double-blind, placebo controlled pivotal trial in biliary atresia is designed to enroll approximately 200 patients at 70 sites globally. Patients will receive either placebo or odevixibat once daily at 120µg/kg. The primary endpoint is survival with native liver after two years of treatment.

Biliary atresia is a partial or total blocking or absence of large bile ducts that causes cholestasis and resulting accumulation of bile that damages the liver. The estimated worldwide incidence of biliary atresia is between 6 and 10 for every 100,000 live births. We estimate the prevalence of biliary atresia to be approximately 18,000 patients across the U.S. and Europe, and approximately 27,000 combined in other jurisdictions worldwide, but we are not able to estimate the prevalence of biliary atresia with precision. There are currently no drugs approved for the treatment of biliary atresia. The current standard of care is a surgery known as the Kasai procedure, or hepatoportoenterostomy, in which the obstructed bile ducts are removed and a section of the small intestine is connected to the liver directly. However, only an estimated 25% of those initially undergoing the Kasai procedure will survive to their twenties without need for liver transplantation.

In addition, we initiated a pivotal trial of Bylvay in ALGS, the ASSERT trial, in the fourth quarter of 2020. The double-blind, randomized, placebo-controlled trial was designed to evaluate the safety and efficacy of 120 µg /kg/day Bylvay (odevixibat) for 24 weeks in relieving pruritus in patients with ALGS. Key secondary endpoints measure serum bile acid levels and safety and tolerability. The trial enrolled 52 patients aged 0 to 17 years of age with a genetically confirmed diagnosis of ALGS across 21 sites in North America, Europe, Middle East and Asia Pacific. The primary efficacy endpoint was a change from baseline to month 6 (weeks 21 to 24) in pruritus measured by scratching with the PRUCISION Observer-Reported Outcome (ObsRO) scratching score caregiver instrument (0-4 point scale). The key secondary efficacy endpoint was a change in serum bile acid responses from baseline to the average of weeks 20 and 24.

In October 2022, we announced topline results from the ASSERT trial. In the primary analysis, the study met the primary endpoint showing statistically significant reduction in pruritus as measured by the ObsRO scratching score (0-4 point scale), from baseline at month 6 (weeks 21 to 24), compared to the placebo arm (p=0.002). The study also met the key secondary endpoint showing a statistically significant reduction in serum bile acid concentration from baseline to the average of weeks 20 and 24 (compared to the placebo arm p=0.001). Statistically significant improvements in multiple sleep parameters were observed as early as week 1-4 compared to patients on placebo with continued improvement through week 24. In the study, there were no patient discontinuations. Bylvay was well tolerated, with an overall adverse event incidence similar to placebo and a low incidence of drug-related diarrhea (11.4% vs. 5.9% placebo).

ALGS is a genetic condition associated with liver, heart, eye, kidney and skeletal abnormalities. In particular, ALGS patients have fewer than normal bile ducts inside the liver, which leads to cholestasis and the accumulation of bile and causes scarring in the liver. ALGS is estimated to affect between one in every 50,000 children born worldwide. We estimate the prevalence of ALGS to be approximately 12,000 patients across the U.S. and Europe, and approximately 13,000 combined in other jurisdictions worldwide, but we are not able to estimate the prevalence of ALGS with precision. Current treatment for ALGS is generally in line with current treatments for PFIC as described above. In August 2012, the European Commission granted orphan designation to odevixibat for the treatment of ALGS. In October 2018, the FDA granted orphan drug designation to odevixibat for the treatment of ALGS. With the results from the ASSERT trial, we intend to complete regulatory submissions in the United States and

Europe no later than the first quarter of 2023, in anticipation of potential regulatory approval and commercial launch in the second half of 2023.

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

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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, 2022, we had an accumulated deficit of \$421.0 million. To date, we have financed our operations primarily through issuances of equity or convertible debt, upfront fees paid upon entering into license agreements, payments received upon the achievement of specified milestone events under license agreements, grants and venture debt borrowings, the HealthCare Royalty Partners III, L.P. (HCR) royalty monetization transactions, and the Sagard Healthcare Partners (Delaware) LP (“Sagard”) royalty monetization transactions.

As previously disclosed, on September 22, 2022, we entered into a purchase and sale agreement with Sagard for the sale of a royalty on revenues generated from Bylvay (odevixibat), or the Purchase Agreement, for an aggregate purchase price of \$115.0 million payable upon the closing of the transaction, which occurred on September 22, 2022. In consideration for the payment of such purchase price, Sagard is entitled to receive tiered, sales-based royalty payments on the worldwide annual consolidated net revenues of Bylvay. These royalty obligations payable to Sagard are capped at \$184.0 million which will be increased to \$230.0 million if Sagard has not received aggregate royalty payments of \$184.0 million by December 31, 2028. In addition, if the aggregate amount of royalty payments received by Sagard as of December 31, 2036 is less than \$230.0 million, we have agreed to pay Sagard the difference between the royalty cap and the aggregate amount of all royalty payments received by Sagard as of December 31, 2036. See Note 1 to the condensed consolidated financial statements in Part I, Item 1 of this report for additional information about our obligations under the Purchase Agreement.

We expect to continue to incur significant expenses and increasing operating losses as we continue our development of, and seek marketing approvals for, our product candidates, commercialize Bylvay, prepare for and begin the commercialization of any other approved products in the future, and add infrastructure and personnel to support our product development and commercialization efforts and operations as a public company in the United States. To date, inflation has not had a material impact on our business, but if the global inflationary trends continue, we expect appreciable increases in clinical trial, selling, labor, and other operating costs. If our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through price increases of our product. Our inability or failure to do so could adversely affect our business, financial condition and results of operations.

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, 2022, we had approximately \$272.5 million in cash, cash equivalents and restricted cash.

Financial Operations Overview

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

Revenue

We generate revenue primarily from the receipt of royalty revenue, upfront or license fees and milestone payments as well as product revenue following our commercial launch of Bylvay. License agreements with commercial partners generally include nonrefundable upfront fees and milestone payments. We recognize revenue on sales of Bylvay when a customer obtains control of the product, which occurs at a point in time and upon delivery, the receipt of which is dependent upon the achievement of

specified development, regulatory or commercial milestone events, as well as royalties on product sales of licensed products, if and when such product sales occur, and payments for pharmaceutical

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ingredient or related procurement services. For these agreements, management applies judgment in the allocation of total agreement consideration to the performance obligations on a reliable basis that reasonably reflects the selling prices that might be expected to be achieved in stand-alone transactions. For additional information about our revenue recognition, refer to Note 1 to our condensed consolidated financial statements included in this quarterly report.

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

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

Product Revenue, Net

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

However, a portion of our royalty and royalty-related revenues generated from Bylvay will be paid to Sagard pursuant to the Purchase Agreement.

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

For the three and nine months ended September 30, 2022, we recognized net sales of Bylvay totaling approximately \$7.5 million and \$18.1 million, respectively. For the three and nine months ended September 30, 2021, we recognized net sales of Bylvay totaling approximately \$1.1 million and \$1.1 million, respectively.

Royalty Revenue

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

For the three months ended September 30, 2022 and 2021, we recognized revenue of \$2.3 million and \$2.6 million, respectively, related to our agreement with EA Pharma. For the nine months ended September 30, 2022 and 2021, we recognized revenue of \$6.8 million and \$7.0 million, respectively, related to our agreement with EA Pharma. We expect that any future revenue recognized under our license agreement with EA Pharma will fluctuate from quarter to quarter and year to year as a result of royalties for the period from EA Pharma, as well as the uncertain timing of future milestone payments, if any.

In October 2021, Albireo entered into an agreement with Jadeite Medicines Inc. to license, develop and commercialize Bylvay within Japan. For the three and nine months ended September 30, 2022 and 2021, no revenue was

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recognized under the agreement. Currently, Jadeite is commencing bridging and other clinical studies to pursue New Drug Application (NDA) filings and obtain approval in Japan for PFIC, ALGS, and biliary atresia indications. Future royalty revenue recognized under our license agreement with Jadeite will not commence until after NDA approval in Japan. The next anticipated milestone payment will be received upon NDA filings in Japan for Bylvay and the timing of future milestone payments, if any, is uncertain.

Costs and Operating Expenses

Cost of Product Revenue

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

Research and Development Expenses

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

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

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of personnel costs (including salaries, benefits and stock-based compensation) for our executive, finance and other administrative employees. In addition, selling, general and administrative expenses include fees for third-party professional services, including consulting, information technology, legal and accounting services. Other selling, general and administrative expenses include marketing expenses related to the commercial launch of Bylvay, as well as corporate expenses.

Other Operating Expense, Net

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

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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).

Loss on Extinguishment of Note Payable, net of discount

Loss on extinguishment of note payable, net of discount consists primarily of the payoff of our Loan and Security Agreement with Hercules.

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, the purchase and sale agreement with Sagard, and both cash and non-cash interest expense associated with our note payable, which we paid off on July 27, 2022. 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 maintain a full valuation allowance against our 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 March 1, 2022, the date we filed our Annual Report on Form 10-K for the year ended December 31, 2021. Due to the commercialization of Bylvay (odevixibat) the Company implemented accounting policies related to revenue recognition and inventory. See Note 1, "*Summary of significant accounting policies and basis of presentation*" for more information on revenue recognition and inventory accounting policies. For more information on other critical accounting policies, refer to our Annual Report on Form 10-K for the year ended December 31, 2021.

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Results of Operations for the Three Months Ended September 30, 2022 and 2021

The following tables summarizes our results of operations for three months ended September 30, 2022 and September 30, 2021

	Three Months Ended September 30,		Change
	2022	2021	\$
	(in thousands)		
Revenue			
Product revenue, net	\$ 7,543	\$ 1,060	\$ 6,483
Royalty revenue	2,289	2,604	(315)
Total revenue	9,832	3,664	6,168
Cost and operating expenses:			
Cost of product revenue	612	431	181
Research and development	23,312	21,083	2,229
Selling, general and administrative	20,564	17,612	2,952
Other operating expense, net	1	3,719	(3,718)
Total cost and operating expenses	44,489	42,845	1,644
Operating loss	(34,657)	(39,181)	4,524
Other (loss) income			
Gain from sale of priority review voucher, net of transaction costs	—	103,387	(103,387)
Loss on extinguishment of note payable, net of discount	(613)	—	(613)
Interest expense, net	(2,530)	(3,331)	801
Net (loss) income before income taxes	(37,800)	60,875	(98,675)
Provision for income taxes	—	3,789	(3,789)
Net loss	\$ (37,800)	\$ 57,086	\$ (94,886)

Revenue

	Three Months Ended September 30,		Change
	2022	2021	\$
	(in thousands)		
Product revenue, net	\$ 7,543	\$ 1,060	\$6,483
Royalty revenue	2,289	2,604	(315)
Total revenue	\$ 9,832	\$ 3,664	\$6,168

Product revenue, net was \$7.5 million for the three months ended September 30, 2022 compared with \$1.1 million for the three months ended September 30, 2021 due to higher Bylvay unit product sales. Product revenue, net for the three months ended September 30, 2022 was \$4.1 million in the United States and \$3.4 million in international markets. Product revenue, net for the three months ended September 30, 2021 was \$0.8 million in the United States and \$0.3 million in International markets.

Royalty revenue was \$2.3 million for the three months ended September 30, 2022 compared with \$2.6 million for the three months ended September 30, 2021, a decrease of \$0.3 million. The decrease relates to estimated royalty revenue to be received from EA Pharma for elobixibat for the treatment of chronic constipation.

Cost of product revenue

	Three Months Ended September 30,		Change
	2022	2021	\$

	(in thousands)		
Cost of product revenue	<u>\$ 612</u>	<u>\$ 431</u>	<u>\$ 181</u>

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Cost of product revenue was \$0.6 million for the three months ended September 30, 2022 compared with \$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 were expensed prior to approval. Bylvay was not approved until July 2021.

Research and development expenses

	<u>Three Months Ended September 30,</u>		<u>Change</u>
	<u>2022</u>	<u>2021</u>	<u>\$</u>
	(in thousands)		
Research and development expenses	<u>\$ 23,312</u>	<u>\$ 21,083</u>	<u>\$2,229</u>

Research and development expenses were \$23.3 million for the three months ended September 30, 2022 compared with \$21.1 million for the three months ended September 30, 2021, an increase of \$2.2 million. The increase in research and development expenses for the 2022 period was principally due to clinical program activities and other costs as we continue to increase our headcount and program activities. The increase in program activities related to Bylvay – PFIC primarily related to clinical costs, regulatory costs and medical affairs and were partially offset by ongoing Phase 3 clinical trials for biliary atresia and Alagille syndrome. The other project costs decreased by \$0.5 million primarily due to a decrease in personnel costs primarily related to share-based compensation.

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, 2022 and 2021.

	<u>Three Months Ended September 30,</u>		<u>Change</u>
	<u>2022</u>	<u>2021</u>	<u>\$</u>
	(in thousands)		
Direct third-party project costs:			
Bylvay - PFIC	\$ 6,847	\$ 3,697	\$ 3,150
Bylvay - biliary atresia and ALGS	6,789	7,254	(465)
A3907	1,407	1,423	(16)
Preclinical	949	915	34
Total	<u>\$ 15,992</u>	<u>\$ 13,289</u>	<u>\$ 2,703</u>
Other project costs ⁽¹⁾ :			
Personnel costs	\$ 6,420	\$ 7,741	\$(1,321)
Other costs ⁽²⁾	900	53	847
Total	<u>\$ 7,320</u>	<u>\$ 7,794</u>	<u>\$ (474)</u>
Total research and development costs	<u>\$ 23,312</u>	<u>\$ 21,083</u>	<u>\$ 2,229</u>

(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

	<u>Three Months Ended September 30,</u>		<u>Change</u>
	<u>2022</u>	<u>2021</u>	<u>\$</u>
	(in thousands)		
Selling, general and administrative	<u>\$ 20,564</u>	<u>\$ 17,612</u>	<u>\$2,952</u>

Selling, general and administrative expenses were \$20.6 million for the three months ended September 30, 2022 compared with \$17.6 million for the three months ended September 30, 2021, an increase of \$3.0 million. The increase is attributable to personnel and related expenses as we continue to increase our headcount, and commercialization activities related to Bylvay including our sales force and support for global expansion efforts.

[Table of Contents](#)*Other operating expense, net*

	<u>Three Months Ended September 30,</u>		<u>Change</u>
	<u>2022</u>	<u>2021</u>	<u>\$</u>
	(in thousands)		
Other operating expense, net	<u>\$ 1</u>	<u>\$ 3,719</u>	<u>\$(3,718)</u>

Other operating expense, net totaled \$0.0 million for the three months ended September 30, 2022 compared with \$3.7 million for the three months ended September 30, 2021. 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

	<u>Three Months Ended September 30,</u>		<u>Change</u>
	<u>2022</u>	<u>2021</u>	<u>\$</u>
	(in thousands)		
Gain from sale of priority review voucher, net of transaction costs	<u>\$ —</u>	<u>\$ 103,387</u>	<u>\$(103,387)</u>

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, 2022.

Loss on extinguishment of note payable, net of discount

	<u>Three Months Ended September 30,</u>		<u>Change</u>
	<u>2022</u>	<u>2021</u>	<u>\$</u>
	(in thousands)		
Loss on extinguishment of note payable, net of discount	<u>\$ (613)</u>	<u>\$ —</u>	<u>\$(613)</u>

Loss on extinguishment of note payable, net of discount totaled \$0.6 million for the three months ended September 30, 2022 primarily related to the payoff of our Loan and Security Agreement with Hercules. There was no loss on extinguishment of note payable, net of discount for the three months ended September 30, 2021.

Interest expense, net

	<u>Three Months Ended September 30,</u>		<u>Change</u>
	<u>2022</u>	<u>2021</u>	<u>\$</u>
	(in thousands)		
Interest expense, net	<u>\$ (2,530)</u>	<u>\$ (3,331)</u>	<u>\$ 801</u>

Interest expense, net totaled \$2.5 million for the three months ended September 30, 2022 compared with \$3.3 million for the three months ended September 30, 2021. The difference was principally attributable to interest expense associated with the purchase and sale agreement with Sagard, partially offset by lower non-cash interest expense recorded in connection with the sale of future royalties related to sales of elobixibat in Japan, and interest income associated with our interest bearing cash accounts.

Provision for income taxes

Three Months Ended

	September 30,		Change
	2022	2021	\$
	In thousands		
Provision for income taxes	\$ —	\$ 3,789	\$ (3,789)

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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 maintain a full valuation allowance against the net deferred tax assets for the year. There was no provision for incomes taxes for the three months ended September 30, 2022.

Results of Operations for the Nine Months Ended September 30, 2022 and 2021

The following table summarizes our results of operations for the nine months ended September 30, 2022 and 2021

	Nine Months Ended September 30,		Change
	2022	2021	\$
	(in thousands)		
Revenue			
Product revenue, net	\$ 18,090	\$ 1,060	\$ 17,030
Royalty revenue	6,780	6,998	(218)
Total revenue	<u>24,870</u>	<u>8,058</u>	<u>16,812</u>
Cost and operating expenses:			
Cost of product revenue	1,622	431	1,191
Research and development	68,103	61,920	6,183
Selling, general and administrative	59,019	49,825	9,194
Other operating expense, net	7,544	7,873	(329)
Total cost and operating expenses	<u>136,288</u>	<u>120,049</u>	<u>16,239</u>
Operating loss	(111,418)	(111,991)	573
Other (loss) income			
Gain from sale of priority review voucher, net of transaction costs	—	103,387	(103,387)
Loss on extinguishment of note payable, net of discount	(613)	—	(613)
Interest expense, net	(8,152)	(10,675)	2,523
Net loss before income taxes	(120,183)	(19,279)	(100,904)
Provision for income taxes	—	3,789	(3,789)
Net loss	<u>\$ (120,183)</u>	<u>\$ (23,068)</u>	<u>\$ (97,115)</u>

Revenue

	Nine Months Ended September 30,		Change
	2022	2021	\$
	(in thousands)		
Product revenue, net	\$ 18,090	\$ 1,060	\$17,030
Royalty revenue	6,780	6,998	(218)
Total revenue	<u>\$ 24,870</u>	<u>\$ 8,058</u>	<u>\$16,812</u>

Product revenue, net was \$18.1 million for the nine months ended September 30, 2022 compared with \$1.1 million for the nine months ended September 30, 2021 due to higher Bylvay unit product sales. Product revenue, net for the nine months ended September 30, 2022 was \$10.4 million in the United States and \$7.7 million in international markets. Product revenue, net for the nine months ended September 30, 2021 was \$0.8 million in the United States and \$0.3 million in International markets.

Royalty revenue was \$6.8 million for the nine months ended September 30, 2022 compared with \$7.0 million for the nine months ended September 30, 2021, a decrease of \$0.2 million. The decrease relates to estimated royalty revenue to be received from EA Pharma for elobixibat for the treatment of chronic constipation.

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Cost of product revenue

	<u>Nine Months Ended September 30,</u>		<u>Change</u>
	<u>2022</u>	<u>2021</u>	<u>\$</u>
	(in thousands)		
Cost of product revenue	<u>\$ 1,622</u>	<u>\$ 431</u>	<u>\$ 1,191</u>

Cost of product revenue was \$1.6 million for the nine months ended September 30, 2022 compared with \$0.4 million for the nine 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, were expensed prior to approval. Bylvay was not approved until July 2021.

Research and development expenses

	<u>Nine Months Ended September 30,</u>		<u>Change</u>
	<u>2022</u>	<u>2021</u>	<u>\$</u>
	(in thousands)		
Research and development expenses	<u>\$ 68,103</u>	<u>\$ 61,920</u>	<u>\$6,183</u>

Research and development expenses were \$68.1 million for the nine months ended September 30, 2022 compared with \$61.9 million for the nine months ended September 30, 2021, an increase of \$6.2 million. The increase in research and development expenses for the 2022 period was principally due to clinical and preclinical program activities and other costs as we continue to increase our headcount and program activities. The increase in program activities related to Bylvay – PFIC primarily related to clinical costs, regulatory costs and medical affairs, ongoing Phase 3 clinical trials for biliary atresia and Alagille syndrome and ongoing preclinical trials. The other project costs increased by \$1.1 million primarily due other costs offset by a decrease in personnel costs primarily related to share-based compensation.

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, 2022 and 2021.

	<u>Nine Months Ended September 30,</u>		<u>Change</u>
	<u>2022</u>	<u>2021</u>	<u>\$</u>
	(in thousands)		
Direct third-party project costs:			
Bylvay - PFIC	\$ 17,693	\$ 15,181	\$2,512
Bylvay - biliary atresia and ALGS	19,168	18,008	1,160
A3907	5,335	5,241	94
Preclinical	<u>4,203</u>	<u>2,873</u>	<u>1,330</u>
Total	\$ 46,399	\$ 41,303	\$5,096
Other project costs ⁽¹⁾ :			
Personnel costs	\$ 19,239	\$ 19,668	\$ (429)
Other costs ⁽²⁾	<u>2,465</u>	<u>949</u>	<u>1,516</u>

Total	<u>\$ 21,704</u>	<u>\$ 20,617</u>	<u>\$1,087</u>
Total research and development costs	<u>\$ 68,103</u>	<u>\$ 61,920</u>	<u>\$6,183</u>

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

[Table of Contents](#)*Selling, general and administrative expenses*

	<u>Nine Months Ended September 30,</u>		<u>Change</u>
	<u>2022</u>	<u>2021</u>	<u>\$</u>
	(in thousands)		
Selling, general and administrative	<u>\$ 59,019</u>	<u>\$ 49,825</u>	<u>\$9,194</u>

Selling, general and administrative expenses were \$59.0 million for the nine months ended September 30, 2022 compared with \$49.8 million for the nine months ended September 30, 2021, an increase of \$9.2 million. The increase is attributable to personnel and related expenses as we continue to increase our headcount, and commercialization activities related to Bylvay including our sales force and support for global expansion efforts.

Other operating expense, net

	<u>Nine Months Ended September 30,</u>		<u>Change</u>
	<u>2022</u>	<u>2021</u>	<u>\$</u>
	(in thousands)		
Other operating expense, net	<u>\$ 7,544</u>	<u>\$ 7,873</u>	<u>\$(329)</u>

Other operating expense, net totaled \$7.5 million for the nine months ended September 30, 2022 compared with \$7.9 million for the nine months ended September 30, 2021. 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

	<u>Nine Months Ended September 30,</u>		<u>Change</u>
	<u>2022</u>	<u>2021</u>	<u>\$</u>
	(in thousands)		
Gain from sale of priority review voucher, net of transaction costs	<u>\$ —</u>	<u>\$ 103,387</u>	<u>\$(103,387)</u>

Gain from sale of priority review voucher, net of transaction costs totaled \$103.4 million for the nine months ended September 30, 2021. There was no gain from the sale of priority review voucher, net for the nine months ended September 30, 2022.

Loss on extinguishment of note payable, net of discount

	<u>Nine Months Ended September 30,</u>		<u>Change</u>
	<u>2022</u>	<u>2021</u>	<u>\$</u>
	(in thousands)		
Loss on extinguishment of note payable, net of discount	<u>\$ (613)</u>	<u>\$ —</u>	<u>\$(613)</u>

Loss on extinguishment of note payable, net of discount totaled \$0.6 million for the nine months ended September 30, 2022 primarily related to the payoff of our Loan and Security Agreement with Hercules. There was no loss on extinguishment of note payable, net of discount for the nine months ended September 30, 2021.

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Interest expense, net

	Nine Months Ended September 30,		Change
	2022	2021	\$
	(in thousands)		
Interest expense, net	\$ (8,152)	\$ (10,675)	\$ 2,523

Interest expense, net totaled \$8.2 million for the nine months ended September 30, 2022 compared with \$10.7 million for the nine months ended September 30, 2021. The difference was principally attributable to interest expense associated with the purchase and sale agreement with Sagard, partially offset by lower non-cash interest expense recorded in connection with the sale of future royalties related to sales of elobixibat in Japan, and interest income associated with our interest bearing cash accounts.

Provision for income taxes

	Nine Months Ended		Change
	September 30,	September 30,	\$
	2022	2021	
	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 maintain a full valuation allowance against the net deferred tax assets for the year. There was no provision for incomes taxes for the nine months ended September 30, 2022.

Liquidity and Capital Resources

Sources of Liquidity

We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we commercialize Bylvay and continue the development of and seek regulatory approvals for Bylvay in other indications and for our other product candidates. We are subject to all of the risks applicable to the development and commercialization of new pharmaceutical products and may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may harm our business. We expect that we will need substantial additional funding to complete development of and potentially commercialize our other product candidates.

Our operations have historically been financed primarily through issuances of equity or convertible debt, upfront fees paid upon entering into license agreements, payments received upon the achievement of specified milestone events under license agreements, grants and venture debt borrowings, the HealthCare Royalty Partners III, L.P. (HCR) royalty monetization transactions and the Sagard Healthcare Partners (Delaware) LP (Sagard) revenue interest transaction. Our primary uses of capital are, and we expect will continue to be, personnel-related costs, third party expenses associated with our research and development programs, including the conduct of clinical trials, and manufacturing-related costs for our other product candidates as well as commercialization and pre-commercialization efforts.

As of September 30, 2022, our cash, cash equivalents and restricted cash were approximately \$272.5 million.

During the first quarter of 2018, following the Japanese Ministry of Health, Labour and Welfare's approval of elobixibat for the treatment of chronic constipation in January 2018, we received a \$44.5 million payment, net of certain transaction expenses, from HCR under our royalty interest acquisition agreement (RIAA). Additionally, this approval triggered a milestone payment to us from EA Pharma of \$11.2 million. In June 2020, we entered into an

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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, 2022, we have received approximately \$59.3 million in upfront and milestone payments from EA Pharma under a license agreement for the development and commercialization of elobixibat in specified countries in Asia. We are eligible to receive additional amounts of up to \$4.2 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.

On February 25, 2021, we filed an automatic shelf registration statement on Form S-3 with the SEC, which became effective upon filing, pursuant to which we registered for sale an unlimited amount of any combination of our common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that we may determine, so long as we continued to satisfy the requirements of a "well-known seasoned issuer" under SEC rules, which we refer to as the 2021 Form S-3. Because we no longer qualified as a well-known seasoned issuer, the 2021 Form S-3 was no longer available for us to offer and sell securities pursuant to the 2021 Form S-3 following the filing of our Annual Report on Form 10-K for the year ended December 31, 2021 on March 1, 2022. On February 25, 2021, we also entered into a sales agreement with Cowen, which we refer to as the 2021 Sales Agreement, with respect to an at-the-market offering program which provided for us to offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to \$100.0 million. Subsequently in July 2021, we sold 7,508 shares of our common stock for net proceeds of approximately \$0.2 million pursuant to the 2021 Sales Agreement. The 2021 Sales Agreement was terminated on August 15, 2022 in connection with us entering into the 2022 Sales Agreement (as defined below) with Cowen.

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.

On August 16, 2022, we filed a new universal shelf registration on Form S-3 with the SEC, which was declared effective on August 25, 2022, pursuant to which we registered for sale up to \$400.0 million of any combination of our common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that we may determine, which we refer to as the 2022 Form S-3. The 2022 Form S-3 includes a prospectus covering up to \$100.0 million in shares of common stock that can be issued and sold under a new sales agreement we entered into with Cowen on August 15, 2022, which we refer to as the 2022 Sales Agreement, with respect to an at-the-market offering program under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to \$100.0 million. Subsequently in the third quarter of 2022, we sold 1,072,310 shares of our common stock for net proceeds of approximately \$20.6 million pursuant to the 2022 Sales Agreement.

On September 22, 2022, we entered into the Purchase Agreement with Sagard for the sale of a revenue interest on sales generated from Bylvay (odevixibat) for an aggregate purchase price of \$115.0 million payable upon the closing of the transaction, which occurred on September 22, 2022. In consideration for the payment of such purchase price, we are obligated to pay to Sagard revenue interest payments on the worldwide annual consolidated net sales of Bylvay, or the Included Product Revenue, at a rate of (A) 12.5%

for Included Product Revenue up to and including \$250.0 million, (B) 5% for Included Product Revenue in excess of \$250.0 million but less than or equal to \$350.0 million, and (C) prior to approval of a New Drug Application by the FDA of Bylvay for the treatment of biliary atresia, or the Marketing Approval, 5% for Included Product Revenue in excess of \$350.0 million and, from and after Marketing Approval, the rate is decreased to 1% for Included Product Revenue in excess of \$350.0 million. These obligations payable to Sagard are capped at \$184.0

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million which will be increased to \$230.0 million if Sagard has not received aggregate payments of \$184.0 million by December 31, 2028. In addition, if the aggregate amount of payments received by Sagard as of December 31, 2036 is less than \$230.0 million, we have agreed to pay Sagard the difference between the cap and the aggregate amount of all payments received by Sagard as of December 31, 2036 (such difference, the True-Up Payment). In addition, at any time after the closing, we have the right, but not the obligation, or the Call Option, to buy out Sagard's interest in the payments at a repurchase price, or the Put/Call Payment, equal to the difference between (a) a specified amount ranging from \$149.5 million up to \$230.0 million, based on the period of time between the closing and the exercise of the Call Option, and (b) the aggregate amount of payments that have been received by Sagard. Further, Sagard has the right, but not the obligation, to require us to make the Put/Call Payment at any time during the 180 days following the occurrence of certain specified events, including, but not limited to, a sale or merger of the Company resulting in a change of control, certain uncured material breaches of the Purchase Agreement by the Company, the withdrawal or suspension of marketing approval for Bylvay, or any sale or other disposition of Bylvay by the Company within the United States. We also agreed that the Put/Call Payment will be automatically payable upon the occurrence of a bankruptcy event.

Cash Flows

Nine months ended September 30, 2022 and September 30, 2021

	Nine Months Ended September 30,	
	2022	2021
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	\$ (101,431)	(93,668)
Investing activities	(960)	102,922
Financing activities	127,666	2,389
Total	\$ 25,275	\$ 11,643
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(906)	(303)
Net increase in cash, cash equivalents and restricted cash	24,369	11,340

Operating activities

Cash used in operating activities of \$101.4 million during the nine months ended September 30, 2022 was primarily a result of our \$120.2 million net loss from operations and a net decrease in assets and liabilities of \$8.7 million. The net decrease in operating assets and liabilities during the nine months ended September 30, 2022 was primarily driven by decreases in accrued expenses, inventory, and other current and long-term liabilities, offset by increases in prepaid expenses and other current assets and accounts receivable, net and accounts payable. This decrease was primarily offset by non-cash items, including \$10.7 million of share-based compensation expense, \$8.3 million of accretion of liability related to sale of future royalties and \$7.0 million of foreign currency adjustments. 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, \$103.4 million net gain from the 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 payable, 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.

Investing activities

Cash used in investing activities of \$1.0 million during the nine months ended September 30, 2022 was primarily related to purchases of property and equipment. 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.

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Financing activities

Cash provided by financing activities of \$127.7 million during the nine months ended September 30, 2022 was primarily related to proceeds from the royalty agreement, net of issuance costs of \$111.6 million, proceeds of issuance of common stock, net of issuance costs of \$20.6 million, proceeds from exercise of options of \$6.3 million offset by payment of principal on borrowings of \$10.8 million. Cash provided by financing activities of \$2.4 million during the nine months ended September 30, 2021 was primarily related to proceeds from the exercise of options.

Funding Requirements

Cash used to fund operating expenses is affected by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

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

- Future revenue from commercial sales of Bylvay for patients with PFIC;
- any unfavorable development or delay in our Bylvay program in ALGS, including the submission, review or approval of our Bylvay marketing applications in the United States and Europe for ALGS and the costs and timing of our pre-commercialization preparations;
- the costs, design, duration and any potential delays of the pivotal clinical trial of Bylvay in biliary atresia;
- 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;
- our ability to fulfill our obligations under the Purchase Agreement with Sagard, including our ability to make royalty payments and our ability to buy out Sagard's interest or at Sagard's request, in certain circumstances, repurchase Sagard's interest in the royalty interest payments;
- 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;

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- the current and potential impacts of the COVID-19 pandemic on our business;
- global economic uncertainty, rising inflation, rising interest rates, market disruptions and volatility in commodity prices;
- 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 on Form S-3 with the SEC pursuant to which we registered for sale up to \$400.0 million of any combination of our common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that we may determine, which we refer to as the 2022 Form S-3. The 2022 Form S-3 includes a prospectus covering up to \$100.0 million in shares of common stock that can be issued and sold under a new sales agreement we entered into with Cowen on August 15, 2022, which we refer to as the 2022 Sales Agreement, with respect to an at-the-market offering program under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to \$100.0 million. Subsequently in the third quarter of 2022, we sold 1,072,310 shares of our common stock for net proceeds of approximately \$20.6 million pursuant to the 2022 Sales Agreement. As of September 30, 2022, approximately \$379.2 million of securities remain available for issuance under the 2022 Form S-3, including up to \$79.2 million of our common stock that we may offer and sell, from time to time at our discretion, through Cowen as sales agent under the 2022 Sales Agreement.

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.

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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, 2022, our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Form 10-Q, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

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

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

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

Failure to meet our obligations under our Purchase Agreement with Sagard could adversely affect our business, financial condition and stock price.

In September 2022, we entered into the Purchase Agreement with Sagard for the sale of a revenue interest on sales generated from Bylvay (odevixibat) in exchange for our obligation to pay to Sagard a revenue interest on the worldwide annual consolidated net sales of Bylvay. The Purchase Agreement contains various covenants and obligations, including restrictions on, among other things, our ability to incur indebtedness and dispose of material intellectual property related to Bylvay. We also agreed to grant a first lien security interest on our right, title and interest in the payments and related collateral, and agreed to a negative pledge on our assets, including our intellectual property. There can be no assurance that we will not breach the covenants or other terms of, or that an event of default will not occur under, the Purchase Agreement and, if a breach or event of default occurs, there can be no assurance that we will be able to cure the breach within the time permitted. In the event of any failure to pay our obligations when due, any breach or default of our covenants or other obligations, or any other event that causes an acceleration of payment at a time when we do not have sufficient resources to meet these obligations, Sagard could foreclose on the collateral which includes our secured revenue interest on sales generated from Bylvay and related collateral. Further, the negative pledge on all of our assets, including our intellectual property, may inhibit us from raising additional funds or entering into other strategic arrangements. If adequate funds are not available to us on a timely basis or on terms acceptable to us, we may be required to delay, limit, reduce or terminate our research and development, commercialization or growth efforts. Any of these consequences could have a material adverse effect on our business, financial condition and stock price.

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Item 6. Exhibits

<u>Exhibit No.</u>	<u>Description</u>	<u>Filed Herewith</u>	<u>Incorporated by Reference Herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File/ Req. Number</u>
10.1*#	Purchase and Sale Agreement, dated as of September 22, 2022, by and among the Registrant, Albireo AB and Sagard Healthcare Partners (Delaware) LP.	X			
10.2	Sales Agreement, dated as of August 15, 2022, by and between the Registrant and Cowen and Company, LLC.		Form S-3 (Exhibit 1.2)	8/16/2022	333-266893
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, 2022, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets (unaudited) at September 30, 2022 and December 31, 2021, (ii) Condensed Consolidated Statements of Operations (unaudited) for the three and nine months ended September 30, 2022 and 2021, (iii) Condensed Consolidated Statements of Comprehensive (Loss) Income (unaudited) for the three and nine months ended September 30, 2022 and 2021, (iv) Condensed Consolidated Statement of Stockholders' Equity (unaudited) for the three and nine months ended September 30, 2022 and 2021, (v) Condensed Consolidated Statements of Cash Flows (unaudited) for the nine months ended September 30, 2022 and 2021, and (vi) Notes to Condensed Consolidated Financial Statements (unaudited).	X			
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).	X			

* 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) is the type that the registrant treats as private or confidential.

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.

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 8, 2022

By: /s/ Ronald H.W. Cooper

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

Dated: November 8, 2022

By: /s/ Simon N.R. Harford

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

CERTAIN INFORMATION IDENTIFIED BY “[*]” HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

PURCHASE AND SALE AGREEMENT

BY AND AMONG

ALBIREO PHARMA, INC.

AND

ALBIREO AB

AND

SAGARD HEALTHCARE PARTNERS (DELAWARE) LP

DATED AS OF SEPTEMBER 22, 2022

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Exhibit A: Bill of Sale

Annex 1: Collateral Description for Albireo Pharma “Seller/Buyer” Financing Statement

Annex 2: Collateral Description for Albireo AB “Seller/Buyer” Financing Statement

Annex 3: Collateral Description for Albireo Pharma “Debtor/Secured Party” Financing Statement

Annex 4: Collateral Description for Albireo AB “Debtor/Secured Party” Financing Statement

PURCHASE AND SALE AGREEMENT

This PURCHASE AND SALE AGREEMENT, dated as of September 22, 2022 (this “Agreement”), is made and entered into by and among (i) Sagard Healthcare Partners (Delaware) LP, a Delaware limited partnership (“Buyer”), (ii) Albireo Pharma, Inc., a Delaware corporation (“Albireo Pharma”), and (iii) Albireo AB, a company incorporated under the laws of Sweden with registration number 556737-4631 (each of Albireo Pharma and Albireo AB, a “Seller” and, collectively, the “Sellers”).

WITNESSETH:

WHEREAS, Sellers are in the business of, among other things, developing and commercializing the Product; and

WHEREAS, Buyer desires to purchase the Sold Assets from Sellers in exchange for payment of the Purchase Price, and Sellers desire to sell the Sold Assets to Buyer in exchange for Buyer’s payment of the Purchase Price, in each case on the terms and conditions set forth in this Agreement.

NOW THEREFORE, in consideration of the representations, warranties, covenants and agreements set forth herein and for good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Sellers and Buyer hereby agree as follows:

ARTICLE 1 DEFINITIONS

Section 1.1 Definitions. The following terms, as used herein, shall have the following meanings:

“Affiliate” means, with respect to any particular Person, any other Person directly or indirectly controlling, controlled by or under common control with such particular Person. For purposes of the foregoing sentence, the term “control” means direct or indirect ownership of: (a) fifty percent (50%) or more (or, solely for purposes of Section 5.12(f), [***] percent ([***]%) or more), including ownership by trusts with substantially the same beneficial interests, of the voting and equity rights of such Person or (b) the power to direct the management or policies of such Person, whether through ownership of voting securities, by contract or otherwise.

“Agreement” is defined in the preamble.

“Albireo Pharma” is defined in the preamble

“Anti-Corruption Laws” means all laws, rules, regulations and orders of any jurisdiction from time to time concerning or relating to bribery or corruption, including the United States Foreign Corrupt Practices Act of 1977, the UK Bribery Act 2010 and other similar legislation in any other jurisdictions.

“Anti-Terrorism Laws” means all laws, rules, regulations and orders of any jurisdiction from time to time concerning or relating to terrorism or money laundering, including Executive



Order No. 13224, the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act and the laws administered by the U.S. Department of Treasury Office of Foreign Assets Control.

“Authorized Buyer Representatives” means [***].

“Bankruptcy Laws” means, collectively, bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance, fraudulent transfer or other similar laws affecting the enforcement of creditors’ rights generally.

“Bill of Sale” is defined in Section 3.2(b).

“Blended Rate” is defined in Section 5.12(a).

“Business Day” means any day other than (a) a Saturday or Sunday or (b) a day on which banking institutions located in New York, New York or Toronto, Canada are permitted or required by applicable law or regulation to remain closed.

“Buyer” is defined in the preamble.

“Buyer Indemnified Parties” is defined in Section 6.1(a).

“Change of Control” means (a) an issuance, sale or exchange of shares (or similar transaction or series of related transactions) of a Seller that results in the voting securities of such Seller outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent at least fifty percent (50%) of the outstanding voting securities of the surviving entity (or the parent of the surviving entity if such surviving entity is wholly owned by such parent) immediately after such transaction or series of related transactions, (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the direct or indirect beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of a Seller, (c) consummation of such other arrangement or agreement whereby the shareholders of a Seller with the actual power to appoint a majority of the board of directors (if any) no longer have the actual power, either directly or indirectly, to appoint a majority of the board of directors or (d) a “Change of Control” or any comparable term as defined in any agreement or obligation of a Seller involving, or relating to, any Indebtedness permitted by Section 5.12(a).

“Clinical Trial” means any clinical study involving the administration of a product to a human subject for the purpose of evaluating the safety, efficacy, performance or other characteristic of such product.

“Closing” means the closing of the sale, transfer, assignment and conveyance of the Sold Assets hereunder.

“Closing Date” has the meaning set forth in Section 3.1.

“Collateral” is defined in Section 2.1(b).

“Commercialization” means any and all activities directed to the distribution, marketing, detailing, promotion and selling of, and the securing of reimbursement with respect to, the Products in the Product Territory (including the using, importing, exporting, transporting, customs clearance, warehousing, invoicing, selling and offering for sale of the Products, and the handling and delivering of the Products to customers), and shall include post-Marketing Approval studies to the extent required by a Regulatory Authority and regulatory compliance with respect to each of the foregoing. When used as a verb, “Commercialize” means to engage in Commercialization. Except with respect to post-Marketing Approval studies required by a Regulatory Authority, Commercialization shall not include any activities directed to the research or development (including pre-clinical and clinical development) or manufacture of the Products.

“Commercially Reasonable Efforts” means [***].

“Competing Product” means [***].

“Compound” means the chemical compound odevixibat (also known as A4250, [***]), [***].

“Confidential Information” is defined in Section 7.1.

“Control Agreement” means a control agreement in favor of Buyer and in form and substance satisfactory to Buyer, among Albireo Pharma, Buyer and Silicon Valley Bank, pursuant to which Buyer obtains “control” (as defined in Article 9 of the UCC) over the Controlled Account.

“Control Agreement Conditions” is defined in Section 3.4(a).

“Controlled Account” is defined in Section 5.18(a).

“Controlled Account Assets” means, collectively, (a) the Controlled Account, (b) all money deposited in or credited to the Controlled Account, (c) all rights to access the books and records relating to or evidencing any of the foregoing and (d) all “proceeds” (as defined in Article 9 of the UCC) (cash or non-cash) of each of the foregoing.

“COVID-19” means SARS-CoV-2 or COVID-19, and any evolutions or variants thereof or related or associated epidemics, pandemic or disease outbreaks.

“COVID-19 Measures” means quarantine, “shelter in place,” “stay at home,” workforce reduction, social distancing, shut down, closure, sequester, safety or similar laws, directives, restrictions, guidelines, responses or recommendations of or promulgated by any Governmental Entity, including the Centers for Disease Control and Prevention and the World Health Organization, or other reasonable actions taken, in each case, in connection with or in response to COVID-19 and any evolutions, variants or mutations thereof or related or associated epidemics, pandemics or disease outbreaks.

“Disclosing Party” is defined in Section 7.1.



“Disclosure Schedule” means the Disclosure Schedule, dated as of the date hereof, delivered to Buyer by Sellers concurrently with the execution of this Agreement.

“Disposition” or “Dispose” means, with respect to any Person, directly or indirectly, the sale, assignment, conveyance, transfer, license, sublicense or other disposition (whether in a single transaction or a series of related transactions) (including by way of a sale and leaseback transaction) of property or assets by any Person.

“Distributor” means a Third Party that (a) purchases or has the option to purchase the Products in finished form from or at the direction of a Seller or any of its Affiliates, (b) has the right, option or obligation to distribute, market and sell the Products (with or without packaging rights) in one or more regions and (c) does not otherwise make any royalty, milestone, profit share or other similar payment to a Seller or its Affiliates based on such Third Party’s sale of the Products. The term “packaging rights” in this definition will mean the right for the Distributor to package or have packaged the Products supplied in unpackaged bulk form into individual ready-for-sale packs.

“EMA” means the European Medicines Agency, or any successor agency thereto.

“Event of Default” means the following:

(a) Non-Payment. Sellers fail to pay any amount to Buyer when and as required to be paid herein pursuant to this Agreement and such failure continues for more than [***] ([***)] Business Days after written notice of such failure is given to Sellers by Buyer.

(b) Certain Covenants. Sellers or any of their Subsidiaries fail to perform or observe any of the terms and conditions set forth in Section 5.1(d), Section 5.12, Section 5.15 or Section 5.18.

(c) Security Interests. The Security Interests granted by Albireo Pharma shall cease to be in full force and effect, or shall cease to give the rights, powers and privileges purported to be created and granted hereunder in favor of Buyer pursuant hereto, or shall be asserted by a Seller not to be a valid, perfected first lien security interest in and to all right, title and interest in, to and under the Collateral granted by Albireo Pharma (or any material portion thereof).

(d) Marketing Approval. There occurs (i) any revocation, withdrawal, suspension or cancellation of any Marketing Approval of any Product which results in Sellers being prevented from marketing or selling such Product in any country located within the Major Markets other than the United States, and such revocation, withdrawal, suspension or cancellation continues for at least [***] ([***)] calendar days or (ii) any revocation, withdrawal, suspension or cancellation of any Marketing Approval of any Product by the FDA which results in Sellers being prevented from marketing or selling such Product in the United States.

(e) Bankruptcy. (i) A Seller or any Subsidiary of a Seller institutes or consents to the institution of any proceeding under any Bankruptcy Law, (ii) any receiver, trustee, custodian, conservator, liquidator, rehabilitator or similar officer is appointed for a Seller or for any Subsidiary of a Seller under any Bankruptcy Law without the application or consent of such

Seller or such Subsidiary, as the case may be, and the appointment continues undischarged or unstayed for [***] ([***)] calendar days, (iii) a Seller or any Subsidiary of a Seller seeks or consents to the appointment under any Bankruptcy Law of any receiver, trustee, custodian, conservator, liquidator, rehabilitator or similar officer, (iv) any proceeding under any Bankruptcy Law relating to a Seller or any Subsidiary of a Seller or relating to all or any material portion of the property of a Seller or of any Subsidiary of a Seller is instituted without the consent of such Seller or such Subsidiary, as the case may be, and continues undismissed or unstayed for [***] ([***)] calendar days or an order for relief is entered in any such proceeding, (v) a Seller or any Subsidiary of a Seller makes a general assignment for the benefit of creditors, (vi) a Seller or any Subsidiary of a Seller becomes unable to pay its debts as they become due, or becomes unable to pay or perform under this Agreement, or becomes insolvent, (vii) a Seller is liquidated or dissolved, (viii) any action is taken or proceeding instituted, or any relief is granted, under any non-U.S. laws that are similar to the actions, proceedings and relief described in the immediately preceding clauses (i) through (vi), or (ix) a Seller or any Subsidiary of a Seller shall take any corporate action to authorize any of the foregoing items described in clauses (i) through (vii) above.

(f) Financial Statements; Seller Actions. A Seller or any of its Subsidiaries fails to perform or observe any of the terms and conditions set forth in Section 5.10 or Section 5.11, provided that in the case any such failure is capable of being cured, Sellers and their Subsidiaries shall have [***] ([***)] Business Days after written notice of such failure shall have been given to Sellers by Buyer to cure such failure.

(g) Breach of Obligations. Except as set forth in clause (a), clause (b) and clause (f) above, the breach or default by a Seller or any of its Subsidiaries of any of their obligations, covenants or agreements contained in this Agreement, provided that in the case any such breach or default is capable of being cured, Sellers and their Subsidiaries shall have [***] ([***)] Business Days after written notice of such breach or default shall have been given to Sellers by Buyer to cure such breach or default.

(h) Representations. Any representation or warranty made by a Seller in or pursuant to this Agreement shall have been false or misleading in any material respect when made or when deemed made.

(i) Other Debt. Any event or condition shall occur which results in the acceleration of the maturity of any Indebtedness permitted by Section 5.12(a) or enables the holder of such Indebtedness or any Person acting on such holder's behalf to accelerate the maturity thereof.

“Excluded Assets” means (a) the Included Product Revenue, (b) any and all Specified Agreements and (c) all other Collateral pledged pursuant to Section 2.1(b).

“Existing Confidentiality Agreement” means that certain Confidentiality Agreement, dated [***], by and between Albireo Pharma and Sagard Healthcare Royalty Partners, LP (an affiliate of Buyer).

“Existing In-License” is defined in Section 4.1(h)(i).

“Existing Patent Rights” is defined in Section 4.1(k)(i).

“Existing Specified Agreement” is defined in Section 4.1(h)(ii).

“Existing Trademark Rights” is defined in Section 4.1(k)(i).

“FD&C Act” means the federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.), as amended, and the regulations promulgated thereunder.

“FDA” means the U.S. Food and Drug Administration, or any successor agency thereto.

“FDA Application Integrity Policy” is defined in Section 4.1(g)(ii).

“GAAP” means generally accepted accounting principles in the United States or under local law, as applicable, in effect from time to time.

“Governmental Entity” means any: (a) nation, principality, republic, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or other entity and any court, arbitrator or other tribunal); or (d) individual, body or other entity exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

“Gross Sales” is defined in the definition of “Net Sales.”

“Guarantee Agreement” is defined in Section 5.20.

“IFRS” means International Financial Reporting Standards in effect from time to time.

“Improvements” means any improvement, invention or discovery relating to a Compound or a Product, including any formulation, method of use, or method of manufacture of a Product.

“Included Product Revenue” means (a) Net Sales of all Products and (b) all Other Product Revenue.

“Included Product Revenue Royalty Rate” means, for the purposes of Royalty Payments payable hereunder, (a) prior to Marketing Approval of a Product by the FDA to treat biliary atresia, the tiered percentages of Included Product Revenue set forth in the first chart below and (b) from and after Marketing Approval of a Product by the FDA to treat biliary atresia, the tiered percentages of Included Product Revenue set forth in the second chart below; provided, that the aggregate amount of Royalty Payments, together with any Specified Other Amounts, hereunder shall in no event exceed the Royalty Cap.



Adjusted Payment Tiers Prior to Marketing Approval of a Product by the FDA to Treat Biliary Atresia	Included Product Revenue Royalty Rate
For Included Product Revenue in respect of the Products in the Product Territory in any calendar year up to and including \$250,000,000	12.5%
For Included Product Revenue in respect of the Products in the Product Territory in any calendar year in excess of \$250,000,000 but less than or equal to \$350,000,000	5.0%
For Included Product Revenue in respect of the Products in the Product Territory in any calendar year in excess of \$350,000,000	5.0%

Adjusted Payment Tiers from and after Marketing Approval of a Product by the FDA to Treat Biliary Atresia	Included Product Revenue Royalty Rate
For Included Product Revenue in respect of the Products in the Product Territory in any calendar year up to and including \$250,000,000	12.5%
For Included Product Revenue in respect of the Products in the Product Territory in any calendar year in excess of \$250,000,000 but less than or equal to \$350,000,000	5.0%
For Included Product Revenue in respect of the Products in the Product Territory in any calendar year in excess of \$350,000,000	1.0%

“In-License” means any license, settlement agreement or other agreement or arrangement between a Seller or any of its Affiliates and any Third Party pursuant to which such Seller or any of its Affiliates obtains a license or sublicense or a covenant not to sue or similar grant of rights to any Patents or other intellectual property rights of such Third Party that is necessary or reasonably useful for the research, development, manufacture, supply, testing, seeking or obtaining regulatory approval (including Marketing Approval), use, distribution or Commercialization of the Compound or any Product in any country in the Product Territory. For the avoidance of doubt, the Parties agree that ordinary course, non-exclusive reagent agreements,

software agreements, clinical trial agreements, services agreements, sponsorship agreements, material transfer agreements and research agreements shall not be considered In-Licenses.

“Indebtedness” of any Person means (i) all obligations of such Person for borrowed money, (ii) all obligations of such Person evidenced by a note, bond, debenture or similar instrument, (iii) all obligations of such Person under conditional sale or other title retention agreements relating to property acquired by such Person, (iv) all obligations of such Person in respect of the deferred purchase price of property or services (excluding deferred compensation and accounts payable incurred in the ordinary course of business and not overdue by more than [***] days), (v) all indebtedness of others secured by (or for which the holder of such indebtedness has an existing right, contingent or otherwise, to be secured by) any Lien on property owned or acquired by such Person if the indebtedness secured thereby has been assumed, (vi) all guarantees by such Person of indebtedness of others, (vii) all capital lease obligations of such Person, (viii) all obligations, contingent or otherwise, of such Person as an account party in respect of letters of credit and letters of guaranty, (ix) all obligations of such Person under any interest rate exchange agreement, foreign currency exchange agreement, commodity price protection agreement, currency swap, forward, future or derivative transactions or other interest or currency exchange rate or commodity price hedging arrangement, (x) all obligations, contingent or otherwise, of such Person in respect of bankers’ acceptances, surety bonds and letters of credit, (xi) any equity securities of such Person subject to repurchase or redemption other than at the sole option of such Person and (xii) all other obligations required to be classified as indebtedness of such Person under GAAP or IFRS; provided that, notwithstanding the foregoing, Indebtedness shall not include accrued expenses, deferred rent, deferred taxes, deferred compensation or customary obligations under employment agreements.

“Indemnified Party” is defined in Section 6.2.

“Indemnifying Party” is defined in Section 6.2.

“Intellectual Property Rights” means any and all of the following as they exist in the Product Territory in respect of any Compound or Product at any time: (a) the Patent Rights, (b) the Know-How Rights, (c) the Trademark Rights, and (d) any and all other intellectual property rights and/or proprietary rights, whether or not patentable (including any non-published and proprietary information or data contained in any Marketing Approval for any Product), in each case of clauses (a)-(d), owned or controlled by a Seller or any of its Affiliates or under which a Seller or any of its Affiliates is or may become empowered to grant licenses, in each case of clauses (a)-(d), that are necessary or reasonably useful for the research, development, manufacture, supply, testing, seeking or obtaining regulatory approval (including Marketing Approval), use, distribution or Commercialization of the Compound or any Product in any country in the Product Territory.

“Intercreditor Agreement” is defined in Section 5.12(a).

“Judgment” means any judgment, order, writ, injunction, citation, award or decree of any nature.



“Know-How” means any and all proprietary and confidential information, know-how, discoveries, enhancements, improvements, developments, technical information, and trade secrets, including processes, formulae, models, techniques, operating records, development reports, compositions, manufacturing technology, validations, package specifications, copies of the master batch records (manufacturing and packaging), chemical specifications, chemical and finished goods analytical test methods, stability samples and prototypes, clinical data, safety data and other regulatory information, product and raw material specifications, scale-up and other technical data, reports, documentation and samples (but excluding rights in research in progress, algorithms, data, databases, data collections, chemical and biological materials and the results of experimentation and testing).

“Know-How Rights” means any and all Know-How owned or controlled by a Seller or any of its Affiliates or under which a Seller or any of its Affiliates is or may become empowered to grant licenses (including, for the avoidance of doubt, Know-How related to Improvements), in each case, that are necessary or reasonably useful for the research, development, manufacture, supply, testing, seeking or obtaining regulatory approval (including Marketing Approval), use, distribution or Commercialization of the Compound or any Product in any country in the Product Territory.

“Knowledge of Seller” means, with respect to each Seller, the actual knowledge of the individuals listed on Schedule 1.1(b) of the Disclosure Schedule, after reasonable due inquiry.

“Licensee” means the counterparty under any Out-License. For clarity, a Distributor shall not be deemed to be a “Licensee.”

“Lien” means any mortgage, lien, pledge, participation interest, charge, adverse claim, security interest, encumbrance or restriction of any kind, including any restriction on use, transfer or exercise of any other attribute of ownership of any kind.

“Loss” means any and all Judgments, damages, losses, claims, costs, liabilities and expenses, including Taxes and reasonable fees and out-of-pocket expenses of counsel.

“Major Markets” means the United States, the United Kingdom and the European Union.

“Marketing Approval” means, an NDA approved by the FDA, a Marketing Authorization Application approved by the EMA under the centralized European procedure, or any corresponding non-U.S. or non-EMA application, registration or certification, as applicable, necessary or reasonably useful to Commercialize any Product approved by the corresponding Regulatory Authority in the Product Territory, including pricing and reimbursement approvals where required.

“Material Adverse Effect” means

(a) a material adverse effect on the value of the Royalty Payments (including the timing, duration or amount thereof); or

(b) a material adverse effect on (i) a Product in the Product Territory, (ii) any of the Patent Rights claiming the composition of matter of a Product, including a Seller’s rights in or to

any such Patent Rights, (iii) any Marketing Approval of a Product or the timing thereof in the Major Markets, (iv) the legality, validity or enforceability of any provision of this Agreement or the other Transaction Documents, (v) the ability of a Seller to perform any of its obligations under this Agreement or the other Transaction Documents or to consummate the transactions contemplated hereby or thereby, (vi) the rights or remedies of Buyer under this Agreement or the other Transaction Documents (including the Security Interests (subject to Section 1.2(d)) and Buyer's rights in, to and under the Revenue Participation Right) (in each instance of this clause (vi), to the extent such rights or remedies have not been specifically waived by Buyer in accordance with Section 9.5) or (vii) the business, assets, properties, liabilities (actual or contingent), operations or condition (financial or otherwise) of a Seller, individually, or of Sellers and their Subsidiaries taken as a whole. For the avoidance of doubt, notwithstanding anything to the contrary in this Agreement, neither the signing by Seller of a definitive written agreement with respect to a Specified Transaction nor the consummation of a Specified Transaction in compliance with Section 5.12(e) shall, in and of itself, constitute a Material Adverse Effect.

“NDA” means a New Drug Application, as defined in Section 505 of the FD&C Act (21 U.S.C. § 355) and the implementing regulations promulgated thereunder by the FDA and codified at 21 C.F.R. Part 314.

“Net Sales” means, for any period, the gross amount invoiced, billed or otherwise recorded for sales of any Product anywhere in the Product Territory, as applicable, for that period by or on behalf of Sellers, any of their Affiliates, any Distributors, any Licensees, any other Specified Counterparties or any sublicensees of any of the foregoing (regardless of tier) (each of the foregoing Persons, for purposes of this definition, shall be considered a “Related Party”) to a Third Party (“Gross Sales”) less the following amounts, to the extent actually incurred or accrued (in accordance with GAAP, consistently applied) by a Related Party and not reimbursed by such Third Party, provided that any given amount may be taken as a permitted deduction only once: [***].

For clarity, “Net Sales” will not include (i) sales or dispositions (at no cost or substantially reduced cost) for charitable, promotional, pre-clinical, clinical, regulatory, compassionate use, named patient use or indigent or other similar programs, Products used as samples, and Products used in the development of the Products or (ii) sales or dispositions between any of the Related Parties (unless a Related Party is the final end-user of the Products); provided that the first sale or disposition of a given unit of a Product to a non-Related Party will be included within “Net Sales.”

With respect to sales of a Product invoiced in U.S. dollars, Net Sales shall be determined in U.S. dollars. With respect to sales of a Product invoiced in a currency other than U.S. dollars, Net Sales shall be determined by converting the currencies at which the sales are made into U.S. dollars, at rates of exchange determined in a manner consistent with Sellers' method for calculating rates of exchange in the preparation of Sellers' annual financial statements in accordance with GAAP consistently applied. For purposes of determining Net Sales, a Product shall be deemed to be sold when recorded by the applicable Related Party in accordance with GAAP consistently applied. “Net Sales” shall also include the amounts described in Section 5.4(c).



“New York Courts” is defined in Section 9.9(a).

“Orange Book Patents” is defined in Section 5.4(b).

“Other Product Revenue” shall mean all payments, compensation, consideration, proceeds and other amounts that Sellers or any of their Affiliates actually receive from (and is not required to repay or refund to) a Specified Counterparty or any of such Specified Counterparty’s affiliates or sublicensees (regardless of tier) under or pursuant to a Specified Agreement (or any sublicense under or other agreement ancillary to such Specified Agreement), including: [***].

Notwithstanding the foregoing, Other Product Revenue specifically excludes (i) amounts received by Sellers solely in consideration for a Change of Control (and not in respect of any related transaction that constitutes an Out-License or other Specified Agreement), but only if (A) Buyer has delivered a Put Option Notice in respect of such Change of Control in accordance with Section 2.3(b) and (B) Buyer has actually received the Put/Call Payment Amount in respect of such Change of Control in accordance with Section 2.3(b), (ii) any consideration received by Sellers or any of their Affiliates as payment or reimbursement for research costs incurred by Sellers or any of their Affiliates, including costs associated with materials, equipment or clinical testing and (iii) any amount that constitutes Net Sales under clause (a) of the definition of “Included Product Revenue.” If a Specified Agreement involves the granting of Commercialization rights with respect to a Product and also grants rights with respect to any product that is not a Product, then “Other Product Revenue” shall be the amounts of the consideration attributable to the grant of rights with respect to such Product, as reasonably determined by the Parties in good faith.

[***].

“Out-License” means each license, settlement agreement or other agreement, contract or arrangement between a Seller or any of its Affiliates and any Third Party (other than Distributors) pursuant to which a Seller or any of its Affiliates grants a license, sublicense or similar grant of any Intellectual Property Right that is necessary or reasonably useful for the research, development, manufacture, supply, testing, seeking or obtaining regulatory approval (including Marketing Approval), use, distribution or Commercialization of the Compound or any Product in any country in the Product Territory. For the avoidance of doubt, any co-promotion agreement for the Product within the Product Territory between a Seller or any of its Affiliates and any Third Party shall not be deemed an “Out-License” hereunder.

“Party” means Buyer or any Seller, individually, and “Parties” means Buyer and Sellers collectively.

“Patent Rights” means any and all Patents owned or controlled by a Seller or any of its Affiliates or under which such Seller or any of its Affiliates is or may become empowered to grant licenses (including, for the avoidance of doubt, Patents related to Improvements) that are necessary or reasonably useful for the research, development, manufacture, supply, testing, seeking or obtaining regulatory approval (including Marketing Approval), use, distribution or Commercialization of the Compound or any Product in any country in the Product Territory, as

well as existing or future Patents covering any Improvements in any country in the Product Territory.

“Patents” means (i) any and all national, regional and international patents and patent applications, including United States and foreign patents and provisional patent applications; (ii) any patent applications claiming priority or filed from such patents, patent applications or provisional applications or from an application claiming priority to any of these, including continuations, continuations-in-part, divisions, provisionals, converted provisionals, continued prosecution applications, and substitutions; (iii) any patents that have issued or in the future issue from the foregoing patent applications described in clauses (i) and (ii), including utility models, patents of addition, petty patents and design patents and certificates of invention; and (iv) any patent term extension under 35 U.S.C. §156 or any non-U.S. counterpart or equivalent of the foregoing, including [***].

“Permits” is defined in Section 4.1(g)(vi).

“Permitted Debt” means the following:

- (a) any Indebtedness of Sellers in favor of Buyer arising under this Agreement;
- (b) unsecured Indebtedness to trade creditors incurred in the ordinary course of business;
- (c) guarantees of Sellers and their Subsidiaries in respect of Indebtedness and other obligations of any Seller and of any of its Subsidiaries otherwise permitted hereunder;
- (d) Indebtedness incurred by Sellers or their Subsidiaries consisting of (i) the financing of the payment of insurance premiums, (ii) take or pay obligations contained in supply agreements, in each case, in the ordinary course of business and consistent with past practice, (iii) deferred compensation or equity based compensation to current or former officers, directors, consultants, advisors or employees thereof, in each case in the ordinary course of business and consistent with past practice and (iv) customer deposits and advance payments received in the ordinary course of business and consistent with past practice from customers for goods or services purchased in the ordinary course of business and consistent with past practice;
- (e) Indebtedness owed to any Person providing worker’s compensation, health, disability or other employee benefits or property, casualty or liability insurance to Sellers or any of their Subsidiaries incurred in connection with such Person providing such benefits or insurance pursuant to customary reimbursement or indemnification obligations to such Person;
- (f) Indebtedness in respect of performance, indemnity, bid, stay, customs, appeal, replevin and surety bonds, performance and completion guarantees and other similar bonds or guarantees, trade contracts, government contracts and leases, in each case, incurred in the ordinary course of business;

- (g) Indebtedness arising from (i) the honoring by a bank or other financial institution of a check, draft or similar instrument drawn against insufficient funds in the ordinary course of business and (ii) any treasury management or hedging arrangements entered into in the ordinary course of business;
- (h) (i) letters of credit, bankers' acceptances, guarantees or other similar instruments or obligations issued or relating to liabilities or obligations incurred in the ordinary course of business and (ii) Indebtedness arising from other cash management services in the ordinary course of business (provided, however, that Indebtedness described in, and permitted by, this clause (h) shall not at any time, individually or in the aggregate, exceed \$[***]);
- (i) judgments, decrees, attachments or awards (to the extent that they would be deemed Indebtedness) (provided, however, that Indebtedness described in, and permitted by, this clause (i) shall not at any time, individually or in the aggregate, exceed \$[***]);
- (j) Indebtedness in the form of (i) guarantees of loans and advances to officers, directors, consultants, managers and employees, in the ordinary course of business and consistent with past practice and (ii) reimbursements owed to officers, directors, managers, consultants and employees of Sellers or any of their Subsidiaries for business expenses of Sellers or any of their Subsidiaries;
- (k) Indebtedness consisting of obligations to make payments to current or former officers, directors and employees of Sellers or any of their Subsidiaries, their respective estates, spouses or former spouses with respect to the cancellation, purchase or redemption of equity interests of Sellers or any of their Subsidiaries;
- (l) Indebtedness (i) of a Person existing at the time such Person becomes a Subsidiary of Sellers through the acquisition of the equity interests in such Subsidiary, (ii) assumed in connection with the acquisition of assets from such Person or (iii) of a Person at the time such Person merges or amalgamates with or into or consolidates or otherwise combines with any of the Sellers or any of their Subsidiaries, in each case, so long as such Indebtedness was not incurred in connection with, or in anticipation or contemplation of, such Person becoming a Subsidiary or such acquisition, merger, amalgamation or consolidation, as the case may be (provided, however, that Indebtedness described in, and permitted by, this clause (l) shall not at any time, individually or in the aggregate, exceed \$[***]);
- (m) Indebtedness arising from agreements providing for indemnification, holdback, earnout, adjustment of purchase price, working capital adjustments or similar obligations, in each case incurred in connection with the disposition or acquisition of any business or assets of a Seller or any of its Subsidiaries or equity interests of a Subsidiary that is permitted under this Agreement;



- (n) Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness, in each case, incurred to finance the acquisition, repair, improvement or construction of fixed or capital assets of such Person, provided that the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the property so acquired or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made) (provided, further, however, that Indebtedness described in, and permitted by, this clause (n) shall not at any time, individually or in the aggregate, exceed \$[***]);
- (o) Indebtedness incurred in the ordinary course of business with corporate credit cards (including, without limitation, travel and entertainment expenses and similar expenses incurred in the ordinary course of business); and
- (p) intercompany Indebtedness of any of the Sellers or of any of their Subsidiaries owing to any of the Sellers or to any of their Subsidiaries (provided, however, that, the aggregate outstanding balance of Indebtedness described in, and permitted by, this clause (p) in respect of which a Seller is a lender (other than such Indebtedness that constitutes a Permitted Payment) shall at no time exceed \$[***]); and
- (q) other unsecured Indebtedness in an amount not to exceed \$[***] at any time outstanding.

“Permitted License” means:

- (a) [***];
 - (b) any license or sublicense of any Intellectual Property Right between Sellers; and
 - (c) any license or sublicense of any Trademark Rights or any copyrights constituting Intellectual Property Rights between Sellers and their Subsidiaries;
- provided, that [***].

“Permitted Liens” means the following:

- (a) Liens for Taxes, assessments or governmental charges or levies not yet due or which are being contested in good faith and by appropriate proceedings and for which adequate reserves determined in accordance with GAAP have been established;
- (b) statutory Liens of landlords and Liens of carriers, warehousemen, mechanics, materialmen and suppliers and other Liens imposed by law or pursuant to customary reservations or retentions of title arising in the ordinary course of business, provided that such Liens secure only amounts not yet due and payable or, if due and payable, are unfiled and no other action has been taken to enforce the same or are being contested in good faith by appropriate proceedings for

which adequate reserves determined in accordance with GAAP have been established;

- (c) rights of any counterparty pursuant to (i) any Existing In-Licenses or (ii) any other In-Licenses that constitute Permitted Licenses, including any interest or title of a counterparty under (A) an Existing In-License or (B) any other In-License that constitutes a Permitted License;
- (d) Liens created in favor of Buyer pursuant to this Agreement;
- (e) any license grant to a Licensee under a Permitted License;
- (f) pledges or deposits made in the ordinary course of business in connection with bids, contract leases, appeal bonds, workers' compensation, unemployment insurance or other similar social security legislation;
- (g) servitudes, easements, rights of way, restrictions and other similar encumbrances on real property imposed by any law and Liens consisting of zoning or building restrictions, easements, licenses, restrictions on the use of property or minor imperfections in title thereto which, individually and in the aggregate, are not material, and which do not in any case materially detract from the value of the property subject thereto or interfere with the ordinary conduct of the business of a Seller or any of its Subsidiaries;
- (h) Liens in favor of customs and revenue authorities arising as a matter of law to secure payment of customs duties in connection with the importation of goods and incurred in the ordinary course of business;
- (i) bankers' liens, rights of setoff and similar Liens incurred on deposits made in the ordinary course of business;
- (j) Liens arising from precautionary UCC financing statement filings regarding operating leases of personal property and consignment arrangements entered into in the ordinary course of business;
- (k) Liens securing capitalized lease obligations and purchase money Indebtedness that, in each case, are permitted under clause (n) of the definition of "Permitted Debt";
- (l) leasehold interests in leases or subleases and licenses or sublicenses (excluding, in each case, In-Licenses, Out-Licenses and other Specified Agreements) granted in the ordinary course of business and not interfering in any material respect with the business of a Seller or any of its Subsidiaries;
- (m) Liens on insurance proceeds securing the payment of financed insurance premiums that are promptly paid on or before the date they become due (provided that such Liens extend only to such insurance proceeds and not to any other property or assets);

- (n) (A) Liens on cash securing obligations permitted under clause (h) of the definition of “Permitted Debt” and (B) security deposits in connection with real property leases, the combination of (A) and (B) in an aggregate amount not to exceed \$[***] at any time;
- (o) Liens on property existing at the time of acquisition of such property, provided, that such Liens (i) were in existence prior to such acquisition and not incurred in contemplation thereof and (ii) do not extend to any other property or assets; and
- (p) additional Liens that do not exceed \$[***] in the aggregate.

“Permitted Payments” means the following:

- (a) payments by a Seller in the ordinary course of business to any of its Subsidiaries (other than a Subsidiary that is (x) a Seller, (y) a Subsidiary Guarantor or (z) Elobix AB, in accordance with clause (c) below) to allow such Subsidiaries to pay (i) Taxes, (ii) compensation, benefits and other employee related expenses, and (iii) expenses necessary to maintain such Subsidiaries’ legal existence (provided, however, that the net value of all payments described in, and permitted by, this clause (a), together with the net value of all payments described in, and permitted by, clause (b) below, shall not, individually or in the aggregate, exceed \$[***] in any calendar year) (it being understood and agreed that (1) the amount of any payment described in, and permitted by, this clause (a) that constitutes intercompany Indebtedness shall be measured by reference to the aggregate outstanding balance of such Indebtedness and (2) for the calendar year ending December 31, 2022, the dollar limit set forth in this clause (a) shall instead be \$[***]);
- (b) payments by a Seller in the ordinary course of business to any of its Subsidiaries (other than a Subsidiary that is (x) a Seller, (y) a Subsidiary Guarantor or (z) Elobix AB, in accordance with clause (c) below) to fund payments to Third Parties that Sellers and/or one or more of their Subsidiaries are otherwise permitted to make under this Agreement (provided, however, that the net value of all payments described in, and permitted by, this clause (b), together with the net value of all payments described in, and permitted by, clause (a) above, shall not, individually or in the aggregate, exceed \$[***] in any calendar year) (it being understood and agreed that (1) the amount of any payment described in, and permitted by, this clause (b) that constitutes intercompany Indebtedness shall be measured by reference to the aggregate outstanding balance of such Indebtedness and (2) for the calendar year ending December 31, 2022, the dollar limit set forth in this clause (b) shall instead be \$[***]);
- (c) payments by Albireo AB to Elobix AB in the ordinary course of business in connection with Swedish group company tax rules (it being understood and agreed that the amount of any such payments shall not be included in the calculation of any aggregate payment to be determined pursuant to clauses (a) and (b) of this definition);

- (d) payments between Albireo Pharma and Albireo AB (it being understood and agreed that the amount of any such payments shall not be included in the calculation of any aggregate payment to be determined pursuant to clauses (a) and (b) of this definition); and
- (e) all payments between a Seller and a Subsidiary Guarantor or wholly between Subsidiary Guarantors (it being understood and agreed that the amount of any such payments shall not be included in the calculation of any aggregate payment to be determined pursuant to clauses (a) and (b) of this definition, including for any applicable calendar year in which such Subsidiary becomes a Subsidiary Guarantor).

For the purposes of clauses (a) – (e), a “payment” shall be deemed to include intercompany Indebtedness pursuant to which a Seller is the lender. The Parties hereby acknowledge and agree that (I) clauses (a), (b), (c) and (d) above may be modified by mutual agreement of the Parties, and (II) other payments not described in, nor permitted by, clauses (a), (b), (c) and (d) above may be made, in each case with Buyer’s prior written consent (such consent not to be unreasonably withheld, conditioned or delayed). Buyer hereby agrees to respond to any written request for such consent [***] following Buyer’s receipt of such written request from the Sellers for such consent and that any failure by Buyer to so respond shall be deemed consent.

“Person” means any individual, firm, corporation, company, partnership, limited liability company, trust, joint venture, association, estate, trust, Governmental Entity or other entity, enterprise, association or organization.

“Phase 2 Clinical Trial” means a Clinical Trial of one or more products that is designed to be conducted on a sufficient number of patients with the disease or condition for which the product is being developed for, and that generally provides for making a preliminary determination of whether such product(s) is safe for its intended use and to obtain information about such product(s)’ efficacy, in a manner that meets the requirements of 21 C.F.R. § 312.21(b) (or its successor regulation), or a similar Clinical Trial prescribed by the applicable Regulatory Authority(ies) in a country outside the United States, to permit the design of further Clinical Trials of such product(s) (regardless of whether such Clinical Trial is denominated “Phase 2,” “Phase 1/2a,” “Phase 1/2b,” “Phase 2/2b” or otherwise denominated).

“Pivotal/Phase 3 Clinical Trial” means a pivotal, registration-enabling, randomized and controlled Clinical Trial of one or more products with a defined dose or a set of defined doses of such product(s), which is designed to be conducted on a sufficient number of patients with the disease or condition for which the product is being developed for ascertaining the efficacy and safety of the intended use of such product(s), in a manner that meets the requirements of 21 C.F.R. § 312.21(c), or a similar Clinical Trial prescribed by the applicable Regulatory Authority(ies) in a country outside the United States.

“Post-Closing Specified Transaction Notice” is defined in Section 5.12(e)(ii).

“Pre-Closing Specified Transaction Notice” is defined in Section 5.12(e)(i)(C).

“Prime Rate” means the prime rate published by *The Wall Street Journal*, from time to time, as the prime rate.

“Product” and “Products” means, individually and collectively, any and all pharmaceutical products, including all forms, presentations, strengths, doses and formulations (including any method of delivery), containing the Compound alone or in combination with at least one other therapeutically active ingredient. For the avoidance of doubt, “Product” shall include odevixibat (also known as A4250, [***]) [***].

“Product Exit” a sale, Out-License or other form of Disposition of any Product by a Seller within the United States. For the avoidance of doubt, neither (i) a Change of Control nor (ii) [***] shall be deemed a “Product Exit” hereunder.

“Product Rights” means any and all of the following, as they exist throughout the Product Territory at any time: [***].

“Product Territory” means, solely with respect to the Products, the entire world.

“Purchase Price” is defined in Section 2.2.

“Put Option Event” is defined in Section 2.3(b).

“Put Option Notice” is defined in Section 2.3(b).

“Put/Call Payment Amount” means:

(a) on or before the third anniversary of the Closing Date, an amount equal to one hundred thirty percent (130%) of the Purchase Price *less* the aggregate amount of all of the Royalty Payments and Specified Other Amounts actually received by Buyer (or any Buyer Indemnified Party) pursuant to this Agreement as of the Business Day prior to the date that Sellers actually wire such amount to Buyer pursuant to Section 2.3 or Section 5.12(e);

(b) after the third anniversary of the Closing Date but on or before the fourth anniversary of the Closing Date, an amount equal to one hundred forty-five percent (145%) of the Purchase Price *less* the aggregate amount of all of the Royalty Payments and Specified Other Amounts actually received by Buyer (or any Buyer Indemnified Party) pursuant to this Agreement as of the Business Day prior to the date that Sellers actually wire such amount to Buyer pursuant to Section 2.3 or Section 5.12(e);

(c) after the fourth anniversary of the Closing Date but on or before the fifth anniversary of the Closing Date, an amount equal to one hundred sixty-five percent (165%) of the Purchase Price *less* the aggregate amount of all of the Royalty Payments and Specified Other Amounts actually received by Buyer (or any Buyer Indemnified Party) pursuant to this Agreement as of the Business Day prior to the date that Sellers actually wire such amount to Buyer pursuant to Section 2.3 or Section 5.12(e); or

(d) after the fifth anniversary of the Closing Date, an amount equal to two hundred percent (200%) of the Purchase Price *less* the aggregate amount of all of the Royalty Payments

and Specified Other Amounts actually received by Buyer (or any Buyer Indemnified Party) pursuant to this Agreement as of the Business Day prior to the date that Sellers actually wire such amount to Buyer pursuant to Section 2.3 or Section 5.12(e).

“Receiving Party” is defined in Section 7.1.

“Register” is defined in Section 9.4(b).

“Regulatory Authority” means any national or supranational governmental authority, including the FDA, the EMA or such equivalent regulatory authority, or any successor agency thereto, that has responsibility in granting a Marketing Approval.

“Regulatory Exclusivity Period” shall mean, with respect to any Product in any country in the Product Territory, any period of data, market or other regulatory exclusivity (other than Patent exclusivity) granted or afforded by law or by a Regulatory Authority in such country that confers exclusive marketing rights with respect to such Product in such country or prevents another party from using or otherwise relying on any data supporting the Marketing Approval for such Product.

“Related Party” is defined in the definition of “Net Sales.”

“Reports” is defined in Section 5.1(a).

“Representative” means, with respect to any Person, (a) any direct or indirect equityholder, member or partner of such Person and (b) any manager, director, trustee, officer, employee, agent, advisor or other representative (including attorneys, accountants, consultants, contractors, actual and potential financing providers, investors, co-investors and assignees, bankers and financial advisers) of such Person.

“Revenue Participation Right” means the right to receive the Royalty Payments payable with respect to Included Product Revenue during the period from (and including) the Closing Date through (and including) the Royalty Termination Date.

“ROFO Notice” is defined in Section 5.16.

“ROFO Period” is defined in Section 5.16.

“Royalty Cap” means one hundred sixty percent (160%) of the Purchase Price; provided that if the aggregate amount of all of the Royalty Payments and Specified Other Amounts actually received by Buyer (or any Buyer Indemnified Party) pursuant to this Agreement is less than one hundred sixty percent (160%) of the Purchase Price as of December 31, 2028, then the Royalty Cap shall mean two hundred percent (200%) of the Purchase Price.

“Royalty Payments” means, for each calendar month through the end of the calendar month in which the Royalty Termination Date occurs, an amount payable to Buyer equal to the amount of all aggregate Included Product Revenue during such calendar month, multiplied by the applicable Included Product Revenue Royalty Rate. For the avoidance of doubt, the Royalty

Payments, together with any Specified Other Amounts, in the aggregate, shall not exceed the Royalty Cap.

“Royalty Report” is defined in Section 5.2(b).

“Royalty Termination Date” means the date on which the aggregate amount of the Royalty Payments, together with any Specified Other Amounts, actually received by Buyer (or any Buyer Indemnified Party) pursuant to this Agreement equals the Royalty Cap.

“Safety Notices” means any recalls, field notifications, market withdrawals, warnings, “dear doctor” letters, investigator notices, safety alerts or other notices of action issued or instigated by a Seller, any of its Affiliates or any Regulatory Authority, relating to an alleged lack of safety or regulatory compliance of any Product.

“Sanctions” means economic or financial sanctions or trade embargoes imposed, administered or enforced from time to time by (a) the U.S. government, including those administered by U.S. Department of Treasury Office of Foreign Assets Control or the U.S. Department of State or (b) the United Nations Security Council, the European Union or Her Majesty’s Treasury of the United Kingdom.

“Security Interests” is defined in Section 2.1(b).

“Seller” is defined in the preamble.

“Seller Bankruptcy Event of Default” means any event with respect to a Seller described in clause (e) of the definition of “Event of Default” herein.

“Seller Indemnified Parties” is defined in Section 6.1(b).

“Senior Lenders” is defined in Section 5.12(a).

“Senior Secured Debt Facility” is defined in Section 5.12(a).

“Sold Assets” means the Revenue Participation Right and all Royalty Payments, including (a) all “accounts,” “payment intangibles,” “instruments,” “chattel paper,” “checks,” “money” and “investment property” (each as defined in Article 9 of the UCC) constituting, relating to, evidencing or underlying (I) the Revenue Participation Right, (II) the Royalty Payments or (III) “proceeds” (as defined in Article 9 of the UCC) of the Revenue Participation Right or the Royalty Payments, (b) all rights to access the books and records relating to or evidencing any of the foregoing and (c) all “proceeds” (as defined in Article 9 of the UCC) (cash or non-cash) of each of the foregoing; provided, that the Sold Assets (i) shall not include Products, general intangibles relating to the Products or any intellectual property used or embedded in any Product, but (ii) for the avoidance of doubt, shall include all “proceeds” (as defined in Article 9 of the UCC) of the Products, of such general intangibles and of such intellectual property that constitute the Revenue Participation Right, constitute the Royalty Payments or constitute any of the assets described in the foregoing clauses (a), (b) or (c).

“Solvent” means, with respect to any Person on any date of determination, that on such date (i) the fair saleable value of such Person’s assets is greater than the total sum of its Indebtedness, liabilities and other obligations, including contingent liabilities, (ii) the present fair saleable value of such Person’s assets is greater than the amount that would be required to pay its probable liabilities on its existing Indebtedness, liabilities and other obligations, including contingent liabilities, as they become absolute and matured, (iii) such Person is able to realize upon its assets and pay its Indebtedness, liabilities and other obligations, including contingent obligations, as they mature, (iv) such Person is not rendered insolvent (within the meaning of any applicable law or otherwise), (v) such Person is not engaged in business or a transaction, and is not about to engage in business or a transaction, for which such Person’s property would constitute an unreasonably small capital, (vi) such Person will be able to pay its Indebtedness, liabilities, obligations and other commitments as they mature and (vii) such Person is not subject to any event described in clause (e) of the definition of “Event of Default” herein.

“Source of Sales Information” is defined in Section 5.2(b).

“Specified Agreements” means any and all (i) In-Licenses, (ii) Out-Licenses, (iii) agreements, contracts and arrangements with Distributors and (iv) other agreements, contracts and arrangements (including promotion agreements, co-promotion agreements, supply agreements and manufacturing agreements) that are necessary or reasonably useful for the research, development, manufacture, supply, testing, seeking or obtaining regulatory approval (including Marketing Approval), use, distribution or Commercialization of the Compound or any Product in any country in the Product Territory. [***].

“Specified Assets” is defined in Section 5.12(a).

“Specified Counterparties” means the Third Parties that are party to any and all Specified Agreements.

“Specified Other Amounts” means amounts actually paid by or on behalf of Sellers to or on behalf of any Buyer Indemnified Party (excluding attorneys’ fees) in respect of claims for indemnification under Article 6 of any Buyer Indemnified Party against a Seller or its Affiliates arising or relating to, or in connection with, any breach of this Agreement by Sellers hereunder (except to the extent such amounts are paid to make any Buyer Indemnified Party whole with respect to an out-of-pocket Loss incurred by any Buyer Indemnified Party). For the avoidance of doubt, amounts constituting late fees pursuant to Section 5.2(a) are not “Specified Other Amounts” and shall not be credited towards the Royalty Cap.

“Specified Transaction” is defined in Section 5.12(e)(i).

“SSDF Option” is defined in Section 5.16.

“Subsidiary” means, with respect to any Person, any and all corporations, partnerships, limited liability companies, joint ventures, associations and other entities controlled (by contract or otherwise) by such Person directly or indirectly through one or more intermediaries. For purposes hereof, a Person shall be deemed to control a partnership, limited liability company, association or other business entity if such Person, directly or indirectly through one or more intermediaries, shall be allocated a majority of partnership, limited liability company, association

or other business entity gains or losses or shall be or control the managing director or general partner of such partnership, limited liability company, association or other business entity.

“Subsidiary Guarantor” is defined in Section 5.20.

“Tax” or “Taxes” means any federal, state, local or foreign income, gross receipts, license, payroll, employment, excise, severance, occupation, premium, windfall profits, environmental, customs duties, capital stock, franchise, profits, withholding, social security, unemployment, disability, real property, personal property, abandoned property, value added, alternative or add-on minimum, estimated or other tax of any kind whatsoever, including any interest, penalty or addition thereto, whether disputed or not.

“Third Party” means any Person that is neither a Seller nor an Affiliate of a Seller.

“Third Party Claim” is defined in Section 6.2(a).

“Trademark” means any trademark, service mark, trade names, trade dress, word, name, symbol, color, logo, slogan, designation or device, or any combination thereof, that functions as an identifier of the source or origin of goods or services, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo, business symbol or domain names, whether or not registered, including the goodwill associated with each of the foregoing and all registrations and applications for registration of any of the foregoing.

“Trademark Rights” means any and all Trademarks owned or controlled by a Seller or any of its Affiliates or under which such Seller or any of its Affiliates is or may become empowered to grant licenses (including, for the avoidance of doubt, Trademarks related to Improvements) necessary or reasonably useful for the research, development, manufacture, supply, testing, seeking or obtaining regulatory approval (including Marketing Approval), use, distribution or Commercialization of the Compound or any Product in any country in the Product Territory.

“Transaction Documents” means this Agreement, the Bill of Sale and the Control Agreement.

“True Up Date” is defined in Section 2.3(e).

“True Up Payment” is defined in Section 2.3(e).

“UCC” means the Uniform Commercial Code as in effect from time to time in the State of New York; provided that, if, with respect to any financing statement or by reason of any provisions of applicable law, the perfection or the effect of perfection or non-perfection of the Security Interests or any portion thereof granted pursuant to Section 2.1(b) is governed by the Uniform Commercial Code as in effect in a jurisdiction of the United States other than the State of New York, then “UCC” means the Uniform Commercial Code as in effect from time to time in such other jurisdiction for purposes of the provisions of this Agreement and any financing statement relating to such perfection or effect of perfection or non-perfection.

“Update Report” is defined in Section 5.1(a).

Section 1.2 Certain Interpretations.

(a) Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement:

(i) “either” and “or” are not exclusive and “include,” “includes” and “including” are not limiting and shall be deemed to be followed by the words “without limitation”;

(ii) “extent” in the phrase “to the extent” means the degree to which a subject or other thing extends, and such phrase does not mean simply “if”;

(iii) “hereof,” “hereto,” “herein” and “hereunder” and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement;

(iv) references to a Person are also to its permitted successors and permitted assigns;

(v) definitions are applicable to the singular as well as the plural forms of such terms;

(vi) references to an “Article,” “Section,” “Annex” or “Exhibit” refer to an Article or Section of, or an Annex or Exhibit to, this Agreement, and references to a “Schedule” refer to the corresponding part of the Disclosure Schedule;

(vii) references to “\$” or otherwise to dollar amounts refer to the lawful currency of the United States;

(viii) references to a law include any amendment or modification to such law and any rules and regulations issued thereunder, whether such amendment or modification is made, or issuance of such rules and regulations occurs, before or after the date of this Agreement; and

(ix) references to an agreement or other document include references to such agreement or document as from time to time amended, restated, reformed, supplemented or otherwise modified in accordance with the terms thereof (subject to any restrictions on such amendments, restatements, reformations, supplements or modifications set forth in this Agreement) and include any annexes, exhibits and schedules attached thereto.

(b) The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any of the provisions of this Agreement.

(c) The Disclosure Schedule is qualified in its entirety by reference to specific provisions of the Agreement, and is not intended to constitute, and shall not be construed as

constituting, representations or warranties. The disclosures in any section or paragraph of the Disclosure Schedule shall qualify only (i) the corresponding section or paragraph in Article 4 and (ii) other sections or paragraphs in Article 4 to which its relevance is reasonably apparent from a reading of such disclosure. The inclusion of any information in the Disclosure Schedule shall not be deemed to be an admission or acknowledgment, in and of itself, that such information is required by the terms hereof to be disclosed, is material, has had or would reasonably be expected to result in a Material Adverse Effect, or is outside the ordinary course of business.

(d) Notwithstanding anything herein to the contrary, the Parties acknowledge that Albireo AB has not and will not be obligated to perfect any security interest granted hereunder (except to the extent any such security interest can be perfected by the filing of financing statements with the Washington, DC Recorder of Deeds), and neither any breach of representation or warranty nor any default under this Agreement on the part of the Sellers shall result therefrom.

ARTICLE 2

PURCHASE, SALE AND ASSIGNMENT OF THE REVENUE INTEREST

Section 2.1 Purchase, Sale and Assignment.

(a) At the Closing and upon the terms and subject to the conditions of this Agreement, Sellers shall sell, transfer, assign and convey to Buyer, and Buyer shall purchase, acquire and accept from Sellers, the Sold Assets, free and clear of all Liens (except for any Liens contemplated by clause (d) of the definition of Permitted Liens). Immediately upon the Closing pursuant to this Section 2.1, all of Sellers' respective right, title and interest in and to the Sold Assets shall terminate, and all such right, title and interest in and to the Sold Assets shall vest in Buyer.

(b) It is the intention of the Parties that the sale, transfer, assignment and conveyance of the Sold Assets contemplated by this Agreement be, and is, a true, complete, absolute and irrevocable sale, transfer, assignment and conveyance by Sellers to Buyer of all of Sellers' respective right, title and interest in and to the Sold Assets. Neither Sellers nor Buyer intend the transactions contemplated by this Agreement to be characterized or treated as (other than for financial reporting, accounting and tax purposes) a loan from Buyer to Sellers or a financing transaction or a borrowing. It is the intention of the Parties that the beneficial interest in and title to the Sold Assets (including any "proceeds" (as such term is defined in the UCC) thereof) shall not be part of either Seller's estate in the event of the filing of a petition by or against a Seller under any Bankruptcy Laws. Each Seller hereby waives, to the maximum extent permitted by applicable law, any right to contest or otherwise assert that the transfer of the Sold Assets contemplated herein does not constitute a true, complete, absolute and irrevocable sale, transfer, assignment and conveyance by Sellers to Buyer of all of Sellers' right, title and interest in and to the Sold Assets (including, for the avoidance of doubt, such amounts received from Licensees, Distributors, other Specified Counterparties or other Related Parties and constituting a part of the Royalty Payments) under applicable law, which waiver shall, to the maximum extent permitted by applicable law, be enforceable against Sellers in any bankruptcy or insolvency proceeding relating to Sellers. Accordingly, Sellers shall treat the sale, transfer, assignment and conveyance of the Sold Assets as a sale of an "account" or a "payment intangible" (as

appropriate) in accordance with the UCC, and each Seller hereby authorizes Buyer and the agents and representatives of the Parties hereto (for purposes of Section 9-509 of the UCC) to file financing statements (and continuation statements with respect to such financing statements when applicable) naming Sellers as the debtors/sellers in respect to the Sold Assets, and naming Buyer as the secured party/buyer in respect to the Sold Assets, with a description of collateral as set forth in Annex 1 hereto (for the financing statement against Albireo) and with a description of collateral as set forth in Annex 2 hereto (for the financing statement against Albireo AB). Not in derogation of the foregoing statement of the intent of the Parties in this regard, and for the purposes of providing additional assurance to Buyer in the event that, despite the intent of the Parties, the sale, transfer, assignment and conveyance contemplated hereby is hereafter held not to be a sale, each Seller does hereby grant to Buyer, as security for the payment, observance and performance of Sellers' obligations under this Agreement (including, for the avoidance of doubt, (I) Sellers' obligation to make payments of the Put/Call Payment Amount pursuant to Section 2.3(a), Section 2.3(b), Section 2.3(c) and Section 5.12(e), (II) Sellers' obligation to make payments of the Royalty Payments pursuant to Section 5.2(a) and (III) Sellers' obligation to make the True Up Payments pursuant to Section 2.3(e)), a first lien security interest in and to all of Sellers' right, title and interest in, to and under the Sold Assets. In addition, in light of Sellers' payment and other obligations under this Agreement, Albireo Pharma does hereby further grant to Buyer, as security for the payment, observance and performance of such obligations of Sellers (including, for the avoidance of doubt, (A) Sellers' obligation to make payments of the Put/Call Payment Amount pursuant to Section 2.3(a), Section 2.3(b), Section 2.3(c) and Section 5.12(e), (B) Sellers' obligation to make payments of the Royalty Payments pursuant to Section 5.2(a) and (C) Sellers' obligation to make the True Up Payments pursuant to Section 2.3(e)), a first lien security interest in and to all of Albireo Pharma's right, title and interest in, to and under the Controlled Account Assets. The security interests granted in the two immediately preceding sentences are referred to herein collectively as the "Security Interests." The Sold Assets together with the Controlled Account Assets are referred to herein collectively as the "Collateral." Each Seller hereby authorizes Buyer and the agents and representatives of the Parties hereto (for purposes of Section 9-509 of the UCC), from and after the Closing Date, to file such financing statements (and continuation statements with respect to such financing statements when applicable) in such manner and such jurisdictions as are necessary or appropriate to perfect the Security Interests, with a description of collateral as set forth in Annex 3 hereto (for the financing statement against Albireo) and with a description of collateral as set forth in Annex 4 hereto (for the financing statement against Albireo AB). Notwithstanding such authorization, Sellers shall ensure, at Sellers' expense, that the Security Interests (i) granted by Albireo Pharma in the Collateral is and remains perfected as of the Closing and at all times thereafter until the Royalty Termination Date and (ii) granted by Albireo AB in the Sold Assets is and remains perfected (to the extent such Security Interest can be perfected by the filing of financing statements with the Washington, DC Recorder of Deeds) as of the Closing and at all times thereafter until the Royalty Termination Date. Sellers shall provide Buyer written evidence of all filed financing statements with respect to the Security Interests granted by Sellers (with appropriate continuations as applicable): (x) promptly following the Closing Date, (y) at Buyer's written request, at least [***] days prior to the [***] anniversary of the Closing Date and each [***] anniversary thereafter until the Royalty Termination Date (and shall, in each such case described in this clause (y), include evidence of the filing of appropriate continuation statements to continue such perfection beyond such [***] anniversary) and (z) at other times upon the

reasonable written request of Buyer (which shall be no more than [***]). Notwithstanding the foregoing, Sellers shall have no obligation to file any amendment to any financing statement to reflect a change in Buyer's name or address and shall not be deemed to represent and warrant to any such change.

Section 2.2 Purchase Price. Upon the terms and subject to the conditions of this Agreement, the purchase price to be paid as consideration to Sellers for the sale, transfer, assignment and conveyance to Buyer of the Sold Assets is \$115,000,000 (the "Purchase Price"). At the Closing, subject to the satisfaction (or waiver by Buyer in accordance with Section 9.5) of Section 3.2, Buyer shall pay (or cause to be paid) to Sellers the Purchase Price in cash (by wire transfer of immediately available funds to an account or accounts designated in writing by Sellers). The Purchase Price shall be non-creditable and non-refundable, and notwithstanding anything to the contrary herein, the Purchase Price shall not be subject to any withholding or offset or reduction for any Tax.

Section 2.3 Buyout.

(a) Call Option. At any time after the Closing Date, Sellers may elect to purchase the remainder of the Sold Assets from Buyer in full for an amount equal to the applicable Put/Call Payment Amount, and upon such payment to Buyer of such Put/Call Payment Amount by wire transfer of immediately available funds to such account or accounts as an Authorized Buyer Representative shall designate both orally by telephone and in writing to Sellers, no further payments of the Sold Assets shall be due to Buyer hereunder and the Royalty Termination Date shall be deemed to have occurred.

(b) Put Option. Following the occurrence of any of (i) the signing of a definitive written agreement with respect to a Product Exit (it being understood that, for the avoidance of doubt, the signing of a definitive written agreement with respect to a Specified Transaction shall not constitute a Product Exit and shall not constitute a Put Option Event (as defined below), but that the consummation of such Specified Transaction other than in compliance with Section 5.12(e) shall constitute a Product Exit and shall constitute a Put Option Event), (ii) a Change of Control or (iii) an Event of Default other than a Seller Bankruptcy Event of Default (each of the foregoing events set forth in clauses (i), (ii) and (iii), a "Put Option Event"), Buyer may elect by notification to Sellers in writing (a "Put Option Notice") to sell the remainder of the Sold Assets to Sellers in exchange for an amount in cash equal to the Put/Call Payment Amount. In the event that Buyer delivers a Put Option Notice to Sellers, then upon the later of (i) the occurrence of the applicable Put Option Event and (ii) the date that is [***] ([***) Business Days following receipt of a Put Option Notice from Buyer, Sellers shall pay to Buyer the Put/Call Payment Amount by wire transfer of immediately available funds to such account or accounts as an Authorized Buyer Representative shall designate both orally by telephone and in writing to Sellers. Upon such payment by Sellers to Buyer of the Put/Call Payment Amount, no further payments of the Sold Assets shall be due to Buyer hereunder and the Royalty Termination Date shall be deemed to have occurred. With respect to any Put Option Event, if Buyer does not deliver a Put Option Notice to Sellers within one hundred eighty (180) days after Buyer's receipt of written notice from Sellers (in accordance with Section 5.1(d) hereof) of the occurrence of such Put Option Event, then Buyer's right to deliver a Put Option Notice with respect to such Put Option Event shall terminate at the end of such one hundred eighty (180) day

period. The Put/Call Payment Amount due in respect of any Put Option Event shall be fully earned on the Closing Date.

(c) Seller Bankruptcy Event of Default. If a Seller Bankruptcy Event of Default occurs, the Put/Call Payment Amount shall automatically (without any action or notice by Buyer) be due and payable immediately upon the occurrence of such Seller Bankruptcy Event of Default, and Sellers shall pay to Buyer the Put/Call Payment Amount by wire transfer of immediately available funds to such account or accounts as an Authorized Buyer Representative shall designate both orally by telephone and in writing to Sellers. The Put/Call Payment Amount due in respect of a Seller Bankruptcy Event of Default shall be fully earned on the Closing Date.

(d) Other Remedies Upon Event of Default. If an Event of Default has occurred and is continuing, Buyer may, without further notice to Sellers, exercise all remedies available at law or in equity in respect of the Collateral, including (i) exercising any and all rights and remedies of a secured party upon default under the UCC (whether or not the UCC applies to the affected Collateral) and (ii) directing Sellers and their Subsidiaries to assemble and deliver the Collateral as directed by Buyer, notifying any Third Party holding such Collateral (or portion thereof) of Buyer's rights in such Collateral (or portion) and directing such Third Party to transfer such Collateral or make payments in respect thereof to Buyer (and each Seller hereby consents to such transfer or payment).

(e) True Up Payment. If the aggregate amount of all of the Royalty Payments and Specified Other Amounts actually received by Buyer (or Buyer Indemnified Parties) pursuant to this Agreement is less than two hundred percent (200%) of the Purchase Price as of December 31, 2036 (the "True Up Date"), Sellers will purchase the remainder of the Sold Assets from Buyer in full for an amount equal to the Royalty Cap *less* the aggregate amount of all of the Royalty Payments and Specified Other Amounts actually received by Buyer (or Buyer Indemnified Parties) pursuant to this Agreement as of the True Up Date (the "True Up Payment"), and no further payments of the Sold Assets shall be due to Buyer hereunder, and the Royalty Termination Date shall be deemed to have occurred as of the True Up Date. The True Up Payment shall be paid by Sellers in [***] ([***) equal installments payable on each of [***] (and if any such date is not a Business Day, then on the immediately preceding Business Day), in each case, by wire transfer of immediately available funds to such account or accounts as an Authorized Buyer Representative shall designate both orally by telephone and in writing to Sellers.

Section 2.4 No Assumed Obligations, Etc. Notwithstanding any provision in this Agreement to the contrary, Buyer is only agreeing, on the terms and conditions set forth in this Agreement, to purchase, acquire and accept the Sold Assets and is not assuming any liability or obligation of Sellers of whatever nature, whether presently in existence or arising or asserted hereafter.

Section 2.5 Certain Seller Payment Obligations. Sellers' obligations to pay the True Up Payments and the Put/Call Payment Amount if and when they may become due under this Agreement (including, for the avoidance doubt, if and when the Put/Call Payment Amount becomes due under Section 5.12(e) hereof) shall be absolute. The Parties agree that the True Up Payments and Put/Call Payment Amount, if and when due, shall be presumed to be the liquidated

damages sustained by Buyer, and the Parties agree that such presumption is reasonable under the circumstances currently existing. Sellers expressly waive (to the fullest extent they may lawfully do so) the provisions of any present or future applicable law that prohibits or may prohibit the collection of the True Up Payments or the Put/Call Payment Amount by Buyer. Sellers agree (to the fullest extent that they may lawfully do so) that (i) each of the True Up Payments and the Put/Call Payment Amount are reasonable and are the product of an arm's-length transaction between sophisticated business people, ably represented by counsel, (ii) each of the True Up Payments and the Put/Call Payment Amount shall be payable notwithstanding the then-prevailing market rates at the time payment is made, (iii) there has been a course of conduct between Buyer, on the one hand, and Sellers, on the other hand, giving specific consideration in the transactions contemplated hereby for such agreement to pay the True Up Payments and the Put/Call Payment Amount as a charge (and not interest) to the extent they become due and (iv) Sellers shall be estopped from claiming differently than as agreed to in this Section 2.5. Sellers expressly acknowledge that their agreement to pay each of the True Up Payments and the Put/Call Payment Amount to Buyer if and when they may become due as herein described is a material inducement to Buyer to pay the Purchase Price.

Section 2.6 Joint and Several Liability of Sellers. Notwithstanding anything to the contrary in this Agreement but subject to Section 1.2(d), (a) the representations, warranties, covenants, agreements and obligations of a Seller or of Sellers under this Agreement shall be joint and several and (b) Sellers shall be jointly and severally liable for any and all liabilities of a Seller or of Sellers under this Agreement (including in respect of any Losses). Notwithstanding anything to the contrary in this Agreement, (i) Sellers acknowledge and agree that Sellers prepare consolidated financial statements and each Seller will obtain benefits from the incurrence of obligations under this Agreement and the consummation of the transactions contemplated by the Transaction Documents, and accordingly each Seller desires to execute this Agreement and agree to the joint and several liability referred to in the immediately preceding sentence to induce Buyer to enter into this Agreement and consummate the transactions contemplated by the Transaction Documents, and (ii) Albireo Pharma represents, warrants, confirms and agrees that the provisions of the Swedish Companies Act referred to in Section 2.7 below do not apply to, and do not affect, (A) Albireo Pharma's joint and several liability set forth in the first sentence of this Section 2.6 (including Albireo Pharma's joint and several liability in respect of Albireo AB's representations, warranties, covenants, agreements and obligations under this Agreement) or (B) Albireo Pharma's grant of security interests in the Sold Assets and in the Controlled Account Assets pursuant to Section 2.1(b) hereof (or the legality, validity, enforceability, priority or perfection thereof).

Section 2.7 Swedish Law Limitations. Notwithstanding anything to the contrary in this Agreement, the obligations and liabilities of Albireo AB under this Agreement and the other Transaction Documents shall be limited if and to the extent required by an application of the provisions of the Swedish Companies Act (Sw. *Aktiebolagslagen* (2005:551)) regulating (i) distribution of assets (Chapter 17, Sections 1-4 (or their equivalents from time to time)) (including profits and dividends and any other form of transfer of value (Sw. *värdeöverföring*) within the meaning of the Swedish Companies Act) and/or (ii) prohibited loans, guarantees and security (Chapter 21, Section 1-3 (or their equivalents from time to time)) and it is agreed that the obligations and liabilities of Albireo AB only applies to the extent permitted by the above mentioned provisions of the Swedish Companies Act.

ARTICLE 3
CLOSING AND PAYMENT OF PURCHASE PRICE

Section 3.1 Closing. The Closing shall take place at 10:00 a.m. New York City time on the date hereof, or at such other time and date as Buyer and Sellers may mutually agree. Buyer and Sellers expect to exchange documents electronically, and Buyer and Sellers shall not be required to appear at any specific physical location to effect the Closing. The date on which the Closing occurs is referred to in this Agreement as the “Closing Date.”

Section 3.2 Seller Closing Deliverables. The obligation of Buyer to consummate the transactions contemplated by this Agreement on the Closing Date, including the obligation of Buyer to deliver (or cause to be delivered) payment of the Purchase Price to Sellers in accordance with Section 2.2, is subject to the satisfaction (or waiver by Buyer in accordance with Section 9.5) of the following conditions:

(a) Sellers shall have delivered to Buyer a counterpart to this Agreement duly executed by Sellers;

(b) Sellers shall deliver to Buyer a counterpart to a bill of sale evidencing the sale, transfer, assignment and conveyance of the Sold Assets to Buyer in the form attached hereto as Exhibit A (the “Bill of Sale”), duly executed by Sellers;

(c) Sellers shall deliver to Buyer a counterpart to the Control Agreement duly executed by Albireo Pharma, and Buyer shall have received a counterpart to the Control Agreement duly executed by Silicon Valley Bank;

(d) Sellers shall deliver or cause to be delivered to Buyer (i) an opinion of Paul, Weiss, Rifkind, Wharton & Garrison LLP, special counsel to Sellers, (ii) an opinion of Advokatfirman Vinge KB, Swedish counsel to Sellers and (iii) an opinion of Shartsis Friese LLP, California counsel to Sellers, in each case, dated the Closing Date and in form and substance satisfactory to Buyer;

(e) each Seller shall deliver to Buyer a certificate of an officer of such Seller, dated as of the Closing Date, certifying as to (i) such Seller’s organizational documents, (ii) the attached thereto copies of resolutions adopted by such Seller authorizing the execution and delivery by such Seller of this Agreement and the other Transaction Documents to which it is a party and the consummation by such Seller of the transactions contemplated hereby and thereby and (iii) the incumbency and signature of each officer of such Seller executing this Agreement and the other Transaction Documents to which such Seller is a party;

(f) Sellers shall have filed financing statements in such manner and such jurisdictions as are necessary or appropriate to perfect the Security Interests granted by Sellers as described in Section 2.1(b) and shall have provided evidence of such filings to Buyer (provided, however, with respect to Albireo AB, financing statements need only be filed with the Washington, DC Recorder of Deeds);

(g) Buyer shall have received copies, dated as of a recent date, of lien searches on Sellers, accompanied by written evidence (including any UCC termination

statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, concurrently with the Closing, will be terminated or released;

(h) Sellers shall have provided to Buyer evidence of (i) the payoff and termination of all obligations under the Loan and Security Agreement, dated as of June 8, 2020, among Sellers, the other borrowers from time to time party thereto, the lenders from time to time party thereto and Hercules Capital, Inc. and (ii) all UCC-3 termination statements, terminations and other releases evidencing the termination of all security interests thereunder;

(i) each Seller shall deliver to Buyer a valid, properly executed Internal Revenue Service Form W-9 or Form W-8, as applicable, establishing a complete exemption from U.S. federal withholding tax (including backup withholding) in respect of amounts payable to Sellers under this Agreement; and

(j) Albireo Pharma shall deliver to Buyer a certificate of good standing with respect to Albireo Pharma, dated as of the Closing Date, certified by the Secretary of State of the State of Delaware.

Section 3.3 Buyer Closing Deliverables. The obligation of Sellers to consummate the transactions contemplated by this Agreement on the Closing Date is subject to the satisfaction (or waiver by Sellers in accordance with Section 9.5) of the following conditions:

(a) Buyer shall have delivered to Sellers a counterpart to this Agreement duly executed by Buyer;

(b) Buyer shall deliver to Sellers a certificate of an officer or other authorized signatory of Buyer, dated as of the Closing Date, certifying as to (i) Buyer's organizational documents, (ii) the attached thereto copies of resolutions adopted by Buyer authorizing the execution and delivery by Buyer of this Agreement and the other Transaction Documents and the consummation by Buyer of the transactions contemplated hereby and thereby and (iii) the incumbency and signature of each officer (or officers) or other authorized signatory (or authorized signatories) of such Buyer executing this Agreement and the other Transaction Documents;

(c) Buyer shall deliver to Sellers a valid, properly executed Internal Revenue Service Form W-9 establishing a complete exemption from U.S. federal withholding tax (including backup withholding) in respect of amounts payable to Buyer under this Agreement; and

(d) Buyer shall deliver to Sellers a counterpart to the Bill of Sale, duly executed by Buyer.

Section 3.4 Control Agreement Conditions. Notwithstanding anything to the contrary in this Agreement, the Parties have agreed as follows:

(a) If all conditions described in Section 3.2 and Section 3.3 have been satisfied on the date hereof, with the exception of the conditions set forth in Section 3.2(c) and Section 3.2(d)(iii) (the "Control Agreement Conditions"), then the parties will sign this

Agreement and the Bill of Sale and the Closing will be deemed to have occurred on the date hereof; provided, however, that Buyer will not be obligated to pay the Purchase Price on the date hereof, unless and until such time on the date hereof as the Control Agreement Conditions have been satisfied.

(b) If the Control Agreement Conditions have not been satisfied by 3:00 pm (New York time) on the date hereof, this Agreement and the Bill of Sale shall automatically terminate (without the need for any Party to take any action), and will be void and of no further force and effect, all without liability of any Party to any other Party.

ARTICLE 4 REPRESENTATIONS AND WARRANTIES

Section 4.1 Sellers' Representations and Warranties. Except as set forth on the Disclosure Schedule attached hereto, each Seller represents and warrants to Buyer that as of the date hereof:

(a) Existence. Such Seller is, in the case of Albireo Pharma, a corporation duly incorporated and validly existing under the laws of the State of Delaware and, in the case of Albireo AB, a company duly incorporated and validly existing under the laws of Sweden. Such Seller is duly licensed or qualified to do business in each jurisdiction in which the nature of the business conducted by it or the character or location of the properties and assets owned, leased or operated by it makes such licensing or qualification necessary, except where the failure to be so licensed or qualified has not and would not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect.

(b) Authorization. Such Seller has all requisite corporate power and authority to execute, deliver and perform its obligations under this Agreement and the other Transaction Documents to which it is a party. The execution, delivery and performance of this Agreement and the other Transaction Documents to which such Seller is a party, and the consummation of the transactions contemplated hereby and thereby, have been duly authorized by all necessary corporate action on the part of such Seller.

(c) Enforceability. This Agreement and the other Transaction Documents to which such Seller is a party has been duly executed and delivered by an authorized officer of such Seller and constitutes the valid and binding obligation of such Seller, enforceable against such Seller in accordance with their respective terms, except as may be limited by applicable Bankruptcy Laws or by general principles of equity (whether considered in a proceeding in equity or at law).

(d) No Conflicts. The execution, delivery and performance by such Seller of this Agreement and the other Transaction Documents to which it is a party and the consummation of the transactions contemplated hereby and thereby do not and will not (i) contravene or conflict with the certificate of incorporation or bylaws or articles of association (as applicable) of such Seller, (ii) contravene or conflict with or constitute a material default under any law or Judgment binding upon or applicable to such Seller or the Sold Assets, (iii) contravene or conflict with or constitute a default under any Existing Specified Agreement or

any Marketing Approval binding upon or applicable to such Seller or the Sold Assets or (iv) contravene or conflict with or constitute a material default under any contract or other agreement (other than those referred to in the immediately preceding clause (iii)) binding upon or applicable to such Seller or the Sold Assets.

(e) Consents. Except for the UCC financing statements contemplated by Section 2.1(b), or any filings required by the federal securities laws or stock exchange rules, no consent, approval, license, order, authorization, registration, declaration or filing with or of any Governmental Entity or other Person is required to be done or obtained by such Seller in connection with (i) the execution and delivery by such Seller of this Agreement and the other Transaction Documents to which it is a party, (ii) the performance by such Seller of its obligations under this Agreement and the other Transaction Documents to which it is a party or (iii) the consummation by such Seller of any of the transactions contemplated by this Agreement and the other Transaction Documents to which it is a party.

(f) No Litigation. Neither such Seller nor any of its Affiliates is a party to, and has not received any written notice of, any action, suit, investigation or proceeding pending before any Governmental Entity and, to the Knowledge of Seller, no such action, suit, investigation or proceeding has been threatened against such Seller, that, individually or in the aggregate, has had or would, if determined adversely, reasonably be expected to have a Material Adverse Effect.

(g) Compliance.

(i) All applications, submissions, information and data related to a Product submitted or utilized as the basis for any request to any Regulatory Authority by or on behalf of such Seller, were true and correct in all material respects as of the date of such submission or request, and, to the Knowledge of Seller, any material updates, changes, corrections or modifications to such applications, submissions, information or data required under applicable laws or regulations to be made by or on behalf of such Seller have been submitted to the necessary Regulatory Authorities.

(ii) Neither such Seller nor any of its Affiliates has committed any act, made any statement or failed to make any statement that would reasonably be expected to provide a basis for the FDA to invoke its policy with respect to “Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities” (the “FDA Application Integrity Policy”), or similar policies implemented and enforced by the FDA, EMA or comparable foreign Regulatory Authorities. Neither such Seller, nor, to the Knowledge of Seller, any of its officers, employees, contractors or agents is the subject of any pending or, to the Knowledge of Seller, threatened investigation by the FDA, EMA or any other Regulatory Authority that could reasonably result in the invocation of the FDA Application Integrity Policy or any similar policy by any Regulatory Authority.

(iii) Such Seller has provided to Buyer prior to the date hereof in a data room available to Buyer true and correct copies or summaries of all material written communications sent or received by such Seller and any of its Affiliates to or from any Regulatory Authorities in the Product Territory that relate to the Products since [***].

(iv) None of such Seller, any of its Affiliates and, to the Knowledge of Seller, any Third Party manufacturer of a Product, has received from the FDA a “Warning Letter,” Form FDA-483, “Untitled Letter,” or similar material written correspondence or notice alleging violations of applicable laws and regulations enforced by the FDA, or any comparable material written correspondence from any other Regulatory Authority in the Product Territory with regard to any Product or the manufacture, processing, packaging or holding thereof, the subject of which communication is unresolved and if determined adversely to such Seller or such Affiliate would, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

(v) Since [***], (A) there have been no Safety Notices with respect to a Product issued in the Product Territory, (B) to the Knowledge of Seller, there are no unresolved Product complaints with respect to a Product which if validated would result in a Material Adverse Effect and (C) to the Knowledge of Seller, there are no facts currently in existence that would, individually or in the aggregate, reasonably be expected to result in (1) a material Safety Notice with respect to a Product or (2) a material change in the labeling of a Product in the Product Territory. Since [***], neither such Seller nor any of its Affiliates has experienced any failures in the manufacturing of a Product for clinical use or commercial sale in the Product Territory that, individually or in the aggregate, have had or would reasonably be expected to result in, if such failures occurred again, a Material Adverse Effect.

(vi) Such Seller possesses all material permits, licenses, registrations, certificates, authorizations, orders and approvals from the appropriate federal, state or foreign regulatory authorities necessary to conduct its business, including all such material permits, licenses, registrations, certificates, authorizations, orders and approvals required by the FDA, EMA or any other Regulatory Authority (collectively, “Permits”). Such Seller has not received any written notice of proceedings relating to the suspension, modification, revocation or cancellation of any Permit. Neither such Seller nor, to the Knowledge of Seller, any officer, employee or agent of such Seller has been convicted of any crime or engaged in any conduct that has previously caused or would reasonably be expected to result in (A) disqualification or debarment by the FDA under 21 U.S.C. Sections 335(a) or (b), or any similar law, rule or regulation of any other Governmental Entity, (B) debarment, suspension, or exclusion under any federal healthcare programs or by the General Services Administration or (C) exclusion under 42 U.S.C. Section 1320a-7 or any similar law, rule or regulation administered by any Regulatory Authority. To the Knowledge of Seller, neither such Seller nor any of its officers, employees, contractors, agents or Specified Counterparties has made an untrue statement of material fact on, or material omissions from, any notifications, applications, approvals, reports and other submissions to the FDA, EMA or any similar Regulatory Authority.

(vii) Such Seller is and has been in compliance with all applicable laws administered or issued by the FDA, EMA or any similar Regulatory Authority, including the FD&C Act, applicable requirements in FDA and EMA regulations, any applicable orders issued by the FDA, EMA or similar Regulatory Authorities, and all other laws regarding ownership, developing, testing, manufacturing, packaging, storage, import, export, disposal, marketing, distributing, promoting, and complaint handling or adverse event reporting for the Products, except to the extent that such failure to comply with such applicable laws would not reasonably be expected to result in a Material Adverse Effect.

(h) Specified Agreements.

(i) In-Licenses. Except as set forth on Schedule 4.1(h)(i) of the Disclosure Schedule, there are no In-Licenses (any In-License set forth on Schedule 4.1(h)(i) of the Disclosure Schedule, an “Existing In-License”). A true, correct and complete copy of each Existing In-License has been provided to Buyer by Sellers in a data room available to Buyer. Neither such Seller nor, to the Knowledge of Seller, the respective counterparty thereto has made or entered into any amendment, supplement or modification to any provision of any Existing In-License or granted any waiver under any material provision of any Existing In-License (other than any such amendment, supplement, modification or waiver that has been provided to Buyer in a data room available to Buyer).

(ii) Other Specified Agreements. Except as set forth on Schedule 4.1(h)(ii) of the Disclosure Schedule, there are no Specified Agreements in the Product Territory (any Specified Agreement set forth on Schedule 4.1(h)(ii) of the Disclosure Schedule, an “Existing Specified Agreement”). A true, correct and complete copy of each Existing Specified Agreement has been provided to Buyer by such Seller in a data room available to Buyer. Neither such Seller nor, to the Knowledge of Seller, the respective counterparty thereto has made or entered into any amendment, supplement or modification to any provision of any Existing Specified Agreement or granted any waiver under any material provision of any Existing Specified Agreement (other than any such amendment, supplement, modification or waiver that has been provided to Buyer in a data room available to Buyer).

(iii) Validity and Enforceability. Each Existing Specified Agreement (including each Existing In-License) to which such Seller is a party is a valid and binding obligation of such Seller and, to the Knowledge of Seller, the counterparty thereto. Each Existing Specified Agreement to which such Seller is a party is enforceable against such Seller and, to the Knowledge of Seller, each counterparty thereto in accordance with its terms except as may be limited by applicable Bankruptcy Laws or by general principles of equity (whether considered in a proceeding in equity or at law). Such Seller has not received any written notice in connection with any Existing Specified Agreement challenging the validity or enforceability or interpretation of any provision of such agreement.

(iv) No Termination. Such Seller has not (A) given notice to a counterparty of the termination of any Existing Specified Agreement (whether in whole or in part) or any notice to a counterparty expressing any intention or desire to terminate any Existing Specified Agreement or (B) received from a counterparty thereto any written notice of termination of any Existing Specified Agreement (whether in whole or in part) or any written notice from a counterparty expressing any intention or desire to terminate any Existing Specified Agreement.

(v) No Breaches or Defaults. No material breach or default under any provision of any Existing Specified Agreement exists or has occurred, either by such Seller or, to the Knowledge of Seller, by the respective counterparty (or any predecessor thereof) thereto, and there is no event that upon notice or the passage of time, or both, would reasonably be expected to give rise to any breach or default either by such Seller or, to the Knowledge of Seller, by the respective counterparty to such agreement.

(vi) Payments Made. Such Seller has made all payments to the respective counterparty of each Existing Specified Agreement required under each Existing Specified Agreement as of the date hereof and the respective counterparty of each Existing Specified Agreement has made all payments to such Seller required under each Existing Specified Agreement as of the date hereof.

(vii) No Assignments. Such Seller has not consented to any assignment by the counterparty to any Existing Specified Agreement of any of its rights or obligations under any such Existing Specified Agreement and, to the Knowledge of Seller, the counterparty has not assigned any of its rights or obligations under any such Existing Specified Agreement to any Person. Such Seller has not assigned, in whole or in part, and has not granted any Liens upon or security interests with respect to, any Existing Specified Agreement.

(viii) No Indemnification Claims. Such Seller has not notified any Person of any claims for indemnification under any Existing Specified Agreement nor has such Seller received any claims for indemnification under any Existing Specified Agreement.

(ix) No Infringement. Neither such Seller nor any of its Affiliates has received any written notice from, or given any written notice to, any counterparty to any Existing Specified Agreement regarding any infringement of any of the Existing Patent Rights licensed thereunder.

(i) No Liens; Title to Sold Assets. None of the Product Rights (but excluding the Revenue Participation Right) owned or purported to be owned by Sellers or their Affiliates are subject to any Liens other than Permitted Liens. The Sold Assets (including the Revenue Participation Right) are not subject to any Liens other than any Liens contemplated by clause (d) of the definition of Permitted Liens. Upon the Closing, Buyer will have acquired, subject to the terms and conditions set forth in this Agreement, good and marketable title to the Sold Assets (including the Revenue Participation Right), free and clear of all Liens, other than any Liens contemplated by clause (d) of the definition of Permitted Liens.

(j) Manufacturing; Supply. The Products have, since [***], been manufactured, transported, stored and handled in all material respects in accordance with applicable law and with applicable current good manufacturing practices in the Product Territory. Since [***], neither such Seller nor any Affiliate of such Seller has experienced any failures in the manufacturing or supply of the Products in the Product Territory that, individually or in the aggregate, have had or would reasonably be expected to result in, if such failures occurred again, a Material Adverse Effect. [***].

(k) Intellectual Property.

(i) Schedule 4.1(k)(i)(A) of the Disclosure Schedule lists all of the currently existing Patents owned by such Seller or its Affiliates included within the Patent Rights (the "Existing Patent Rights"), including as to each listed patent or patent application (w) the jurisdictions by or in which each such patent has issued as a patent or such patent application has been filed, (x) the respective patent or application numbers, (y) the respective registered owner thereof and (z) the respective scheduled expiration date thereof, provided that the scheduled

expiration dates may be subject to potential patent term extensions, patent term adjustments, supplementary protection certificates, Regulatory Exclusivity Periods, and the like, as applicable. Schedule 4.1(k)(i)(B) of the Disclosure Schedule lists all of the currently existing Trademarks owned by such Seller or its Affiliates included within the Trademark Rights (the “Existing Trademark Rights”). Except as set forth on Schedule 4.1(k)(i)(A) of the Disclosure Schedule, as of the date hereof, such Seller is the sole and exclusive owner of all of the Existing Patent Rights, free and clear of any Liens other than Permitted Liens. Except as set forth on Schedule 4.1(k)(i)(B) of the Disclosure Schedule, as of the date hereof, such Seller is the sole and exclusive owner of all of the Existing Trademark Rights, free and clear of any Liens other than Permitted Liens.

(ii) Neither such Seller nor any of its Affiliates, nor to the Knowledge of Seller, any of the Specified Counterparties, is a party to any pending and, to the Knowledge of Seller, there is no threatened, litigation, interference, reexamination, reissue, *inter partes* review, post-grant review, opposition or like patent office proceeding or procedure involving any of the Existing Patent Rights.

(iii) [***]. To the Knowledge of Seller, the issued patents within the Existing Patent Rights are valid, enforceable and in full force and effect. None of the issued Patents within the Existing Patent Rights have lapsed, have been abandoned or disclaimed, or have expired or otherwise been terminated. Neither such Seller nor any of its Affiliates has received any written notice relating to the lapse, expiration or other termination of any of the issued Patents owned by such Seller or its Affiliates within the Existing Patent Rights, and neither such Seller nor its Affiliates has received any legal opinion of outside counsel, whether preliminary in nature or qualified in any manner, which alleges or concludes that, an issued Patent within any of the Existing Patent Rights, or patent claims therein, is invalid or unenforceable. Such Seller has not committed any act, or failed to commit any required act, that would reasonably be expected to cause any of the issued patents within the Existing Patent Rights to not be eligible for potential patent term extensions, supplementary protection certificates, and the like, as applicable, based on the Marketing Approvals of the Products.

(iv) To the Knowledge of Seller, (1) each Person associated with the filing and prosecution of the Existing Patent Rights has complied in all material respects with all applicable duties of candor and good faith in dealing with their respective patent offices, including any duty to disclose to any patent office all information known by such Persons to be material to the patentability of each of the Existing Patent Rights (including any relevant prior art), in each case, in those jurisdictions where such duties exist, and (2) each of the Existing Patent Rights correctly names each inventor of the claims thereof as determined in accordance with the laws of the jurisdiction in which such Existing Patent Right was issued or is pending, and there is no Person who is or claims to be an inventor under any of the Existing Patent Rights who is not a named inventor thereof.

(v) Neither such Seller nor its Affiliates has received any written notice of any claim by any Person challenging the inventorship or ownership of, the rights of such Seller in and to, or the patentability, validity or enforceability of, any of the Existing Patent Rights or asserting that the development, manufacture, importation, sale, offer for sale or use of any Product infringes, misappropriates or otherwise violates or will infringe, misappropriate or

otherwise violate such Person's Patents or other intellectual property rights in the Product Territory.

(vi) To the Knowledge of Seller, the research, discovery, development, manufacture, Commercialization or use of the Products, in each case in the form the Products exist as of the date hereof and as such activity is currently contemplated by such Seller, has not infringed, misappropriated or otherwise violated, and is not infringing, misappropriating or otherwise violating, any Patents or other intellectual property rights owned by any Third Party in the Product Territory.

(vii) To the Knowledge of Seller, no Person has infringed, misappropriated or otherwise violated, or is infringing, misappropriating or otherwise violating, any of the Intellectual Property Rights in the Product Territory.

(viii) Such Seller has paid, or has caused to be paid, all prosecution and maintenance fees, annuities and like payments required as of the date hereof with respect to each of the Existing Patent Rights.

(l) Taxes. Such Seller and each of its Subsidiaries has (A) filed all Tax returns and reports required to have been filed by it, (B) paid all Taxes required to be paid by it and (C) established adequate accruals, charges and reserves in accordance with GAAP in their applicable financial statements in respect of all Taxes not yet due and payable, except, in each case, (i) any such Taxes that are being diligently contested in good faith by appropriate proceedings and for which adequate reserves have been established in accordance with GAAP or (ii) any failure that would not result, individually or in the aggregate, in a Material Adverse Effect.

(m) Brokers' Fees. Other than Morgan Stanley & Co. LLC (whose fees and expenses shall be paid by Sellers), there is no investment banker, broker, finder, financial advisor or other intermediary who has been retained by or is authorized to act on behalf of Sellers who might be entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

(n) Indebtedness. There is no Indebtedness of such Seller or any of its Subsidiaries other than Permitted Debt.

(o) Legal Entity Name and Jurisdiction. Albireo Pharma's exact legal entity name is, and in the past five years has been, "Albireo Pharma, Inc." Albireo Pharma is, and has been since its incorporation, incorporated in the State of Delaware. Albireo AB's exact legal entity name is, and in the past five years has been, "Albireo AB". Albireo AB is, and has been since its incorporation, incorporated in Sweden.

(p) Ownership. As of immediately prior to the Closing, Sellers are the exclusive owners of the entire right, title (legal and equitable) and interest in, to and under the Sold Assets and have good and valid title thereto. Sellers (and neither any of their Subsidiaries nor any other Person) are the exclusive owners of the entire right, title (legal and equitable) and interest in, to and under the Product Rights.

(q) No Material Adverse Effect; No Default. No Material Adverse Effect has occurred and is continuing, and, to the Knowledge of Seller, no event or circumstance has occurred and is continuing that would reasonably be expected to result in a Material Adverse Effect. To the Knowledge of Seller, no event or circumstance is likely to occur that would reasonably be expected to result in a Material Adverse Effect. No Event of Default has occurred and is continuing, and no event or circumstance has occurred and is continuing that, upon notice, lapse of time or both, would reasonably be expected to result in an Event of Default. As of the date of this Agreement, Seller has not signed a definitive written agreement with respect to a Specified Transaction.

(r) Solvency. Such Seller is, and will be (upon consummation of the transactions contemplated by this Agreement and the application of the proceeds therefrom), both individually and together with its Subsidiaries on a consolidated basis, Solvent. No step has been taken by such Seller or, to the Knowledge of Seller, any other Person, to make such Seller or to make any Subsidiary of such Seller subject to any event described in clause (e) of the definition of “Event of Default” herein.

(s) No Subordination. The claims and rights of Buyer created by this Agreement and the other Transaction Documents in and to the Sold Assets and the Security Interests are not and shall not be subordinated to any creditor of a Seller (including, for the avoidance of doubt, any Senior Lender under the Senior Secured Debt Facility).

(t) Investment Company Act. Neither such Seller nor any of its Subsidiaries is an “investment company” as defined in, or subject to regulation under, the Investment Company Act of 1940, as amended.

(u) Security Interests. This Agreement is effective to create in favor of Buyer legal, valid and enforceable security interests in all right, title and interest of Albireo Pharma in the Collateral. This Agreement is effective to create in favor of Buyer legal, valid and enforceable security interests in all right, title and interest of Albireo AB in the Sold Assets (to the extent such security interests can be perfected by the filing of UCC financing statements with the Washington, DC Recorder of Deeds). Upon (i) the filing of the UCC financing statements contemplated by Section 2.1(b) and (ii) the signing of the Control Agreement by all parties thereto, the Security Interests granted by Albireo Pharma will constitute valid and perfected first priority security interests in all of the Collateral in favor of Buyer, prior to all other Liens on the Collateral (except for Permitted Liens having priority by operation of law). To the extent the Security Interests granted by Albireo AB in the Sold Assets can be perfected by the filing of UCC financing statements with the Washington, DC Recorder of Deeds, upon the filing of the UCC financing statements contemplated by Section 2.1(b) with the Washington, DC Recorder of Deeds, the Security Interests granted by Albireo AB will constitute valid and perfected first priority security interests in all of the Sold Assets in favor of Buyer, prior to all other Liens on the Sold Assets (except for Permitted Liens having priority by operation of law).

Section 4.2 Buyer’s Representations and Warranties. Buyer hereby represents and warrants to Sellers that as of the date hereof:



(a) Existence. Buyer is an entity duly organized and validly existing under the laws of the jurisdiction in which it is organized.

(b) Authorization. Buyer has the requisite right, power and authority to execute, deliver and perform its obligations under this Agreement and the other Transaction Documents. The execution, delivery and performance of this Agreement and the other Transaction Documents, and the consummation of the transactions contemplated hereby, have been duly authorized by all necessary action on the part of Buyer.

(c) Enforceability. This Agreement and the other Transaction Documents have been duly executed and delivered by an authorized person or authorized persons of Buyer and constitutes the valid and binding obligation of Buyer, enforceable against Buyer in accordance with their respective terms, except as may be limited by applicable Bankruptcy Laws or by general principles of equity (whether considered in a proceeding in equity or at law).

(d) No Conflicts. The execution, delivery and performance by Buyer of this Agreement and the other Transaction Documents do not and will not (i) contravene or conflict with the organizational documents of Buyer, (ii) contravene or conflict with or constitute a default under any material provision of any law binding upon or applicable to Buyer or (iii) contravene or conflict with or constitute a default under any material contract or other material agreement or Judgment binding upon or applicable to Buyer.

(e) Consents. Except for the consents that have been obtained on or prior to the Closing and the UCC financing statements contemplated by Section 2.1(b), no consent, approval, license, order, authorization, registration, declaration or filing with or of any Governmental Entity or other Person is required to be done or obtained by Buyer in connection with (i) the execution and delivery by Buyer of this Agreement and the other Transaction Documents, (ii) the performance by Buyer of its obligations under this Agreement and the other Transaction Documents or (iii) the consummation by such Buyer of any of the transactions contemplated by this Agreement and the other Transaction Documents.

(f) No Litigation. There is no action, suit, investigation or proceeding pending or, to the knowledge of Buyer, threatened before any Governmental Entity to which Buyer is a party that would, if determined adversely, reasonably be expected to prevent or materially and adversely affect the ability of Buyer to perform its obligations under this Agreement and the other Transaction Documents.

(g) Financing. Buyer has sufficient cash to pay the Purchase Price on the Closing Date and when due pursuant to Section 2.2. Buyer acknowledges that its obligations under this Agreement are not contingent on obtaining financing.

(h) Brokers' Fees. There is no investment banker, broker, finder, financial advisor or other intermediary who has been retained by or is authorized to act on behalf of Buyer who might be entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

ARTICLE 5 COVENANTS

Section 5.1 Information Rights.

(a) From and after the Closing Date until the Royalty Termination Date, representatives of Sellers will meet at the reasonable advance request of Buyer and during normal business hours (no more often than [***]) to discuss, among other things, (i) material commercial, regulatory and intellectual property developments relating to the Products in the Product Territory and (iii) any other matters reasonably requested by Buyer (each such meeting and, if applicable, related materials provided in response to Buyer's request for additional information in accordance with this Section 5.1(a), collectively, an "Update Report"). Sellers shall also provide Buyer with such additional information in their possession and control regarding the Products in the Product Territory as Buyer may reasonably request from time to time. Notwithstanding the foregoing, Sellers will have satisfied their obligations pursuant to the immediately preceding sentence upon delivery of materials provided to their boards of directors in connection with the Products in the Product Territory to the extent relevant and responsive, in the reasonable discretion of Sellers, to Buyer's request, and Sellers are under no obligation to aggregate or otherwise create information, data or other work product in respect of Buyer's request for information pursuant to the immediately preceding sentence. Sellers and their controlled Affiliates shall prepare and maintain, and shall use Commercially Reasonable Efforts to cause their non-controlled Affiliates and their Licensees, Distributors and other Specified Counterparties to prepare and maintain, reasonably complete and accurate records of the information to be disclosed in each Update Report and Royalty Report (together, the "Reports").

(b) Notwithstanding anything to the contrary in this Agreement, any access to information provided by Sellers to Buyer in accordance with this Agreement (including any audits of Sellers conducted pursuant to Section 5.3) (i) shall be provided in such a manner as not to unreasonably interfere with the normal operation of the business of Sellers or any of their Subsidiaries or create material risk of damage or destruction to any material assets or property and (ii) may be limited by Sellers, as Sellers may reasonably determine in good faith, to comply with any applicable COVID-19 Measures and to ensure that such access, in light of COVID-19 or any COVID-19 Measures, does not jeopardize the health and safety of any of Sellers' Representatives or commercial partners. Any such access to information shall be subject to Sellers' reasonable security measures and insurance requirements and shall not include invasive testing. Nothing herein shall require Sellers to disclose or provide access to any information that could be detrimental to Sellers' business or operations or if such disclosure could, in their reasonable discretion, (A) jeopardize any attorney-client or other legal privilege (so long as Sellers have reasonably cooperated with Buyer to permit such inspection of or to disclose such information on a basis that does not waive such privilege with respect thereto) or (B) contravene any applicable law, fiduciary duty or binding agreement entered into prior to the date of this Agreement (including any confidentiality agreement to which a Seller or any of its Affiliates is a party) (so long as Sellers have reasonably cooperated with Buyer to permit such inspection of or to disclose such information on a basis that does not contravene any applicable law, fiduciary duty or binding agreement). All Reports, and the Confidential Information contained therein, shall be the Confidential Information of Sellers and subject to the obligations of confidentiality set forth in Article 7.

(c) [***] after a Seller receives from any Third Party any written notice, demand, certificate, offer, proposal, correspondence, report or other communication relating to any Specified Agreement, the Product Rights, the Revenue Participation Right, any other Sold Assets, the Included Product Revenue or any Product, which notice, demand, certificate, offer, proposal, correspondence, report or other communication would, or relates to any event or circumstance that would, reasonably be expected to have a Material Adverse Effect, Sellers shall provide Buyer written notice thereof (including reasonable details to enable Buyer to understand the applicable matters involved, the facts, events or circumstances that gave rise to such matters, any relief or remedies being sought, any proposed corrective action to be taken, and relevant timelines for any exercise of remedies or for any proposed corrective action), together with a copy of such written notice, demand, certificate, offer, proposal, correspondence, report or other communication.

(d) Sellers shall provide Buyer with written notice [***] after a responsible officer of a Seller becomes aware of any of the following: (i) any breach or default by a Seller of any covenant, agreement or other provision of this Agreement; (ii) any representation or warranty made by a Seller in this Agreement shall prove to be untrue, inaccurate or incomplete in any respect on the date as of which made; (iii) any change, effect, event, occurrence, state of facts, development or condition that would reasonably be expected to result in a Material Adverse Effect; and (iv) the occurrence of any other Put Option Event or Seller Bankruptcy Event of Default.

Section 5.2 Royalty Payments; Revenue Participation and Royalty Payment Details.

(a) From and after the Closing Date until the Royalty Termination Date, Sellers shall pay to Buyer, without any setoff or offset (subject, in each case, to Section 5.8), the Royalty Payment for each calendar month [***] after the end of each applicable calendar month; provided that, for [***] ([***)] calendar days thereafter, Sellers may further remit to Buyer such amounts received from Licensees, Distributors or other Specified Counterparties and constituting a part of the Royalty Payment without penalty; and provided, further, that Royalty Payments based upon Other Product Revenue shall not be due until [***] ([***)] calendar days after the end of the calendar month in which the applicable Other Product Revenue is actually received by a Seller; and provided, further, that, without limiting Section 2.6 of this Agreement and notwithstanding anything to the contrary, [***]. A late fee of [***] percent ([***)% over the Prime Rate (calculated on a per annum basis) will accrue on all unpaid amounts with respect to any Royalty Payment from (and including) the date such obligation was due until (and excluding) the date such obligation is actually paid. The imposition and payment of a late fee shall not constitute a waiver of Buyer's rights with respect to such payment default. Such accrued late fee will be compounded quarterly. Payment of such accrued late fee shall accompany payment of the outstanding obligation. The first calendar month for which a Royalty Payment is due shall be deemed to commence on the Closing Date (with respect to Net Sales of the Products in the Product Territory occurring on or after the Closing Date and with respect to Other Product Revenue actually received by Sellers or any of their Subsidiaries on or after the Closing Date) and extend to the end of such calendar month, and the last calendar month for which a Royalty Payment is due shall be deemed to commence on the first day of such calendar month and extend to the effective date of termination of this Agreement.



(b) From and after the Closing Date until the Royalty Termination Date, for each calendar month, [***] after the end of each of the calendar months (and to be provided on or before the date on which the corresponding Royalty Payment is made to Buyer), Sellers shall provide to Buyer a report setting forth in reasonable detail (a “Royalty Report”): (i) Included Product Revenue for the applicable calendar month and calendar year to date, on a country-by-country and Product-by-Product basis (including a reasonably detailed break-down of all deductions from Gross Sales used to determine Net Sales and any Net Sales described in Section 5.4(c), and including a reasonably detailed breakdown (including by category and by relevant payor) of Other Product Revenue) and (ii) (A) the applicable Included Product Revenue Royalty Rate and the calculation of the Royalty Payment payable to Buyer for the applicable calendar month, identifying, on a country-by-country and Product-by-Product basis, the number of units of the Products sold by each Related Party; provided that Royalty Payments based upon Included Product Revenue set forth in subclause (b) of the definition thereof shall be included in a Royalty Report to the extent such Included Product Revenue is actually received by Sellers in the applicable calendar month; and (B) foreign currency exchange rates used to calculate the Royalty Payment (which shall be rates of exchange determined in a manner consistent with Sellers’ method for calculating rates of exchange in the preparation of Sellers’ annual financial statements in accordance with GAAP). Following delivery of the Royalty Report, representatives of Sellers will meet at the reasonable advance request of Buyer and during normal business hours to discuss the Royalty Report (no more often than [***] and simultaneously with any Update Report, to the extent any Update Report is requested by Buyer). To the extent information relating to the source of sales of the Products (such information, the “Source of Sales Information”) in a Royalty Report is not available, the Sellers agree, at Sellers’ sole expense, to assist Buyer in obtaining such Source of Sales Information.

(c) Any payments required to be made by any Party under this Agreement shall be made in United States Dollars via electronic funds transfer or wire transfer of immediately available funds to such bank account as the receiving Party shall designate in writing prior to the date of such payment (provided, however, that in the case of Buyer, payments shall be made by wire transfer of immediately available funds to such account or accounts as an Authorized Buyer Representative shall designate both orally by telephone and in writing to Sellers).

(d) [***].

Section 5.3 Inspections and Audits of Sellers.

(a) From and after the Closing Date until the Royalty Termination Date, upon at least [***] ([***) Business Days’ written notice and during normal business hours, no more frequently than [***], Buyer may cause an inspection and/or audit by an independent public accounting firm reasonably acceptable to Sellers to be made of Sellers’ (or of their Subsidiaries’) books of account for the [***] ([***) calendar years prior to the audit for the purpose of determining the correctness of Royalty Payments (including the calculation thereof) made under this Agreement. Upon Buyer’s reasonable advance request, no more frequently than [***] while any Specified Agreement remains in effect, Sellers shall use Commercially Reasonable Efforts to exercise any rights they may have under any Specified Agreement relating to a Product to cause an inspection and/or audit by an independent public accounting firm to be made of the books of

account of any Specified Counterparty thereto for the purpose of determining the correctness of Royalty Payments (including the calculation thereof) made under this Agreement. Sellers shall promptly notify Buyer in writing if it initiates an inspection and/or audit of the books of accounts of any Specified Counterparty to a Specified Agreement to the extent such inspection and/or audit is related to the Royalty Payments, and shall provide to Buyer a copy of any report relating thereto within [***] ([***) Business Days of receipt thereof, which copy may be redacted (including to preserve any attorney-client or other legal privilege); provided, that any redactions to such report shall not include any information necessary to determine the correctness of the Royalty Payments (including the calculation thereof) made under this Agreement. All of the out-of-pocket expenses of any inspection or audit requested by Buyer hereunder (including the fees and expenses of such independent public accounting firm designated for such purpose) otherwise payable by Sellers shall be borne solely by Buyer, unless the independent public accounting firm determines that Royalty Payments previously paid to Buyer during the period of the audit were underpaid by an amount greater than [***] percent ([***)%) of the Royalty Payments actually paid during such period, in which case such expenses shall be borne by Sellers. Such accounting firm will enter into a confidentiality agreement and an engagement letter reasonably acceptable to Sellers governing the use and disclosure of Sellers' information disclosed to such accounting firm and such accounting firm's acceptance of the procedures set forth in this Section 5.3. Such accounting firm shall not disclose the confidential information of Sellers or any Specified Counterparty relating to the Products to Buyer, except to the extent such disclosure is necessary to determine the correctness of Royalty Payments (including the calculation thereof) or otherwise would be included in a Report. All information obtained by Buyer as a result of any such inspection or audit shall be Confidential Information of Sellers subject to Article 7. The Parties agree that the calculation of Included Product Revenue and the Royalty Payments by such accounting firm contemplated by this Section 5.3 is to measure Included Product Revenue and the Royalty Payments in accordance with the terms of this Agreement, and such calculation is not intended to permit the introduction of accounting methods, policies, principles, practices, procedures, classifications or estimation methodologies contrary to those specified in this Agreement for the purposes of determining Included Product Revenue and the Royalty Payments. Such accounting firm shall provide a copy of its report to the Parties simultaneously. The Parties shall have [***] ([***) calendar days from the date of delivery of such report to provide the accounting firm with comments on such report, which each Party shall deliver to the accounting firm and the other Parties simultaneously. The accounting firm shall consider such comments in good faith and shall deliver an updated report within [***] ([***) calendar days of the earlier to occur of the end of such [***] ([***)-day review period or the Parties' written confirmation of submission of final comments to such accounting firm's initial report. If the final report of the accounting firm in respect of an audit discloses any underpayments by Sellers to Buyer, then such underpayment, together with the late fees contemplated by Section 5.2(a) shall be paid by Sellers to Buyer within [***] ([***) calendar days of such underpayment being so disclosed. If any audit discloses any overpayments by Sellers to Buyer, then Sellers shall have the right to credit the amount of the overpayment against Buyer's subsequent monthly Royalty Payment due to Buyer until the overpayment has been fully applied. If the overpayment is not fully applied prior to or at the time of the final monthly Royalty Payment due hereunder, Buyer shall promptly refund to Sellers an amount equal to any such remaining overpayment.

(b) Sellers shall use Commercially Reasonable Efforts to (i) include in each Specified Agreement (other than In-Licenses) entered into after the date of this Agreement

provisions permitting Sellers to audit and/or inspect the Specified Counterparties under each Specified Agreement and (ii) include in each Specified Agreement entered into after the date of this Agreement, terms and conditions consistent in all material respects with Buyer's rights to audit and/or inspect Sellers set forth in this Section 5.3.

Section 5.4 Intellectual Property Matters

(a) Subject to the rights and obligations of any Licensees, licensors or co-owners of Patent Rights (including any counterparties to an Existing In-License or other In-License), Sellers shall use Commercially Reasonable Efforts (i) to take any and all reasonably necessary actions, and prepare, execute, deliver and file any and all agreements, documents and instruments, that are reasonably necessary to diligently preserve and maintain the applicable Patents included within the Patent Rights and with respect to which Sellers have prosecution rights, including, as applicable, payment of maintenance fees or annuities when due where it is commercially reasonable to do so and (ii) with respect to the prosecution and maintenance of the Patent Rights with respect to which Sellers have prosecution rights, including, as applicable, prosecution of applications for potential patent term extensions, patent term adjustments, supplementary protection certificates, and the like.

(b) Sellers shall, subject to the rights and obligations of any Licensees, licensors or co-owners of Intellectual Property Rights (including any counterparties to an Existing In-License or other In-License), use Commercially Reasonable Efforts to diligently defend and enforce the applicable Intellectual Property Rights owned or controlled by Sellers or their Affiliates against infringement or interference by any other Person, and against any claims of invalidity or unenforceability, in any jurisdiction (including by bringing any legal action for infringement or defending any counterclaim of invalidity or action of any other Person for declaratory judgment of non-infringement or non-interference). Sellers shall [***] provide to Buyer a copy of any written notice received by it of a claim, legal action, suit or other proceeding involving the Intellectual Property Rights in the Product Territory. Sellers shall [***] inform Buyer of any infringement by a Third Party of any Patent Right in the Product Territory of which any of the individuals named in the definition of "Knowledge of Seller" (or the successors of such Persons at Sellers) becomes aware. Promptly following Sellers' delivery to Buyer or Sellers' receipt of any claim, legal action, suit or other proceeding involving the Intellectual Property Rights in the Product Territory, or Sellers' awareness of any infringement or interference, or any claims of invalidity or unenforceability, under this Section 5.4(b), Sellers and Buyer shall consult with each other with a view to determining the appropriate course of action to take with respect to the applicable claim, legal action, suit or other proceeding, any infringement or interference, or any claims of invalidity or unenforceability. Each Seller may, and if requested in writing by Buyer, shall, proceed, in consultation with Buyer, to institute and enforce a claim, legal action, suit or other proceeding against any infringement by a Third Party with respect to such Seller's Patent Rights that are then-currently listed for the Products in the publication Approved Drug Products with Therapeutic Equivalence Evaluations as published by the FDA (the "Orange Book Patents") and shall otherwise use Commercially Reasonable Efforts to enforce or defend the Orange Book Patents, as applicable. In connection with any such enforcement or defense of the Intellectual Property Rights (including the Orange Book Patents), Sellers shall retain and employ a team of legal counsel from a law firm with an internationally recognized U.S. patent litigation practice of reputable standing and experience related to the

enforcement under the United States Hatch-Waxman Act (1984), as amended, of U.S. patents listed for FDA-approved pharmaceutical products in the publication Approved Drug Products with Therapeutic Equivalence Evaluations as published by the FDA.

(c) As between the Parties, Sellers' actions taken under this Section 5.4 shall be taken at Sellers' or their Licensee's sole expense. If Sellers or their Licensee recovers monetary damages from a Third Party in any action brought for such Third Party's infringement of any Intellectual Property Rights in the Product Territory relating to the Products [***] where such damages, whether in the form of judgment or settlement, are awarded for such infringement of such Intellectual Property Rights, (i) such recovery will be allocated first to the reimbursement of any expenses incurred by Sellers or their Licensees, as applicable, in bringing such action (including all reasonable attorney's fees) and (ii) any remaining amounts, to the extent payable to Sellers or their Licensees, will be treated as Net Sales with respect to the Product Territory.

(d) [***]

Section 5.5 Specified Agreements.

(a) Subject to compliance with this Section 5.5 and Section 5.11, Sellers may enter into Specified Agreements that are In-Licenses or Permitted Licenses without Buyer's prior written consent. Sellers may not enter into any other Specified Agreement without Buyer's prior written consent. Sellers shall [***] provide Buyer with (i) executed copies of any Specified Agreement entered into by a Seller or its Affiliates after the date hereof, and (ii) executed copies of each amendment, supplement, modification or written waiver consummated after the date hereof of any provision of any Specified Agreement; in each case of clauses (i) and (ii), to the extent complete and unredacted copies of such Specified Agreement, amendments, supplements, modifications or written waivers are not publicly filed by a Seller within [***] ([***) Business Days following execution thereof (and, solely in the case of amendments, supplements, modifications or waivers of any Existing Specified Agreement, subject to any confidentiality restrictions applicable to Sellers or their Affiliates under the applicable Existing Specified Agreement). [***] following a Seller's notice to a Specified Counterparty to any Specified Agreement of an alleged material breach by such Specified Counterparty under any such Specified Agreement, Sellers shall provide Buyer a copy thereof (and, solely in the case of breaches of any Existing Specified Agreement, subject to any confidentiality restrictions applicable to Sellers or their Affiliates under the applicable Existing Specified Agreement).

(b) Sellers shall use Commercially Reasonable Efforts to comply in all material respects with their obligations under the Specified Agreements and shall use Commercially Reasonable Efforts to not take any action or forego any action that would reasonably be expected to result in a material breach thereof. [***] after receipt of any (written or oral) notice from a Specified Counterparty to any Specified Agreement or from any Affiliate of such Specified Counterparty of an alleged material breach under any Specified Agreement, Sellers shall provide Buyer a copy (or, in the case of oral notices, a written summary) thereof (and, solely in the case of breaches of any Existing Specified Agreement, subject to any confidentiality restrictions applicable to Sellers or their Affiliates under the applicable Existing Specified Agreement). Sellers shall use their Commercially Reasonable Efforts to cure any material breaches by them under any Specified Agreement and shall give written notice to Buyer

upon curing any such breach. Sellers shall not terminate any Specified Agreement without Buyer's prior written consent to the extent that such termination would reasonably be expected to have a Material Adverse Effect. Sellers shall not make or enter into any amendment, supplement or modification to, or grant any waiver under any provision of, any Specified Agreement without Buyer's prior written consent to the extent that such amendment, supplement, modification or grant would reasonably be expected to have a Material Adverse Effect.

(c) Sellers shall provide Buyer with written notice [***] following becoming aware of a Specified Counterparty's material breach of its obligations under any Specified Agreement. [***] following a Seller's notice to a Specified Counterparty to any Specified Agreement of an alleged breach by such Specified Counterparty under any such Specified Agreement, Sellers shall provide Buyer a copy thereof. Promptly following Sellers' delivery to Buyer of any notice described in the first sentence or second sentence of this Section 5.5(c) in respect of an actual or alleged breach by any Specified Counterparty of a Specified Agreement that would reasonably be expected to result in a Material Adverse Effect, Sellers and Buyer shall consult with each other with a view to determining the appropriate course of action to take with respect to such actual or alleged breach. Sellers may, and if requested in writing by Buyer, shall, proceed, in consultation with Buyer, to institute and enforce a claim, legal action, suit or other proceeding against such Specified Counterparty and to use Commercially Reasonable Efforts to enforce compliance by such Specified Counterparty with the relevant provisions of such Specified Agreement, and as shall be available to Sellers under applicable law. In connection with any such enforcement of such Specified Counterparty's obligations under such Specified Agreement, Sellers shall retain and employ a team of legal counsel from a law firm with an internationally recognized civil litigation practice of reputable standing.

(d) As between the Parties, Sellers' actions taken under Section 5.5 shall be taken at Sellers' sole expense. If Sellers recover monetary damages in any claim, legal action, suit or other proceeding brought against a Specified Counterparty for such Specified Counterparty's breach of its obligations under a Specified Agreement where such damages, whether in the form of judgment or settlement, are awarded for such breach of such Specified Agreement, (i) such recovery will be allocated first to the reimbursement of any expenses incurred by Sellers or their Affiliates in bringing such claim, legal action, suit or other proceeding (including all reasonable attorney's fees) and (ii) any remaining amounts, to the extent payable to Sellers or their Affiliates, will be treated as Other Product Revenue in respect of such Specified Agreement.

Section 5.6 Use of Proceeds; Diligence.

(a) With respect to the amounts paid by Buyer to Sellers under this Agreement, Sellers will use such amounts (i) to support activities to complete clinical development, file for Marketing Approval and Commercialize the Products and (ii) for general corporate purposes.

(b) Sellers shall use Commercially Reasonable Efforts to [***].

Section 5.7 Commercially Reasonable Efforts. Notwithstanding anything in Section 5.6 to the contrary, Sellers agree to use their Commercially Reasonable Efforts to maximize

Included Product Revenue; provided, that, for the avoidance of doubt, notwithstanding anything to the contrary in this Agreement, neither the signing by Seller of a definitive written agreement with respect to a Specified Transaction nor the consummation of a Specified Transaction in compliance with Section 5.12(e) shall, in and of itself, constitute a violation of this Section 5.7.

Section 5.8 Certain Tax Matters.

(a) Sellers and Buyer (i) agree that for U.S. federal and applicable state and local income Tax purposes, the transactions contemplated by this Agreement are intended to constitute a debt instrument that is subject to U.S. Treasury Regulations under Section 1.1275-4(b) governing contingent payment debt instruments. Sellers and Buyer shall cooperate in good faith to determine the comparable yield (as such term is described in the U.S. Treasury Regulations governing contingent payment debt instruments) for the debt instrument within [***] ([***)] days following the date of this Agreement and (ii) intend that the provisions of Treasury Regulation 1.1275-2(a)(1) would apply, subject to the exceptions in Treasury Regulation 1.1275-2(a)(2), to treat any non-contingent payments on the debt instrument (if any) and the projected amount of any contingent payments as first, a payment of any accrued and any unpaid original issue discount at such time and second, a payment of principal (including, to the extent relevant, for purposes of the rules applicable to “applicable high yield discount obligations”). Buyer and Sellers agree not to take and to not cause or permit their Affiliates to take, any position that is inconsistent with the provisions of this Section 5.8(a) on any Tax return or for any other Tax purpose, unless required by law or the good faith resolution of a Tax audit or other Tax proceeding. If there is an inquiry by any Governmental Entity of Buyer or Sellers related to the treatment described in this Section 5.8(a), the Parties shall cooperate with each other in responding to such inquiry in a reasonable manner which is consistent with this Section 5.8(a).

(b) Notwithstanding anything to the contrary in this Agreement, other than as set forth in Section 2.2, but subject to Sellers’ obligations to pay additional amounts pursuant to Section 5.8(d) and Section 5.8(e), Buyer and each Seller shall be entitled to withhold and deduct (or cause to be withheld and deducted) from any amount payable under this Agreement to any other Party any Tax that Buyer or any Seller, as applicable, determines that it is required to withhold and deduct under applicable law (as determined by the Parties after consultation with each other); provided that Buyer and each Seller shall give the other Parties reasonable prior notice and the opportunity, in good faith, to contest and prevent such withholding and deduction. Any amounts so deducted and withheld shall be treated as paid to, and actually received by, Buyer or the applicable Seller, as the case may be, for purposes of this Agreement. The Parties shall use commercially reasonable efforts to give or cause to be given to the other Parties such assistance and such information concerning the reasons for withholding or deduction (including, in reasonable detail, the method of calculation for the deduction or withholding thereof) as may be reasonably necessary to enable Buyer or a Seller, as applicable, to claim exemption therefrom, or credit therefor, or relief (whether at source or by reclaim) therefrom, and, in each case, shall furnish Buyer or Sellers, as applicable, with proper evidence of the Taxes withheld and deducted and remitted to the relevant taxing authority.



(c) Buyer is and at all times from and after the date hereof shall be a “United States person” within the meaning of Section 7701(a)(30) of the Code eligible to deliver an IRS Form W-9.

(d) Notwithstanding anything to the contrary in this Agreement, if Albireo Pharma (including, for the avoidance of doubt for purposes of this Section 5.8(d), (x) any successor to Albireo Pharma under this Agreement or (y) if applicable, an assignee of Albireo Pharma under this Agreement) becomes organized, formed or tax resident in a jurisdiction outside of the United States or any of its Subsidiaries becomes organized, formed or tax resident in a jurisdiction outside of such Subsidiary’s jurisdiction of residence as of the date hereof, then:

(i) if any applicable law requires the deduction or withholding of any amount from any payment hereunder to Buyer which amount results solely as a result of Albireo Pharma being organized, formed or tax resident in a jurisdiction outside of the United States or any of its Subsidiaries being organized, formed or tax resident in a jurisdiction outside of such Subsidiary’s jurisdiction of residence as of the date hereof, then the sum payable by Sellers shall be increased as necessary so that, after such deduction or withholding has been made (including such deductions and withholdings applicable to additional sums payable under this Section 5.8(d)), Buyer receives an amount equal to the sum Buyer would have received had no such deduction or withholding been required or made;

(ii) if Buyer is required to deduct, withhold or pay any amount with respect to payments hereunder under any applicable law, which amount resulted solely as a result of Albireo Pharma being organized, formed or tax resident in a jurisdiction outside of the United States or any of its Subsidiaries being organized, formed or tax resident in a jurisdiction outside of such Subsidiary’s jurisdiction of residence as of the date hereof, then, without duplication of Section 5.8(d)(i) above, Sellers shall indemnify Buyer, within [***] days after demand therefor, for the full amount of such deduction, withholding or payment (including Taxes imposed or asserted on or attributable to amounts payable under this Section 5.8(d) under such law) payable or paid by Buyer;

(iii) Sellers shall not be obligated to pay any additional amounts or indemnity payments under this Section 5.8(d) to the extent that such deduction, withholding or payment obligation arises as a result of (i) an assignment of Buyer’s interest in this Agreement or (ii) Buyer, or any successor to Buyer or assignee of Buyer under this Agreement, becoming organized, formed or tax resident in a jurisdiction outside of the United States, or becoming a disregarded entity of an entity that is organized, formed or tax resident in a jurisdiction outside of the United States); and

(iv) for the avoidance of doubt and notwithstanding anything herein to the contrary, the amount of the increase payable under Section 5.8(d)(i) and the amount of any indemnity payments paid to Buyer under Section 5.8(d)(ii) shall not be creditable towards the Royalty Cap.

(v) In the event that Sellers become obligated to pay any additional amounts or indemnity payments under this Section 5.8(d), Buyer agrees to cooperate in good faith with Sellers to mitigate Sellers’ obligation to make such payments, including by using

commercially reasonable efforts to collect and/or provide such tax forms and other documentation that could be reasonably expected to establish an exemption from or reduction of the applicable tax and taking any such other commercially reasonable steps as may be available to mitigate Sellers' obligation to make payments under this Section 5.8(d).

(e) Notwithstanding anything to the contrary in this Agreement:

(i) if any applicable law in Sweden requires the deduction or withholding of any amount from any payment hereunder to Buyer, then the sum payable by Sellers shall be increased as necessary so that, after such deduction or withholding has been made (including such deductions and withholdings applicable to additional sums payable under this Section 5.8(e)), Buyer receives an amount equal to the sum Buyer would have received had no such deduction or withholding been made;

(ii) if Buyer is required to deduct, withhold or pay any amount with respect to payments hereunder under any applicable law in Sweden, then, without duplication of Section 5.8(e)(i) above, Sellers shall indemnify Buyer, within [***] days after demand therefor, for the full amount of such deduction, withholding or payment (including Swedish Taxes imposed or asserted on or attributable to amounts payable under this Section 5.8(e) under such law) payable or paid by Buyer;

(iii) Sellers shall not be obligated to pay any additional amounts or indemnity payments under this Section 5.8(e) to the extent that such deduction, withholding or payment obligation arises as a result of (i) an assignment of Buyer's interest in this Agreement or (ii) Buyer, or any successor to Buyer or assignee of Buyer under this Agreement, becoming organized, formed or tax resident in a jurisdiction outside of the United States, or becoming a disregarded entity of an entity that is organized, formed or tax resident in a jurisdiction outside of the United States); and

(iv) for the avoidance of doubt and notwithstanding anything herein to the contrary, the amount of the increase payable under Section 5.8(e)(i) and the amount of any indemnity payments paid to Buyer under Section 5.8(e)(ii) shall not be creditable towards the Royalty Cap.

(v) In the event that Sellers become obligated to pay any additional amounts or indemnity payments under this Section 5.8(e), Buyer agrees to cooperate in good faith with Sellers to mitigate Sellers' obligation to make such payments, including by using commercially reasonable efforts to collect and/or provide such tax forms and other documentation that could be reasonably expected to establish an exemption from or reduction of the applicable tax and taking any such other commercially reasonable steps as may be available to mitigate Sellers' obligation to make payments under this Section 5.8(e).

Section 5.9 Further Assurances. After the Closing, but subject to Section 1.2(d), Sellers and Buyer agree to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably necessary in order to give effect to the transactions contemplated by this Agreement.

Section 5.10 Financial Statements. Sellers shall furnish to Buyer the financial statements listed hereinafter:

(a) [***] after the end of the last day of each of the first three fiscal quarters of each fiscal year of Albireo Pharma, unaudited interim and year-to-date financial statements as of the end of such fiscal quarter (prepared on a consolidated and consolidating basis, if applicable), including balance sheet and related statements of income and cash flows accompanied by a report detailing any material contingencies (including the commencement of any material litigation by or against Seller) or any other occurrence that could reasonably be expected to have a Material Adverse Effect, certified by Albireo Pharma's chief executive officer or chief financial officer to the effect that they have been prepared in accordance with GAAP, subject to the absence of footnotes and normal year-end adjustments; and

(b) [***] after the end of each fiscal year of Albireo Pharma, unqualified audited financial statements as of the end of such fiscal year (prepared on a consolidated and consolidating basis, if applicable), including balance sheet and related statements of income and cash flows, and setting forth in comparative form the corresponding figures for the preceding fiscal year, certified by a firm of independent certified public accountants selected by Albireo Pharma and reasonably acceptable to Buyer (Buyer hereby acknowledges that Ernst & Young LLP is acceptable).

Section 5.11 Seller Actions. Sellers agree that, notwithstanding anything herein to the contrary, Sellers shall not enter into any agreements, contracts or arrangements (including any Permitted Licenses or any other Specified Agreements or any amendments, modifications, waivers or terminations thereof, any supplements thereto, or any grant of any waiver or consent thereunder), whether oral or written, or otherwise take any action or fail (except as specifically set forth in Section 1.2(d)) to take any action that, in each case of such agreement, contract, arrangement, action or failure to act, would, individually or in the aggregate, reasonably be expected to (i) result in a Material Adverse Effect, (ii) conflict with this Agreement, (iii) serve or operate to limit or circumscribe any rights of Buyer under this Agreement (or any ability of Buyer to exercise any such right) or (iv) impair any Seller's ability to perform its obligations under this Agreement.

Section 5.12 Negative Covenants.

(a) Indebtedness. Sellers shall not, nor shall they permit any of their Subsidiaries to, directly or indirectly, create, incur, assume or suffer to exist any Indebtedness, except (x) with the prior written consent of Buyer, (y) Permitted Debt and (z) Indebtedness of Sellers and their Subsidiaries in respect of any senior secured debt facility of up to, in the aggregate, \$[***]; provided that (i) such senior secured debt facility shall have been incurred in compliance with (A) the right of first offer provisions set forth in Section 5.16 and (B) the provisions of Section 5.12(b), (ii) the collateral for such senior secured debt Facility shall not include any Excluded Assets, (iii) such senior secured debt facility shall be the subject of an Intercreditor Agreement between the Persons providing such senior secured debt facility (the "Senior Lenders") and Buyer, which Intercreditor Agreement shall be in form and substance reasonably satisfactory to Buyer (the "Intercreditor Agreement"), (iv) the collateral pledged to the Senior Lenders may not include proceeds (as defined in Article 9 of the UCC) thereof, to the

extent such proceeds would constitute Excluded Assets and (v) if the collateral pledged to the Senior Lenders includes Products, Intellectual Property Rights, Marketing Approvals or any other Product Rights not constituting Collateral under this Agreement (collectively, the “Specified Assets”), the Senior Lenders shall agree in the Intercreditor Agreement that the Buyer shall be entitled to the greater of (I) the Blended Rate (as defined below) of the proceeds of any Disposition of such Specified Assets and (II) the aggregate amount that may become payable by Sellers to Buyer pursuant to Section 2.3(b), Section 2.3(c) or Section 5.12(e) by virtue of such Disposition of Specified Assets (such senior secured debt facility, the “Senior Secured Debt Facility”). “Blended Rate” means the blended rate calculated based on the Included Product Revenue Royalty Rates that apply to the Included Product Revenue in respect of the calendar year immediately preceding the calendar year in which the Intercreditor Agreement is signed (for example, if the aggregate Included Product Revenue in respect of the calendar year immediately preceding the calendar year in which the Intercreditor Agreement is signed equals \$[***], and if Marketing Approval of a Product by the FDA to treat Biliary Atresia has not yet occurred during or prior to such immediately preceding calendar year, then the Blended Rate would be [***]% and calculated as follows: [***].

(b) Liens. Sellers shall not, nor shall they permit any of their Subsidiaries to, directly or indirectly, create, incur, assume or suffer to exist any Liens on any of their assets or property, except for (i) with respect to the Collateral, Permitted Liens of the type described in clause (d) of the definition thereof, (ii) with respect to property and assets other than the Collateral, any Permitted Liens and (iii) Liens securing the Senior Secured Debt Facility but only if (A) such Liens do not apply to any Excluded Assets and (B) such Liens and the Senior Secured Debt Facility are incurred in compliance with Section 5.12(a).

(c) Dispositions of Product Rights. (i) Sellers shall not, nor shall they permit any of their Subsidiaries to, Dispose of any of their rights in a Product, in whole or in part, including any Product Rights, in one or more related transactions, to any Person, (ii) Sellers shall not permit any Product Rights that are owned or controlled by Sellers on or after the date hereof to be owned or controlled, respectively, in whole or in part, by any Person other than Sellers, (iii) Sellers shall ensure that all Product Rights remain exclusively owned or controlled by Sellers and (iv) Sellers shall not permit any of their Subsidiaries to acquire or otherwise obtain ownership or control of any Product Rights, unless, in each case of the immediately preceding clauses (i), (ii), (iii) and (iv), (A) in connection with a Change of Control or (B) in connection with a Specified Transaction (as defined below) that complies with Section 5.12(e); provided, however, that this Section 5.12(c) shall not restrict Sellers from (I) licensing any Product Rights pursuant to a Permitted License or (II) transferring the Marketing Approvals for any jurisdiction to a Licensee in connection with a Permitted License covering such jurisdiction (but excluding any transfer of any Marketing Approval to any Subsidiary of the Sellers other than a transfer of any Marketing Approval between the Sellers), so long as, in each case of the immediately preceding clauses (I) and (II), such Permitted License has been entered into in compliance with the provisions of Section 5.5 and Section 5.11. Notwithstanding anything to the contrary in this Agreement, Sellers shall not Dispose of any of their rights in a Product, in whole or in part, including any Product Rights, in one or more related transactions, to any of their Subsidiaries other than (x) any transfer of any Marketing Approval between the Sellers, (y) any license or sublicense of any Intellectual Property Rights between Sellers and (z) any license or sublicense of any Trademark

Rights or any copyrights constituting Intellectual Property Rights between Sellers and their Subsidiaries.

(d) Restricted Payments. Sellers shall not, nor shall they permit any of their Subsidiaries to, (i) repurchase or redeem any class of stock or other equity interest other than pursuant to employee, director or consultant repurchase plans or other similar agreements; provided that, in each case, the repurchase or redemption price does not exceed the original consideration paid for such stock or equity interest or (ii) declare or pay any cash dividend or make a cash distribution on any class of stock or other equity interest, except that (A) a Subsidiary of a Seller may pay dividends or make distributions directly or indirectly through the chain of ownership to such Seller and (B) Albireo AB may pay dividends or make distributions directly to Albireo Pharma.

(e) Specified Transactions.

(i) Sellers shall not, nor shall they permit any of their Subsidiaries to, consummate (w) any merger, consolidation, recapitalization or reorganization (or similar transaction or series of related transactions) with a Third Party in which such Seller or such Subsidiary is not the surviving entity or in which, if such Seller or such Subsidiary is the surviving entity, the holders of such Seller's or such Subsidiary's outstanding shares immediately before consummation of such transaction or series of related transactions do not, immediately after consummation of such transaction or series of related transactions, retain shares representing more than 50.0% of the voting power of the surviving entity of such transaction or series of related transactions (or the parent of such surviving entity if such surviving entity is wholly owned by such parent), (x) any sale of all or substantially all of such Seller's or such Subsidiary's properties or assets (other than (I) in the case of any such Subsidiary, to a Seller and (II) in the case of any such Subsidiary other than Albireo AB, to another Subsidiary of Sellers), (y) any sale of all or substantially all of such Seller's or such Subsidiary's Product Rights or (z) any transaction which results in Albireo Pharma ceasing to directly own 100% of the equity interests of Albireo AB (each of the foregoing transactions described in clauses (w), (x), (y) and (z), a "Specified Transaction"), unless:

(A) with respect to a Specified Transaction involving a Seller, if the acquiring Person or surviving Person, as the case may be, in such Specified Transaction is not such Seller, then upon closing such Specified Transaction, such surviving Person expressly assumes all the obligations of such Seller under the Transaction Documents (in a writing in form and substance satisfactory to Buyer), in which case such surviving Person shall succeed to, and be substituted for, such Seller under the Transaction Documents and such Seller shall automatically be released and discharged from its obligations under the Transaction Documents,

(B) Sellers notify Buyer at least [***] ([***)] Business Days in advance of the anticipated date of the consummation of such Specified Transaction (it being understood and agreed that (I) if Sellers issue a public announcement at least [***] ([***)] Business Days in advance of the anticipated date of the consummation of such Specified Transaction announcing the signing of a definitive written agreement by a Seller or a Subsidiary of a Seller, as the case may be, and the relevant counterparty with

respect to such Specified Transaction, then Sellers shall be deemed to have satisfied the notification obligation described in this clause (B), (II) a public announcement of the signing of a definitive written agreement with respect to such Specified Transaction that is issued by Sellers less than [***] ([***) Business Days in advance of the anticipated date of the consummation of such Specified Transaction shall not satisfy the notification obligation described in this clause (B), and (III) if a Specified Transaction is to be consummated simultaneously with the signing of the definitive written agreement in respect of such Specified Transaction, then Sellers shall notify Buyer at least [***] ([***) Business Days in advance of the anticipated date of such simultaneous signing and consummation), and

(C) if Buyer delivers a Pre-Closing Specified Transaction Notice (as defined below) to Sellers prior to the close of business on the [***] ([***) Business Day preceding the anticipated date of the consummation of such Specified Transaction, then Sellers actually pay (or cause to be actually paid) the Put/Call Payment Amount to Buyer upon the consummation of such Specified Transaction by wire transfer of immediately available funds to such account or accounts as an Authorized Buyer Representative shall designate both orally by telephone and in writing to Sellers. “Pre-Closing Specified Transaction Notice” means, with respect to any Specified Transaction, a notification by Buyer to Sellers in writing stating that Buyer elects to sell the remainder of the Sold Assets to Sellers upon the consummation of such Specified Transaction in exchange for an amount in cash equal to the Put/Call Payment Amount to be paid by Sellers to Buyer upon the consummation of such Specified Transaction.

(ii) It is understood and agreed that if Buyer does not deliver a Pre-Closing Specified Transaction Notice with respect to a Specified Transaction prior to the close of business on the [***] ([***) Business Day preceding the anticipated date of the consummation of such Specified Transaction in accordance with the immediately preceding clause (i), then (A) Sellers shall promptly notify Buyer in writing of the consummation of such Specified Transaction and (B) following the consummation of such Specified Transaction Buyer may elect by notification to Sellers in writing (a “Post-Closing Specified Transaction Notice”) to sell the remainder of the Sold Assets to Sellers in exchange for an amount in cash equal to the Put/Call Payment Amount. In the event that Buyer delivers a Post-Closing Specified Transaction Notice to Sellers, then no later than the date that is [***] ([***) Business Days following receipt of such Post-Closing Specified Transaction Notice from Buyer, Sellers shall pay to Buyer the Put/Call Payment Amount by wire transfer of immediately available funds to such account or accounts as an Authorized Buyer Representative shall designate both orally by telephone and in writing to Sellers. With respect to any such Specified Transaction, if Buyer does not deliver a Post-Closing Specified Transaction Notice to Sellers within [***] ([***) days after Buyer’s receipt of written notice from Sellers (in accordance with the immediately preceding clause (A)) of the consummation of such Specified Transaction, then Buyer’s right to deliver a Post-Closing Specified Transaction Notice with respect to such Specified Transaction shall terminate at the end of such [***] ([***) day period.

(iii) Upon payment by Sellers to Buyer of the Put/Call Payment Amount in accordance with this Section 5.12(e), no further payments of the Sold Assets shall be due to Buyer hereunder and the Royalty Termination Date shall be deemed to have occurred. The

Put/Call Payment Amount due in respect of any Specified Transaction shall be fully earned on the Closing Date.

(f) Transactions with Affiliates. Sellers shall not, nor shall they permit any of their Subsidiaries to, directly or indirectly, enter into or permit to exist any transaction of any kind with any Affiliate of any of the Sellers or of any of their Subsidiaries on terms that are less favorable to any of the Sellers or any of their Subsidiaries, as the case may be, than those that might be obtained in an arm's-length transaction from a Person who is not an Affiliate of any of the Sellers or of any of their Subsidiaries; provided, however, that this Section 5.12(f) shall not apply to transactions between or among Sellers and any of their Subsidiaries that constitute Permitted Payments or any other payment expressly permitted by this Agreement.

(g) Competing Products. From the Closing Date until the Royalty Termination Date, (i) none of the Sellers nor any of their Subsidiaries shall Commercialize any Competing Product in the Product Territory and (ii) none of the Sellers nor any of their Subsidiaries shall Commercialize any compound or product (other than the Compounds and Products) in the Product Territory that is indicated for the treatment of Progressive Familial Intrahepatic Cholestasis, Biliary Atresia, Alagille Syndrome or any other indication for which any Phase 2 Clinical Trial or Pivotal/Phase 3 Clinical Trial has been or is started with any Product in the Product Territory.

(h) Put/Call Payment Amount Provisions Still Apply. For the avoidance of doubt, it is understood and agreed that if a Put Option Event or a Seller Bankruptcy Event of Default occurs, the provisions of Sections 2.3(b) and 2.3(c) shall continue to apply even if Sellers have fully complied with the provisions of Sections 5.12(c) and 5.12(e), as applicable.

Section 5.13 Existence. Subject to Section 5.12(e), each Seller shall (a) preserve and maintain its existence, (b) preserve and maintain its rights, franchises and privileges, unless failure to do any of the foregoing would not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect, (c) qualify and remain qualified in good standing in each jurisdiction where the failure to do so would reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect, including appointing and employing such agents or attorneys in each jurisdiction where it shall be necessary to take action under this Agreement and (d) comply with its organizational documents.

Section 5.14 Compliance with Laws. Each Seller (a) shall maintain, and shall cause each of its Subsidiaries to maintain, compliance in all material respects with all applicable laws, rules or regulations (including applicable Anti-Terrorism Laws, applicable Anti-Corruption Laws and applicable Sanctions), and (b) shall, or shall cause its Subsidiaries to, obtain and maintain all required authorizations, approvals, licenses, permits, certificates, registrations, listings, certificates or exemptions of or issued by any Governmental Entity reasonably necessary in connection with the conduct of such Seller's and its Subsidiaries' businesses, in each case of this clause (b), except where the failure to do so would not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect.

Section 5.15 Change of Name, Jurisdiction, Etc. No Seller shall, except upon not less than [***] ([***) Business Days' prior written notice to Buyer (or, in the case of a Specified

Transaction that complies with Section 5.12(e), so long as notice is provided to Buyer (or a public announcement is made by Sellers with respect to any such change) no later than [***] ([***) Business Days after any such change), (a) change its legal name, type of organization or corporate structure, (b) change the location of its chief executive office or its principal place of business, (c) change its Federal Taxpayer Identification Number or organizational identification number (if any) or (d) change its jurisdiction of organization. At the request of Buyer, Sellers agree to promptly provide Buyer with certified copies of their organizational documents reflecting any of the changes described in this Section 5.15.

Section 5.16 Right of First Offer for Senior Secured Debt Facility. The ability of Sellers to enter into a Senior Secured Debt Facility pursuant to Section 5.12(a) is subject to Sellers' compliance with this Section 5.16. If Sellers desire to obtain a Senior Secured Debt Facility, then Sellers shall first grant Buyer the right to provide such Senior Secured Debt Facility (the "SSDF Option") by delivering to Buyer a written notice stating Sellers' bona fide intention to enter into a Senior Secured Debt Facility and specifying Sellers' proposed material terms and conditions for such Senior Secured Debt Facility (a "ROFO Notice"). Upon receipt of the ROFO Notice, Buyer shall have [***] ([***) Business Days (the "ROFO Period") within which to exercise the SSDF Option by written notice to Sellers stating that Buyer offers to provide the Senior Secured Debt Facility on the terms specified in the ROFO Notice. If Buyer does not exercise the SSDF Option during the ROFO Period, Sellers may, during the [***] ([***) day period following the expiration of the ROFO Period, seek to obtain a Senior Secured Debt Facility (in the same principal amount as that proposed to Buyer) from other third-party financing sources on terms and conditions no more favorable to such third-party financing sources than those set forth in the ROFO Notice. If Sellers are not able to so obtain a Senior Secured Debt Facility (in the same principal amount as that proposed to Buyer) within such [***] ([***) day period, the rights provided under this Section 5.16 shall be deemed to be revived and Sellers shall not seek to obtain the Senior Secured Debt Facility from any Person (regardless of whether on the same or different terms and conditions as set forth in the original ROFO Notice) unless the SSDF Option is first re-offered to Buyer in accordance with this Section 5.16. Within [***] ([***) Business Days after the effectiveness of the commitments for a Senior Secured Debt Facility pursuant to this Section 5.16, Sellers shall provide to Buyer (i) a written notice identifying each lender committing to a portion of the Senior Secured Debt Facility and each such lender's portion (in U.S. dollars) of the Senior Secured Debt Facility and (ii) copies of the definitive documentation for the Senior Secured Debt Facility.

Section 5.17 Public Disclosures. Except for a press release previously approved in form and substance by Sellers and Buyer or any other public announcement using substantially the same text as such press release, neither Buyer nor Sellers shall, and each Party hereto shall cause its respective Representatives, controlled Affiliates and controlled Affiliates' Representatives not to issue a press release or other public announcement or otherwise make any public disclosure with respect to this Agreement, or the subject matter or any terms hereof (including the identity of any of the Parties hereto), without the prior written consent (which consent shall not be unreasonably withheld, conditioned or delayed) of (i) Sellers (in the case of any such press release, public announcement or public disclosure by Buyer) or (ii) Buyer (in the case of any such press release, public announcement or public disclosure by a Seller), except as may be required by applicable law or stock exchange rule (in which case the Party hereto required to make the press release or other public announcement or disclosure shall (x) allow the other

Parties hereto reasonable time to comment on (and, if applicable, reasonably direct the disclosing party to seek confidential treatment in respect of portions of) such press release or other public announcement or disclosure in advance of the issuance or making thereof and (y) if such press release, public announcement or disclosure involves a public disclosure of a copy of this Agreement or any exhibit or schedule hereto, the Party hereto making such disclosure shall first redact from such copy of this Agreement or such exhibit or schedule, as the case may be, such portions as reasonably requested by the other Parties hereto before making such public disclosure; provided that such redactions are consistent with applicable law, regulation or stock exchange rule).

Section 5.18 Minimum Cash Deposit Account.

(a) Sellers shall at all times maintain in the Controlled Account an amount of unrestricted cash, cash equivalents and liquid funds of at least \$[***], free and clear of all Liens other than Permitted Liens of the types described in clauses (d) and (i) of the definition thereof; provided, however, that if the amount of unrestricted cash, cash equivalents and liquid funds in the Controlled Account is at any time less than \$[***] but greater than \$[***], the Sellers shall have [***] ([***) Business Days after becoming aware of such shortfall to cause the amount of unrestricted cash, cash equivalents and liquid funds in the Controlled Account to equal at least \$[***]. “Controlled Account” means a “deposit account” (as defined in Article 9 of the UCC) of Albireo Pharma that is maintained at Silicon Valley Bank in the United States and subject to the Control Agreement.

(b) Sellers shall [***] notify Buyer (i) if the amount of unrestricted cash, cash equivalents and liquid funds in the Controlled Account is at any time less than \$[***], and (ii) after any such shortfall is remedied by the deposit of additional amounts of unrestricted cash, cash equivalents and liquid funds into the Controlled Account. In addition, Sellers shall instruct Silicon Valley Bank to provide Buyer with access to Silicon Valley Bank’s online services in respect of the Controlled Account such that Buyer has the ability at all times to monitor the balance in the Controlled Account.

Section 5.19 Additional Subsidiaries. In the event a Seller creates, forms or acquires additional Subsidiaries on or after the date hereof, Sellers agree to promptly notify Buyer of such new Subsidiary, such notice to include (a) a description in reasonable detail of the assets held by such Subsidiary and the operations conducted by such Subsidiary (and any contemplated changes thereto) and (b) a certification by Sellers that such Subsidiary and the Sellers are in compliance with the provisions set forth in this Agreement (including Section 5.12(c)).

Section 5.20 Subsidiary Guarantors. Sellers may, from time to time, elect by written notification to Buyer to cause any Subsidiary of a Seller (any such Subsidiary, a “Subsidiary Guarantor”) to provide a customary guarantee of the obligations of Sellers under this Agreement. In the event that Sellers so elect to add a Subsidiary Guarantor, then as promptly as practicable following Sellers’ written notification to Buyer of such election (a) Sellers, such Subsidiary Guarantor and Buyer shall enter into a guarantee agreement in form and substance reasonably satisfactory to Buyer (“Guarantee Agreement”), (b) Sellers and such Subsidiary Guarantor shall deliver to Buyer, concurrently with the execution of the Guarante Agreement, legal opinions from New York counsel and from local counsel in the jurisdiction in which such Subsidiary

Guarantor is organized, in each case in form and substance reasonably satisfactory to Buyer, (c) such Subsidiary Guarantor shall deliver to Buyer, concurrently with the execution of the Guarantee Agreement, a certificate of an officer of such Subsidiary Guarantor, in form and substance reasonably satisfactory to Buyer, certifying as to (i) such Subsidiary Guarantor's organizational documents, (ii) the attached thereto copies of resolutions adopted by such Subsidiary Guarantor authorizing the execution and delivery by such Subsidiary Guarantor of the Guarantee Agreement and the performance by such Subsidiary Guarantor of the obligations contemplated thereby and (iii) the incumbency and signature of each officer of such Subsidiary Guarantor executing the Guarantee Agreement and (d) such other documentation as shall be reasonably requested by Buyer in connection with the Guarantee Agreement.

ARTICLE 6 INDEMNIFICATION

Section 6.1 General Indemnity. From and after the Closing Date:

(a) Sellers hereby agree to indemnify, defend and hold harmless Buyer and its Affiliates and the respective directors, managers, partners, trustees, officers, agents and employees of Buyer and of its Affiliates (collectively, the "Buyer Indemnified Parties") from, against and in respect of all Losses suffered or incurred by Buyer Indemnified Parties (in each case whether or not brought by a Third Party) to the extent arising out of or resulting from [***].

(b) Buyer hereby agrees to indemnify, defend and hold harmless Sellers and their respective Affiliates and the respective directors, officers, agents and employees of Sellers and their respective Affiliates (the "Seller Indemnified Parties") from, against and in respect of all Losses suffered or incurred by Seller Indemnified Parties to the extent arising out of or resulting from [***].

Section 6.2 Claims Procedures.

(a) If either a Buyer Indemnified Party, on the one hand, or a Seller Indemnified Party, on the other hand (such Buyer Indemnified Party on the one hand and such Seller Indemnified Party on the other hand being hereinafter referred to as an "Indemnified Party"), has suffered or incurred any Losses for which indemnification may be sought under this Article 6, the Indemnified Party shall so notify the other Party from whom indemnification is sought under this Article 6 (the "Indemnifying Party") promptly in writing describing such Loss, the amount or estimated amount thereof, if known or reasonably capable of estimation, and the method of computation of such Loss, all with reasonable particularity and containing a reference to the provisions of this Agreement in respect of which such Loss shall have occurred. If any claim, action, suit or proceeding is asserted or instituted by or against a Person other than a Seller, Buyer, any Affiliate of a Seller or any Affiliate of Buyer with respect to which an Indemnified Party intends to claim any Loss under this Article 6 (a "Third Party Claim"), such Indemnified Party shall promptly notify the Indemnifying Party of such Third Party Claim and tender to the Indemnifying Party the defense of such Third Party Claim. A failure by an Indemnified Party to give notice and to tender the defense of such Third Party Claim in a timely manner pursuant to this Section 6.2 shall not limit the obligation of the Indemnifying Party under this Article 6, except to the extent such Indemnifying Party is actually prejudiced thereby.

(b) The Indemnifying Party will be entitled to participate in the defense of any Third Party Claim that is the subject of a notice given by or on behalf of any Indemnified Party pursuant to Section 6.2(a). In addition, the Indemnifying Party will have the right to defend the Indemnified Party against the Third Party Claim with counsel of its choice reasonably satisfactory to the Indemnified Party so long as (i) the Indemnifying Party gives written notice that they or it will defend the Third Party Claim to the Indemnified Party within [***] ([***)] days after the Indemnified Party has given notice of the Third Party Claim under Section 6.2(a) stating that the Indemnifying Party will, and thereby covenants to, indemnify, defend and hold harmless the Indemnified Party from and against the entirety of any and all Losses the Indemnified Party may suffer resulting from, arising out of, relating to, in the nature of, or caused by the Third Party Claim, (ii) the Third Party Claim involves only money damages and does not seek an injunction or other equitable relief, (iii) the Indemnified Party has not been advised by counsel that an actual or potential conflict exists between the Indemnified Party and the Indemnifying Party in connection with the defense of the Third Party Claim and (iv) the Third Party Claim does not relate to or otherwise arise in connection with any criminal action, suit, investigation or proceeding.

(c) The Indemnifying Party will not consent to the entry of any Judgment or enter into any compromise or settlement with respect to the Third Party Claim without the prior written consent of the Indemnified Party (which consent will not be unreasonably withheld, conditioned or delayed) unless such Judgment, compromise or settlement (i) provides for the payment by the Indemnifying Party of money as sole relief for the claimant, (ii) results in the general release of all Indemnified Parties and their Affiliates from all liabilities arising or relating to, or in connection with, the Third Party Claim and (iii) involves no finding or admission of any violation of law or the rights of any Person and no effect on any other claims that may be made against the Indemnified Party or any of its Affiliates.

(d) If the Indemnifying Party does not deliver the notice contemplated by Section 6.2(b) within [***] ([***)] days after the Indemnified Party has given notice of the Third Party Claim pursuant to Section 6.2(a), or otherwise at any time fails to conduct the defense of the Third Party Claim diligently, the Indemnified Party may defend, and may consent to the entry of any Judgment or enter into any compromise or settlement with respect to, the Third Party Claim in any manner it may deem appropriate following consultation with the Indemnifying Party in connection therewith. If such notice and evidence is given on a timely basis and the Indemnifying Party conducts the defense of the Third Party Claim diligently but any of the other conditions in Section 6.2(b) is or becomes unsatisfied, the Indemnified Party may defend, and may consent to the entry of any Judgment or enter into any compromise or settlement with respect to, the Third Party Claim; provided that the Indemnifying Party will not be bound by the entry of any such Judgment consented to, or any such compromise or settlement effected, without its prior written consent (which consent will not be unreasonably withheld, conditioned or delayed).

Section 6.3 Limitations on Liability; Time for Claims.

(a) Except for claims arising from a breach of confidentiality obligations under Article 7 or in cases of fraud, gross negligence or willful misconduct, [***]. In connection with the foregoing, the Parties acknowledge and agree that (i) Buyer's damages, if any, for any

such action or claim will typically include [***], and (ii) Buyer shall be entitled to make claims for all such missing, delayed or diminished Royalty Payments as Losses hereunder, [***].

(b) Notwithstanding anything to the contrary herein, (i) Sellers' aggregate liability in respect of claims for indemnification pursuant to Section 6.1(a)(i) will not exceed [***]; and (ii) Buyer's aggregate liability in respect of claims for indemnification pursuant to Section 6.1(b)(i) will not exceed [***].

(c) No claim may be made or suit instituted seeking indemnification pursuant to the provisions of Section 6.1(a)(i) or Section 6.1(b)(i) unless a written notice is provided to Sellers or Buyer, as applicable, prior to the date that is [***] ([***)] years following the Closing Date.

Section 6.4 Exclusive Remedy. The Parties acknowledge and agree that after the Closing, the indemnification provisions of this Article 6 shall be the sole and exclusive remedies of the Parties for any breach of the representations or warranties or nonperformance of or default under any covenants or agreements by any Party contained in this Agreement or any agreement, certificate or document signed and delivered by any Party in connection with this Agreement (other than [***]).

ARTICLE 7 CONFIDENTIALITY

Section 7.1 Confidentiality. Except as (i) provided in this Article 7 or (ii) otherwise agreed in writing by the Parties, the Parties agree that, during the term of this Agreement and for [***] ([***)] years thereafter, each Party (the "Receiving Party") shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any information furnished to it by or on behalf of any other Party (the "Disclosing Party") pursuant to this Agreement (such information, "Confidential Information" of the Disclosing Party), except for that portion of such information that:

(a) was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the Disclosing Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement or any other agreement;

(d) is independently developed by the Receiving Party or any of its Affiliates, as evidenced by written records, without the use of or reference of the Confidential Information; or

(e) is subsequently disclosed to the Receiving Party on a non-confidential basis by a third party without obligations of confidentiality with respect thereto.

Section 7.2 Authorized Disclosure.

(a) Either Party may disclose any other Party's Confidential Information to the extent such disclosure is reasonably necessary in the following situations:

- (i) prosecuting or defending litigation;
- (ii) complying with applicable laws and regulations (including the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, and regulations promulgated by securities exchanges);
- (iii) complying with a valid order of a court of competent jurisdiction or other Governmental Entity;
- (iv) for regulatory, Tax or customs purposes;
- (v) for audit purposes, provided that each recipient of Confidential Information must be bound by customary and reasonable obligations of confidentiality and non-use substantially similar to those imposed upon the Parties hereunder (with appropriate variations to reflect the role of the auditor and the nature of the audit activities to be undertaken) prior to any such disclosure;
- (vi) disclosure to its Affiliates and Representatives on a need-to-know basis, provided that each such recipient of Confidential Information must be bound by customary contractual or professional obligations of confidentiality and non-use prior to any such disclosure;
- (vii) upon the prior written consent of the Disclosing Party;
- (viii) disclosure to its actual and potential investors, and other actual and potential sources of funding, including debt financing, and actual and potential partners, collaborators and acquirers, and their respective accountants, financial advisors and other professional representatives; provided that such disclosure shall be made only to the extent customarily required in connection with such investment, financing transaction, partnership, collaboration or acquisition and that each recipient of Confidential Information must be bound by customary obligations of confidentiality and non-use prior to any such disclosure; or
- (ix) as is necessary in connection with a permitted assignment pursuant to Section 9.4.

(b) For the avoidance of doubt, the existence and terms of this Agreement shall be deemed to be Confidential Information of all Parties. Nothing provided herein limits any Party's use or disclosure of its own Confidential Information if such Confidential Information is not also Confidential Information of another Party.

(c) Notwithstanding the foregoing, in the event the Receiving Party is required to make a disclosure of any Disclosing Party's Confidential Information pursuant to Section 7.2(a)(i), Section 7.2(a)(ii), Section 7.2(a)(iii) or Section 7.2(a)(iv), it will (A) give

reasonable advance notice to each Disclosing Party of such disclosure (including providing a draft of the proposed disclosure reasonably in advance of disclosure to the extent permitted by applicable law), (B) allow each Disclosing Party reasonable time to comment on such disclosure and, if applicable, reasonably direct the Receiving Party to seek confidential treatment in respect of portions of such disclosure, (C) consider in good faith each Disclosing Party's reasonable comments to such disclosure, (D) use commercially reasonable efforts to secure confidential treatment of such information and (E) if such disclosure involves a public disclosure of a copy of this Agreement or any exhibit or schedule hereto, the Party hereto making such disclosure shall first redact from such copy of this Agreement or such exhibit or schedule, as the case may be, such portions as reasonably requested by the other Parties hereto before making such public disclosure; provided that such redactions are consistent with applicable law, regulation or stock exchange rule. Notwithstanding anything in this Agreement to the contrary, Buyer will not be required to give any party hereto any advance notice of the type described in the immediately preceding sentence, nor be required to comply with any of the other provisions of the immediately preceding sentence, if such disclosure by Buyer is made pursuant to Section 7.2(a)(iv) in connection with a routine examination by a regulatory or supervisory authority having jurisdiction over Buyer. In any event, Buyer shall not file any patent application based upon or using the Confidential Information of Seller provided hereunder.

(d) Notwithstanding anything in this Agreement to the contrary, Buyer may (i) include disclosure of (A) the Purchase Price, (B) the amount and nature of the Revenue Participation Right, the Put/Call Payment Amount and the True Up Payments, (C) the anticipated timing of the occurrence of the Royalty Termination Date, (D) any exercise or planned exercise by Seller of the call option described in Section 2.3(a), (E) any occurrence of a Put Option Event or Bankruptcy Event of Default, and (F) Seller's remaining obligations to Buyer under this Agreement in the footnotes to Buyer's audited annual financial statements, to the extent so required by Buyer's independent accountants, or including comparable disclosure in Buyer's unaudited quarterly financial statements, and (ii) provide copies of such audited annual and unaudited quarterly financial statements to Buyer's actual or potential lenders or direct or indirect beneficial owners, as long as such lenders or beneficial owners have agreed to be bound by customary obligations of confidentiality and non-use prior to any such disclosure.

(e) As of the date hereof, the Existing Confidentiality Agreement is hereby terminated without further force and effect (including any provisions of the Existing Confidentiality Agreement that by the terms thereof would have otherwise survived the termination of the Existing Confidentiality Agreement), superseded by this Article 7 of this Agreement and all obligations between the Parties relating to confidentiality shall be governed by this Article 7 of this Agreement.

ARTICLE 8 TERMINATION

Section 8.1 Mutual Termination. This Agreement may be terminated by mutual written agreement of Buyer and Sellers.

Section 8.2 Automatic Termination. Unless earlier terminated as provided in Section 8.1, this Agreement shall continue in full force and effect until such time as Sellers are no longer

obligated to make any Royalty Payments, True Up Payments or payment of the Put/Call Payment Amount under this Agreement, at which point this Agreement shall automatically terminate, except with respect to any rights that shall have accrued prior to such termination. Upon the occurrence of the effective date of termination of this Agreement, Buyer shall release and cooperate with Sellers to release any financing statements and all security interests contemplated by Section 2.1(b) (and execute and deliver any termination or release documents in connection therewith as shall be reasonably requested by Sellers) and all rights, title and interests, in, to and under the Sold Assets shall revert to Sellers.

Section 8.3 Survival. Notwithstanding anything to the contrary in this Article 8, the following provisions (and related definitions) shall survive termination of this Agreement: Section 2.3 (Buyout) (solely with respect to amounts accrued prior to expiration or termination but not paid), Section 5.2 (Royalty Payments; Revenue Participation and Royalty Payment Details) (solely with respect to amounts accrued prior to expiration or termination but not paid), Section 5.3 (Inspections and Audits of Sellers); provided that Section 5.3 shall terminate on the [***] anniversary of the effective date of termination of this Agreement, Section 5.12(e) (Specified Transactions) (solely with respect to amounts accrued prior to expiration or termination but not paid), Article 6 (Indemnification), Article 7 (Confidentiality) (for the time period specified in Section 7.1), this Section 8.3 (Survival) and Article 9 (Miscellaneous). Termination of the Agreement shall not relieve any Party of liability in respect of breaches under this Agreement by any Party on or prior to termination.

ARTICLE 9 MISCELLANEOUS

Section 9.1 Headings. The table of contents and the descriptive headings of the several Articles and Sections of this Agreement, and the descriptive headings of the Annexes, Exhibits and Schedules to this Agreement, are for convenience only, do not constitute a part of this Agreement and shall not control or affect, in any way, the meaning or interpretation of this Agreement.

Section 9.2 Notices. All notices and other communications under this Agreement shall be in writing and shall be by email with PDF attachment, an internationally recognized courier service or personal delivery to the following addresses (and, solely in the case of Section 2.3, Section 5.2(c) and Section 5.12(e), orally by telephone at the telephone number of Sellers designated in writing from time to time by Sellers to Buyer), or to such other addresses as shall be designated from time to time by a Party in accordance with this Section 9.2:

If to Sellers, to them at:

c/o Albireo Pharma, Inc.
53 State Street, 19th Floor
Boston, MA 02109
Attention: General Counsel
Email: [***]



If to Buyer, to it at:

Sagard
161 Bay Street, Suite 5000
Toronto, ON M5J 2S1
Canada
Attention: General Counsel
E-mail: [***]

All notices and communications under this Agreement shall be deemed to have been duly given (a) when delivered by hand, if personally delivered, (b) when sent, if by email with PDF attachment, with an acknowledgement of receipt being produced by the recipient's email account or (c) when received, if sent by internationally recognized courier service. Notwithstanding anything to the contrary in this Section 9.2, (i) all notices and communications under Section 6.2(a) and Section 6.2(b) shall be sent by an internationally recognized courier or by personal delivery and (ii) all service of legal process shall be sent by an internationally recognized courier, by personal delivery or in any other manner permitted by applicable law.

Section 9.3 Expenses. All fees, costs and expenses (including any legal, accounting and banking fees) incurred in connection with the preparation, negotiation, execution and delivery of this Agreement and to consummate the transactions contemplated hereby shall be paid by the Party hereto incurring such fees, costs and expenses.

Section 9.4 Assignment; Register.

(a) Following the Closing, no Seller may assign, pledge or otherwise transfer, in whole or in part, this Agreement or any of such Seller's rights, interests or obligations hereunder without Buyer's prior written consent (which consent shall not be unreasonably withheld, conditioned or delayed), except as permitted under Section 5.12(e) (it being understood and agreed, for the avoidance of doubt, that even if a Seller has fully complied with the provisions of Sections 5.12(c) and 5.12(e), as applicable, the provisions of Sections 2.3(b) and 2.3(c) shall continue to apply). Following the Closing, Buyer may, without the consent of Sellers, assign, pledge or otherwise transfer, in whole or in part, this Agreement or any of Buyer's rights, interests or obligations hereunder to any Person, including to any Third Party or to one or more of its Affiliates; provided that, (a) if any obligations of Buyer to Sellers under this Agreement are assigned to such Person, Buyer shall cause such Person to deliver a writing to Sellers in which such Person assumes such assigned obligations, (b) such Person shall be a "United States person" within the meaning of Section 7701(a)(30) of the Code, and shall deliver to Sellers a validly executed Internal Revenue Service Form W-9 at or prior to the effective time of such assignment establishing a complete exemption from U.S. federal withholding tax (including backup withholding) and (c) the consummation of such assignment, pledge or other transfer shall be at no out-of-pocket cost to Sellers (other than the cost of Sellers' outside legal counsel, if any). Notwithstanding anything to the contrary herein, Buyer may not assign, pledge or otherwise transfer this Agreement without the prior written consent of Sellers (such consent not to be unreasonably withheld, conditioned or delayed) to any Person whose primary business is Commercializing a product for the treatment of any indication to the extent such indication is included in any Marketing Approval of the Product or is the subject of an ongoing or planned

clinical trial in respect of the Product that has been disclosed to Buyer in any Update Report. This Agreement shall be binding upon, inure to the benefit of and be enforceable by, the Parties and their respective permitted successors and assigns. Any purported assignment in violation of this Section 9.4 shall be null and void.

(b) Albireo Pharma (and, if applicable, an assignee of Albireo Pharma under this Agreement) shall maintain at one of its offices in the United States a copy of each assignment by Buyer delivered to Sellers and a register for the recordation of the name and address of Buyer and each assignee of Buyer under this Agreement and, for U.S. federal income tax purposes, principal amounts (and any stated interest) owing to Buyer and each assignee of Buyer pursuant to the terms hereof from time to time (the “Register”). The entries in the Register shall be conclusive absent manifest error, and Sellers, Buyer and each assignee of Buyer shall treat each Person whose name is recorded in the Register pursuant to the terms hereof in the same manner as a Buyer hereunder for all purposes of this Agreement. The Register shall be available for inspection by Sellers, Buyer and any assignee of Buyer, at any reasonable time and from time to time upon reasonable prior written notice.

Section 9.5 Amendment and Waiver.

(a) This Agreement may be amended, modified or supplemented only in a writing signed by Sellers and Buyer. Any provision of this Agreement may be waived only in a writing signed by the Party granting such waiver.

(b) No failure or delay on the part of any Party in exercising any right, power or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or remedy preclude any other or further exercise thereof or the exercise of any other right, power or remedy. No course of dealing among the Parties shall be effective to amend, modify, supplement or waive any provision of this Agreement.

Section 9.6 Entire Agreement. This Agreement, the Annexes and Exhibits annexed hereto and the Disclosure Schedule constitute the entire understanding among the Parties with respect to the subject matter hereof and supersede all other understandings and negotiations with respect thereto.

Section 9.7 No Third Party Beneficiaries. This Agreement is for the sole benefit of Sellers and Buyer and their permitted successors and assigns and nothing herein expressed or implied shall give or be construed to give to any Person, other than the Parties and such successors and assigns, any legal or equitable rights hereunder, except that the Indemnified Parties shall be third-party beneficiaries of the benefits provided for in Section 6.1.

Section 9.8 Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of the State of New York without giving effect to any choice or conflict of law provision or rule that would cause the application of the laws of any other jurisdiction.



Section 9.9 Jurisdiction; Venue; Jury Trial Waiver.

(a) EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY AND UNCONDITIONALLY SUBMITS, FOR ITSELF AND ITS RESPECTIVE PROPERTY AND ASSETS, TO THE EXCLUSIVE JURISDICTION OF THE SUPREME COURT OF THE STATE OF NEW YORK FOR THE COUNTY OF NEW YORK, THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK AND ANY APPELLATE COURT FROM ANY OF THE FOREGOING COURTS (SUCH COURTS, COLLECTIVELY, THE “NEW YORK COURTS”), IN ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT, OR FOR RECOGNITION OR ENFORCEMENT OF ANY JUDGMENT IN RESPECT THEREOF, AND BUYER AND SELLERS HEREBY IRREVOCABLY AND UNCONDITIONALLY AGREE THAT ALL CLAIMS IN RESPECT OF ANY SUCH ACTION OR PROCEEDING MAY BE HEARD AND DETERMINED IN ANY SUCH NEW YORK COURT. BUYER AND SELLERS HEREBY AGREE THAT A FINAL JUDGMENT IN ANY SUCH ACTION OR PROCEEDING SHALL BE CONCLUSIVE AND MAY BE ENFORCED IN OTHER JURISDICTIONS BY SUIT ON THE JUDGMENT OR IN ANY OTHER MANNER PROVIDED BY APPLICABLE LAW. BUYER AND EACH SELLER HEREBY SUBMITS TO THE EXCLUSIVE PERSONAL JURISDICTION AND VENUE OF SUCH NEW YORK COURTS. BUYER AND SELLERS AGREE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, THAT PROCESS MAY BE SERVED ON BUYER OR SELLERS IN THE SAME MANNER THAT NOTICES MAY BE GIVEN PURSUANT TO SECTION 9.2 HEREOF.

(b) EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES, TO THE FULLEST EXTENT IT MAY LEGALLY AND EFFECTIVELY DO SO, ANY OBJECTION THAT IT MAY NOW OR HEREAFTER HAVE TO THE LAYING OF VENUE OF ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT IN ANY SUCH NEW YORK COURT. BUYER AND EACH SELLER HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, THE DEFENSE OF AN INCONVENIENT FORUM TO THE MAINTENANCE OF SUCH ACTION OR PROCEEDING IN ANY SUCH COURT.

(c) EACH PARTY HEREBY JOINTLY AND SEVERALLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY ACTION OR PROCEEDING RELATING TO THIS AGREEMENT OR ANY OTHER DOCUMENT DELIVERED HEREUNDER OR IN CONNECTION HERewith, OR ANY TRANSACTION ARISING FROM OR CONNECTED TO ANY OF THE FOREGOING. EACH OF THE PARTIES REPRESENTS THAT THIS WAIVER IS KNOWINGLY, WILLINGLY AND VOLUNTARILY GIVEN.

Section 9.10 Severability. If any term or provision of this Agreement shall for any reason be held to be invalid, illegal or unenforceable in any situation in any jurisdiction, then the Parties shall replace such term or provision with a new term or provision permitted by applicable law and having an economic effect as close as possible to the invalid, illegal or unenforceable term or provision, and all other terms and provisions of this Agreement shall nevertheless remain in full force and effect and the enforceability and validity of the offending term or provision shall not be affected in any other situation or jurisdiction.

Section 9.11 Specific Performance. Each of the Parties acknowledges and agrees that the other Parties may be damaged irreparably in the event any of the provisions of this Agreement are not performed in accordance with their specific terms or otherwise are breached or violated. Accordingly, each of the Parties agrees that, without posting bond or other undertaking, the other Parties will be entitled to seek an injunction or injunctions to prevent breaches or violations of the provisions of this Agreement and to seek to enforce specifically this Agreement and the terms and provisions hereof in any action, suit or other proceeding instituted in any New York Court in addition to any other remedy to which it may be entitled, at law or in equity. Each of the Parties further agrees that, in the event of any action for specific performance in respect of such breach or violation, it will not assert the defense that a remedy at law would be adequate.

Section 9.12 Counterparts. This Agreement may be executed in any number of counterparts and by the Parties in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. The words “execution,” “signed” and “signature” and words of like import in this Agreement shall include images of manually executed signatures transmitted by facsimile or other electronic format (including “pdf”, “tif” or “jpg”) and other electronic signatures (including DocuSign and AdobeSign). The use of electronic signatures and electronic records (including any contract or other record created, generated, sent, communicated, received or stored by electronic means) shall be of the same legal effect, validity and enforceability as a manually executed signature or use of a paper-based record-keeping system to the fullest extent permitted by applicable law, including the Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act and any other applicable law, including any state law based on the Uniform Electronic Transactions Act or the UCC.

Section 9.13 Relationship of the Parties. The relationship between Buyer, on the one hand, and Sellers, on the other hand, is solely that of purchaser and sellers, respectively, and (i) Buyer does not have any fiduciary or other special relationship with Sellers or any of their Affiliates and (ii) Sellers do not have any fiduciary or other special relationship with Buyer or any of its Affiliates. This Agreement is not a partnership or similar agreement, and nothing contained herein shall be deemed to constitute Buyer and Sellers as a partnership, an association, a joint venture or any other kind of entity or legal form for any purposes, including any Tax purposes. Buyer and Sellers agree that they shall not take any inconsistent position with respect to such treatment in a filing with any Governmental Entity.

Section 9.14 Remedies. The rights and remedies of the Parties under this Agreement are cumulative and not alternative. Neither the failure nor any delay by any Party in exercising any right, power or privilege under this Agreement will operate as a waiver of such right, power or privilege, and no single or partial exercise of such right, power or privilege will preclude any other or further exercise of such right, power or privilege or the exercise of any other right, power or privilege. Unless specifically and expressly stated in this Agreement as exclusive, each remedy of the Parties specified in this Agreement is not exclusive, and, subject to the terms of this Agreement, the Parties shall be entitled to pursue any available legal or equitable remedy for breach of this Agreement or any provision hereof.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed and delivered by their respective representatives thereunto duly authorized as of the date first above written.

SELLER

ALBIREO PHARMA, INC.

By: /s/ Simon Harford

Name: Simon Harford

Title: Chief Financial Officer and Treasurer

SELLER

ALBIREO AB

By: /s/ Jan Mattsson

Name: Jan Mattsson

Title: Authorized Signatory

[Signature Page to Purchase and Sale Agreement]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed and delivered by their respective representatives thereunto duly authorized as of the date first above written.

BUYER

SAGARD HEALTHCARE PARTNERS
(DELAWARE) LP

By: /s/ Sacha Haque

Name: Sacha Haque

Title: General Counsel and Secretary

By: /s/ Jason Sneah

Name: Jason Sneah

Title: Manager

[Signature Page to Purchase and Sale Agreement]

EXHIBIT A
TO PURCHASE AND SALE AGREEMENT

FORM OF BILL OF SALE AND ASSIGNMENT

BILL OF SALE AND ASSIGNMENT made as of September 22, 2022, by and among ALBIREO PHARMA, INC., a Delaware corporation, ALBIREO AB, a company incorporated under the laws of Sweden with registration number [***] (each of Albireo Pharma, Inc. and Albireo AB, a “*Seller*” and, collectively, the “*Sellers*”), and SAGARD HEALTHCARE PARTNERS (DELAWARE) LP, a Delaware limited partnership (“*Buyer*”).

WHEREAS, Sellers and Buyer have entered into that certain Purchase and Sale Agreement, dated as of September 22, 2022 (the “*Purchase Agreement*”), pursuant to which, among other things, Sellers have agreed to sell, transfer, assign and convey to Buyer all of Sellers’ right, title and interest in and to the Sold Assets. Capitalized terms used and not otherwise defined herein shall have the meanings ascribed to such terms in the Purchase Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and obligations set forth herein and in the Purchase Agreement and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as set forth below.

Section 1. Sale and Assignment. Upon the terms of and subject to the conditions of the Purchase Agreement, Sellers hereby sell, transfer, assign and convey to Buyer all of Sellers’ right, title and interest in and to the Sold Assets.

Section 2. Acceptance. Buyer hereby accepts such right, title and interest in and to the Sold Assets. Notwithstanding any provision herein to the contrary, Buyer is not assuming any liability or obligation of Sellers of whatever nature, whether presently in existence or arising or asserted hereafter.

Section 3. Other. This Bill of Sale and Assignment (i) is made pursuant to, and is subject to the terms of, the Purchase Agreement and (ii) shall be binding upon, inure to the benefit of and be enforceable by, the parties hereto and their respective permitted successors and assigns in accordance with the terms of the Purchase Agreement. This Bill of Sale and Assignment is for the sole benefit of the parties hereto and their respective permitted successors and assigns and not for the benefit of any third party.

Section 4. Governing Law. This Bill of Sale and Assignment shall be governed by, and construed in accordance with, the laws of the State of New York without giving effect to any choice or conflict of law provision or rule that would cause the application of the laws of any other jurisdiction.

Section 5. Counterparts. This Bill of Sale and Assignment may be executed in any number of counterparts and by the parties hereto in separate

counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. The words “execution,” “signed” and “signature” and words of like import in this Bill of Sale and Assignment shall include images of manually executed signatures transmitted by facsimile or other electronic format (including “pdf”, “tif” or “jpg”) and other electronic signatures (including DocuSign and AdobeSign). The use of electronic signatures and electronic records (including any contract or other record created, generated, sent, communicated, received or stored by electronic means) shall be of the same legal effect, validity and enforceability as a manually executed signature or use of a paper-based record-keeping system to the fullest extent permitted by applicable law, including the Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act and any other applicable law, including any state law based on the Uniform Electronic Transactions Act or the UCC.

[Signature Pages Follow]

A-2

IN WITNESS WHEREOF, the undersigned have caused this Bill of Sale and Assignment to be executed by their respective representatives thereunto duly authorized as of the date first above written.

SELLER:

ALBIREO PHARMA, INC.

By:

Name: Simon Harford
Title: Chief Financial Officer and
Treasurer

SELLER:

ALBIREO AB

By:

Name: Jan Mattsson
Title: Authorized Signatory

[Signature Page to Bill of Sale and Assignment]

BUYER:

**SAGARD HEALTHCARE PARTNERS (DELAWARE)
LP**

By: _____

Name:

Title:

[Signature Page to Bill of Sale and Assignment]



[Disclosure Schedules to this agreement have been omitted pursuant to Item 601(a)(5) of Regulation S-K. Albireo Pharma, Inc. undertakes to provide a copy of the omitted schedules to the Securities and Exchange Commission or its staff upon request.]

[Annexes 1- 4 to this agreement have been omitted pursuant to Item 601(a)(5) of Regulation S-K. Albireo Pharma, Inc. undertakes to provide a copy of the omitted exhibits to the Securities and Exchange Commission or its staff upon request.]

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 8, 2022

/s/ Ronald H.W. Cooper
Ronald H.W. Cooper

President and Chief Executive Officer
(principal executive officer)

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 8, 2022

/s/ Simon Harford
Simon N.R. Harford

Chief Financial Officer and Treasurer (principal financial officer and principal accounting officer)

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, 2022 (the “Form 10-Q”) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 8, 2022

/s/ Ronald H.W. Cooper

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

Dated: November 8, 2022

/s/ Simon Harford

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

**Document and Entity
Information - shares**

**9 Months Ended
Sep. 30, 2022**

Nov. 01, 2022

Cover [Abstract]

<u>Document Type</u>	10-Q	
<u>Document Quarterly Report</u>	true	
<u>Document Period End Date</u>	Sep. 30, 2022	
<u>Document Transition Report</u>	false	
<u>Entity File Number</u>	001-33451	
<u>Entity Registrant Name</u>	Albireo Pharma, Inc.	
<u>Entity Incorporation, State or Country Code</u>	DE	
<u>Entity Tax Identification Number</u>	90-0136863	
<u>Entity Address, Address Line One</u>	53 State Street	
<u>Entity Address, Address Line Two</u>	19th Floor	
<u>Entity Address, City or Town</u>	Boston	
<u>Entity Address, State or Province</u>	MA	
<u>Entity Address, Postal Zip Code</u>	02109	
<u>City Area Code</u>	857	
<u>Local Phone Number</u>	254-5555	
<u>Title of 12(b) Security</u>	Common Stock, par value \$0.01 per share	
<u>Trading Symbol</u>	ALBO	
<u>Security Exchange Name</u>	NASDAQ	
<u>Entity Current Reporting Status</u>	Yes	
<u>Entity Interactive Data Current</u>	Yes	
<u>Entity Filer Category</u>	Non-accelerated Filer	
<u>Entity Small Business</u>	true	
<u>Entity Emerging Growth Company</u>	false	
<u>Entity Shell Company</u>	false	
<u>Entity Common Stock, Shares Outstanding</u>		20,701,283
<u>Entity Central Index Key</u>	0001322505	
<u>Current Fiscal Year End Date</u>	--12-31	
<u>Document Fiscal Year Focus</u>	2022	
<u>Document Fiscal Period Focus</u>	Q3	
<u>Amendment Flag</u>	false	

**Condensed Consolidated
Balance Sheets - USD (\$)
\$ in Thousands**

	Sep. 30, 2022	Dec. 31, 2021
Current assets:		
<u>Cash and cash equivalents</u>	\$ 222,476	\$ 248,107
<u>Accounts receivable, net</u>	2,029	3,272
<u>Inventory</u>	3,149	194
<u>Prepaid expenses</u>	8,516	5,261
<u>Other current assets</u>	2,666	12,096
<u>Total current assets</u>	238,836	268,930
<u>Restricted cash</u>	50,000	
<u>Property and equipment, net</u>	1,303	668
<u>Goodwill</u>	17,260	17,260
<u>Other assets</u>	13,823	15,193
<u>Total assets</u>	321,222	302,051
Current liabilities:		
<u>Accounts payable</u>	6,950	6,516
<u>Accrued expenses</u>	25,365	35,951
<u>Other current liabilities</u>	5,504	2,880
<u>Total current liabilities</u>	37,819	45,347
<u>Liability related to sale of future royalties</u>	62,053	60,132
<u>Revenue interest liability, net</u>	111,644	
<u>Note payable, net of discount</u>		10,004
<u>Other long-term liabilities</u>	9,635	10,960
<u>Total liabilities</u>	221,151	126,443
Stockholders' Equity:		
<u>Preferred stock, \$0.01 par value per share - 50,000,000 shares authorized at September 30, 2022 and December 31, 2021; 0 and 0 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively</u>		
<u>Common stock, \$0.01 par value per share - 60,000,000 shares authorized at September 30, 2022 and December 31, 2021; 20,700,458 and 20,692,698 shares issued and outstanding at September 30, 2022, respectively, and 19,304,312 and 19,296,552 shares issued and outstanding at December 31, 2021, respectively</u>	207	193
<u>Additional paid-in capital</u>	512,915	475,390
<u>Accumulated other comprehensive income</u>	8,212	1,105
<u>Accumulated deficit</u>	(421,033)	(300,850)
<u>Treasury stock at cost, 7,760 shares at September 30, 2022 and December 31 2021, respectively</u>	(230)	(230)
<u>Total stockholders' equity</u>	100,071	175,608
<u>Total liabilities and stockholders' equity</u>	\$ 321,222	\$ 302,051

**Condensed Consolidated
Balance Sheets
(Parenthetical) - \$ / shares**

Sep. 30, 2022 Dec. 31, 2021

Condensed Consolidated Balance Sheets

<u>Preferred stock, par value (in dollars per share)</u>	\$ 0.01	\$ 0.01
<u>Preferred stock, shares authorized</u>	50,000,000	50,000,000
<u>Preferred stock, shares issued</u>	0	0
<u>Preferred stock, shares outstanding</u>	0	0
<u>Common stock, par value (in dollars per share)</u>	\$ 0.01	\$ 0.01
<u>Common stock, shares authorized</u>	60,000,000	60,000,000
<u>Common stock, shares issued</u>	20,700,458	19,304,312
<u>Common stock, shares outstanding</u>	20,692,698	19,296,552
<u>Treasury stock at cost, shares</u>	7,760	7,760

Condensed Consolidated Statements of Operations - USD (\$) \$ in Thousands	3 Months Ended		9 Months Ended	
	Sep. 30, 2022	Sep. 30, 2021	Sep. 30, 2022	Sep. 30, 2021
Revenue:				
<u>Revenue</u>	\$ 9,832	\$ 3,664	\$ 24,870	\$ 8,058
Cost and operating expenses:				
<u>Cost of product revenue</u>	612	431	1,622	431
<u>Research and development</u>	23,312	21,083	68,103	61,920
<u>Selling, general and administrative</u>	20,564	17,612	59,019	49,825
<u>Other operating expense, net</u>	1	3,719	7,544	7,873
<u>Total cost and operating expenses</u>	44,489	42,845	136,288	120,049
<u>Operating loss</u>	(34,657)	(39,181)	(111,418)	(111,991)
Other (loss) income:				
<u>Gain from sale of priority review voucher, net of transaction costs</u>		103,387		103,387
<u>Loss on extinguishment of debt</u>	(613)		(613)	
<u>Interest expense, net</u>	(2,530)	(3,331)	(8,152)	(10,675)
<u>Net (loss) income before income taxes</u>	(37,800)	60,875	(120,183)	(19,279)
<u>Provision for income taxes</u>	0	3,789	0	3,789
<u>Net (loss) income</u>	\$ (37,800)	\$ 57,086	\$ (120,183)	\$ (23,068)
Net (loss) income per share attributable to holders of common stock:				
<u>Basic (in dollars per share)</u>	\$ (1.92)	\$ 2.96	\$ (6.15)	\$ (1.20)
<u>Diluted (in dollars per share)</u>	\$ (1.92)	\$ 2.90	\$ (6.15)	\$ (1.20)
Weighted-average common shares outstanding:				
<u>Basic (in shares)</u>	19,655,350	19,258,905	19,541,044	19,197,536
<u>Diluted (in shares)</u>	19,655,350	19,651,243	19,541,044	19,197,536
Product				
Revenue:				
<u>Revenue</u>	\$ 7,543	\$ 1,060	\$ 18,090	\$ 1,060
Royalty				
Revenue:				
<u>Revenue</u>	\$ 2,289	\$ 2,604	\$ 6,780	\$ 6,998

Condensed Consolidated Statements of Comprehensive (Loss) Income - USD (\$) \$ in Thousands	3 Months Ended		9 Months Ended	
	Sep. 30,	Sep. 30,	Sep. 30,	Sep. 30,
	2022	2021	2022	2021
<u>Condensed Consolidated Statements of Comprehensive (Loss) Income</u>				
<u>Net (loss) income</u>	\$ (37,800)	\$ 57,086	\$ (120,183)	\$ (23,068)
<u>Other comprehensive (loss) income:</u>				
<u>Foreign currency translation adjustment</u>	(40)	3,657	7,107	7,890
<u>Total other comprehensive (loss) income</u>	(40)	3,657	7,107	7,890
<u>Total comprehensive (loss) income</u>	\$ (37,840)	\$ 60,743	\$ (113,076)	\$ (15,178)

Condensed Consolidated Statements of Shareholders' Equity - USD (\$) \$ in Thousands	Common Stock	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Treasury Stock At Cost	Total
<u>Balance at beginning of period at Dec. 31, 2020</u>	\$ 191	\$ 456,472	\$ (8,612)	\$ (266,820)		\$ 181,231
<u>Balance (in shares) at Dec. 31, 2020</u>	19,107,040					
<u>Increase (Decrease) in Stockholders' Equity</u>						
<u>Stock-based compensation expense</u>		3,062				3,062
<u>Exercise of options and vesting of RSUs</u>	\$ 1	403				404
<u>Exercise of options and vesting of RSUs (in shares)</u>	85,765					
<u>Other comprehensive (loss) income</u>			6,954			6,954
<u>Net (loss) income</u>				(43,733)		(43,733)
<u>Balance at end of period at Mar. 31, 2021</u>	\$ 192	459,937	(1,658)	(310,553)		147,918
<u>Balance (in shares) at Mar. 31, 2021</u>	19,192,805					
<u>Balance at beginning of period at Dec. 31, 2020</u>	\$ 191	456,472	(8,612)	(266,820)		181,231
<u>Balance (in shares) at Dec. 31, 2020</u>	19,107,040					
<u>Increase (Decrease) in Stockholders' Equity</u>						
<u>Other comprehensive (loss) income</u>						7,890
<u>Net (loss) income</u>						(23,068)
<u>Balance at end of period at Sep. 30, 2021</u>	\$ 193	472,363	(722)	(289,888)	\$ (230)	181,716
<u>Balance (in shares) at Sep. 30, 2021</u>	19,283,269				(7,760)	
<u>Balance at beginning of period at Mar. 31, 2021</u>	\$ 192	459,937	(1,658)	(310,553)		147,918
<u>Balance (in shares) at Mar. 31, 2021</u>	19,192,805					
<u>Increase (Decrease) in Stockholders' Equity</u>						
<u>Stock-based compensation expense</u>		3,504				3,504

Exercise of options and vesting of RSUs		1,224				1,224
Exercise of options and vesting of RSUs (in shares)	47,490					
Other comprehensive (loss) income			(2,721)			(2,721)
Net (loss) income				(36,421)		(36,421)
Balance at end of period at Jun. 30, 2021	\$ 192	464,665	(4,379)	(346,974)		113,504
Balance (in shares) at Jun. 30, 2021	19,240,295					
Increase (Decrease) in Stockholders' Equity						
Stock-based compensation expense		6,706				6,706
Exercise of options and vesting of RSUs	\$ 1	751				752
Exercise of options and vesting of RSUs (in shares)	35,466					
Issuance of common stock, net of costs		241				241
Issuance of common stock, net of costs (in shares)	7,508					
Other comprehensive (loss) income			3,657			3,657
Purchases of treasury stock, at cost					\$ (230)	(230)
Purchases of treasury stock, at cost (in shares)					(7,760)	
Net (loss) income				57,086		57,086
Balance at end of period at Sep. 30, 2021	\$ 193	472,363	(722)	(289,888)	\$ (230)	181,716
Balance (in shares) at Sep. 30, 2021	19,283,269				(7,760)	
Balance at beginning of period at Dec. 31, 2021	\$ 193	475,390	1,105	(300,850)	\$ (230)	175,608
Balance (in shares) at Dec. 31, 2021	19,304,312				(7,760)	
Increase (Decrease) in Stockholders' Equity						
Stock-based compensation expense		3,508				3,508
Exercise of options and vesting of RSUs	\$ 2	4,378				4,380
Exercise of options and vesting of RSUs (in shares)	223,683					

<u>Other comprehensive (loss) income</u>			7,124			7,124
<u>Net (loss) income</u>				(42,434)		(42,434)
<u>Balance at end of period at Mar. 31, 2022</u>	\$ 195	483,276	8,229	(343,284)	\$ (230)	148,186
<u>Balance (in shares) at Mar. 31, 2022</u>		19,527,995			(7,760)	
<u>Balance at beginning of period at Dec. 31, 2021</u>	\$ 193	475,390	1,105	(300,850)	\$ (230)	175,608
<u>Balance (in shares) at Dec. 31, 2021</u>		19,304,312			(7,760)	
<u>Increase (Decrease) in Stockholders' Equity</u>						
<u>Other comprehensive (loss) income</u>						7,107
<u>Net (loss) income</u>						(120,183)
<u>Balance at end of period at Sep. 30, 2022</u>	\$ 207	512,915	8,212	(421,033)	\$ (230)	100,071
<u>Balance (in shares) at Sep. 30, 2022</u>		20,700,742			(7,760)	
<u>Balance at beginning of period at Mar. 31, 2022</u>	\$ 195	483,276	8,229	(343,284)	\$ (230)	148,186
<u>Balance (in shares) at Mar. 31, 2022</u>		19,527,995			(7,760)	
<u>Increase (Decrease) in Stockholders' Equity</u>						
<u>Stock-based compensation expense</u>		3,616				3,616
<u>Exercise of options and vesting of RSUs</u>	\$ 1	1,800				1,801
<u>Exercise of options and vesting of RSUs (in shares)</u>		82,565				
<u>Other comprehensive (loss) income</u>			23			23
<u>Net (loss) income</u>				(39,949)		(39,949)
<u>Balance at end of period at Jun. 30, 2022</u>	\$ 196	488,692	8,252	(383,233)	\$ (230)	113,677
<u>Balance (in shares) at Jun. 30, 2022</u>		19,610,560			(7,760)	
<u>Increase (Decrease) in Stockholders' Equity</u>						
<u>Stock-based compensation expense</u>		3,547				3,547
<u>Exercise of options and vesting of RSUs</u>		70				70

<u>Exercise of options and vesting of RSUs (in shares)</u>	17,872						
<u>Issuance of common stock, net of costs</u>	\$ 11	20,606					20,617
<u>Issuance of common stock, net of costs (in shares)</u>	1,072,310						
<u>Other comprehensive (loss) income</u>			(40)				(40)
<u>Net (loss) income</u>				(37,800)			(37,800)
<u>Balance at end of period at Sep. 30, 2022</u>	\$ 207	\$ 512,915	\$ 8,212	\$ (421,033)	\$ (230)		\$ 100,071
<u>Balance (in shares) at Sep. 30, 2022</u>	20,700,742					(7,760)	

**Condensed Consolidated
Statements of Cash Flows -
USD (\$)
\$ in Thousands**

**9 Months Ended
Sep. 30, 2022 Sep. 30, 2021**

Cash flows from operating activities:

Net loss \$ (120,183) \$ (23,068)

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 8,250 9,428

Accretion of revenue interest liability, net 403

Accretion of debt discount and amortization of issuance costs 178 308

Depreciation and amortization 322 167

Extinguishment of debt 613

Share based compensation expense 10,671 13,272

Foreign currency adjustments 7,010 7,776

Changes in operating assets and liabilities:

Accounts receivable, net 1,018 (1,307)

Inventory (3,103) (196)

Prepaid expenses and other current assets 5,946 2,765

Other assets 93 293

Accounts payable 654 2,023

Accrued expenses (9,832) 2,068

Other current and long-term liabilities (3,471) (3,810)

Net cash used in operating activities (101,431) (93,668)

Cash flows from investing activities:

Purchase of property and equipment (960) (465)

Proceeds from sale of priority review voucher, net of transaction costs 103,387

Net cash (used in) provided by investing activities (960) 102,922

Cash flows from financing activities:

Proceeds from issuance of common stock, net of issuance costs 20,633 241

Proceeds from royalty agreement, net of issuance costs 111,577

Payment of principal on borrowings (10,795)

Proceeds from exercise of options 6,251 2,378

Payments related to repurchases of common stock (230)

Net cash provided by financing activities 127,666 2,389

Effect of exchange rate changes on cash, cash equivalents and restricted cash (906) (303)

Net increase in cash, cash equivalents and restricted cash 24,369 11,340

Cash, cash equivalents and restricted cash-beginning of period 248,107 251,272

Cash, cash equivalents and restricted cash-end of period 272,476 \$ 262,612

Supplemental disclosures of cash and non-cash activities

Unpaid transaction cost of royalty agreement 250

Unpaid royalty interest included in accrued expenses 87

Unpaid issuance costs related to common stock \$ 16

**Summary of significant
accounting policies and basis
of presentation**

**Summary of significant
accounting policies and basis
of presentation**

**Summary of significant
accounting policies and basis
of presentation**

9 Months Ended

Sep. 30, 2022

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 drug candidates, including modulators to treat orphan pediatric liver diseases and other liver and gastrointestinal diseases and disorders. The Company's product pipeline includes A3512 (odevixibat) approved in the United States and Europe, elobixibat, approved in Japan and Thailand for the treatment of chronic constipation, A3513, a novel drug candidate for the treatment of adult liver diseases, A2342, our lead preclinical candidate for the treatment of adult viral and liver diseases, and multiple other drug candidates. Bylvay was approved by the U.S. Food and Drug Administration (FDA) on July 20, 2021 for the treatment of pruritus in patients with primary biliary cholangitis (PBC) or intrahepatic cholestasis (PFIC) ages 3 months or older, and authorized by the European Medicines Agency on July 16, 2021 for the treatment of PBC in patients 18 years of age 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 PBC in patients 6 months or older. In October 2022 the Company announced positive results from its Phase 3 trial of Bylvay for the treatment of PBC in patients with Alagille syndrome (ALGS), and Bylvay is also in Phase 3 development for the treatment of biliary atresia. ALGS and biliary atresia are each rare liver disorders 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 and test drug candidates, to commercialize Bylvay in PFIC, to prepare for the commercialization of Bylvay in other indications, if approved, and to provide general and administrative support for these operations.

The Company has primarily funded its operations with proceeds from the sales of common stock, the sale of future royalties, upfront and milestone payments from regional agreements, proceeds from the issuance of debt, and the sale of a Priority Review Voucher (PRV). As of September 30, 2022, the Company has raised total capital of \$377.5 million through the issuance of common stock, net of issuance costs, \$59.3 million from the sale of its future royalties, net of issuance costs, and the revenue interest liability, 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 as it conducts ongoing activities to support the commercialization of Bylvay for PFIC, and if approved, for ALGS and the advancement of Bylvay in clinical trials and general and administrative support.

As a result, the Company will need substantial additional funding to support its continued operations and growth strategy. Until such a time that 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, and other arrangements, including collaborations with other companies or other strategic transactions. The Company may be unable to raise additional funds or enter into such arrangements 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 sign licenses back or discontinue the development and commercialization of one or more of its product candidates or delay its pursuit of potential in-licenses or other strategic transactions.

As of September 30, 2022, the Company had cash, cash equivalents and restricted cash of \$272.5 million. Management believes that its current cash, cash equivalents and restricted cash at September 30, 2022 will be sufficient to allow the Company to fund its current operating plan through at least the next twelve months, but that additional financing may be required for these financial statements.

The Company is subject to those risks associated with any biopharmaceutical company that has substantial expenditures for research and development. Management does not have assurance that the Company's research and development projects will be successful, that products developed will obtain necessary regulatory approvals, that products developed 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 the disclosures and footnotes required by GAAP for complete financial statements and should be read in conjunction with the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021. In the opinion of management, all adjustments (including 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, 2022 and 2021 are not necessarily indicative of the results that may be expected for the full fiscal year 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) or Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB).

Principles of consolidation

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

Foreign currency translation

Functional and presentation currency

Items included in the financial statements of each subsidiary are measured using the currency of the primary economic environment in which they operate (referred to as 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 rate in effect at the respective transaction dates. Foreign exchange gains and losses resulting from the settlement of such transactions and from the remeasurement at the end of the reporting period of monetary assets and liabilities denominated in foreign currencies are recognized within other operating expense, net except for changes in the fair value of future royalties which are recorded in interest expense, net in the Condensed Consolidated Statements of Operations.

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

- a. assets and liabilities presented are translated at the closing exchange rate as of September 30, 2022 and December 31, 2021;
- b. income and expenses for the statement of operations and comprehensive loss are translated at the average exchange rates that are relevant to the periods for which the income and expenses occur; and
- c. significant transactions use the exchange rate on the date of the transaction.

All resulting exchange differences arising from such translations are recognized directly in accumulated other comprehensive income and are a non-cash 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 reported amounts of revenues and expenses reported in the financial statements and accompanying notes. Management must apply significant judgment in this process. The Company evaluates its estimates and assumptions, including but not limited to accruals, including its clinical trial accruals and revenue deduction for chargebacks and other discounts, realizability of deferred tax assets and the accretion of interest on the monetization liability. Actual results could differ from these estimates.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments that are readily convertible into cash without penalty and with original maturities of 90 days or less to purchase to be cash equivalents.

Restricted cash consists of deposits placed in a segregated bank account required under the terms of the Company's Purchase Agreement with Sagard Partners (Delaware) LP ("Sagard").

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the unaudited condensed consolidated statements of cash flows (in thousands):

	September 30, 2022	
Cash and cash equivalents	\$	222,476
Restricted cash		50,000
Total cash, cash equivalents and restricted cash	\$	272,476

Revenue recognition

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services in accordance with ASC 606 *Revenue from Contracts with Customers*. To determine when control is transferred to 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 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 to which 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 determines the amount of revenue to recognize. The Company 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 each 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 up to the point at which the Company sells Bylvay to a limited number of specialty pharmacies and a specialty distributor in the United States which dispense the product directly to patients. 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 through 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. The Company estimates 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 product. The Company's obligations are satisfied when delivery occurs and the customer receives Bylvay. The Company evaluates creditworthiness of each of its customers and the collection is reasonably assured. The wholesale acquisition cost that the Company charges its customers for Bylvay is adjusted to arrive at the Company's net product revenues by deducting components of variable consideration which include (i) estimated government rebates and discounts related to Medicare and Medicaid government programs, (ii) estimated costs of incentives offered to certain indirect customers including patients, (iii) trade allowances, such as inventory discounts, payment and customer fees, and (iv) allowance for sales returns. Product revenue, net was \$4.1 million in the United States and \$3.4 million in international markets for the three months ended September 30, 2022. Product revenue, net was \$10.4 million in the United States and \$7.7 million in international markets for the three months ended September 30, 2021. Product revenue, net was \$0.8 million in the United States and \$0.3 million in international markets for the three and nine months ended September 30, 2022.

Rebates and Discounts

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

The Company contracts with national authorities in Europe to make Bylvay available to eligible patients. In jurisdictions in which final pricing is determined through negotiations with the government, the Company estimates the rebate expected to be due and deducts these estimated amounts from its gross product revenues when the revenues are recognized. The Company's estimates of such liabilities are based on current invoice pricing and total prior units sold and assumptions based on benchmarks of Bylvay pricing approved in other relevant European jurisdictions. The Company recorded \$0.6 million and \$0.2 million in such estimates as of September 30, 2022 and December 31, 2021, respectively, in other current liabilities on the consolidated balance sheets.

Other Incentives

Other incentives that the Company offers to indirect customers include co-pay assistance cards provided by the Company for patients who receive Bylvay through 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 the purchase of Bylvay 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 and the amount dispensed by the specialty pharmacies to the patients. These estimates are based on redemption information provided by third-party claims processors. The Company funds this incentive program through upfront payments. There were no upfront payments made during the quarter ended September 30, 2022. The Company recorded less than \$0.1 million in such estimates as of September 30, 2022 and December 31, 2021 in prepaid expenses on the consolidated balance sheets.

Trade Allowances

The Company provides invoice discounts on Bylvay sales to its customers for prompt payment and records these discounts as a reduction to gross sales. These discounts are based on contractual terms. The Company also pays fees to its distributors for their services as well as data that they provide to the Company. Prompt payment allowances are recorded in accounts receivable, net on the consolidated balance sheets. Prompt payment allowances were less than \$0.1 million as of September 30, 2022 and December 31, 2021. The other distributor fees are recorded as other current liabilities on the consolidated balance sheets and was \$0.1 million as of September 30, 2022 and December 31, 2021.

Milestone Payments

At the inception of each arrangement that includes development milestone payments or upfront payment, the Company evaluates whether the achievement of the milestone is considered probable of being achieved and estimates the amount to be included in the transaction price, which includes any upfront payments, under the accrual accounting method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Once the transaction price is established, the associated consideration is allocated to the performance obligations that have been identified in the respective arrangement. 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 they are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve a milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur at the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on a level of sales, and in which the license is deemed to be the primary 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 associated with 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 Pharma) 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 to EA Pharma, which has completed all of its performance obligations under the Agreement.

As of September 30, 2022, the Company is eligible to receive an additional regulatory-based milestone payment under the Agreement of \$4.2 million if a regulatory event is achieved for elobixibat. The cash payments and any other payments for milestones and royalties from EA Pharma are non-refundable 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 regulatory exclusivity in place for any products subject to royalties. EA Pharma may terminate the Agreement upon 180 days' prior written notice. The other 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

Royalty Interest Acquisition Agreement with HCR

In December 2017, the Company entered into a royalty interest acquisition agreement (RIAA) with HealthCare Royalty Partners III, L.P. (HCR). The Company 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 \$78.8 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 (i) the \$78.8 million cap and (ii) the Company's obligation to receive royalties on sales in Japan and sales milestones for elobixibat in certain other territories that may become payable by EA Pharma and (iii) the Company's obligation 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 to the extent it receives future Japanese royalties, sales milestones or other specified payments from EA Pharma. Although the Company sold its right 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 record royalties and milestones as revenue. Upon receipt of the payments from HCR the Company recorded net cash totaling \$59.3 million as a liability for the royalty obligation (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, 2022:

	September 30, 2022
	(in thousands)
Liability related to sale of future royalties—beginning balance	\$
Accretion of interest expense on liability related to royalty monetization	\$
Repayment of the liability	\$
Liability related to sale of future royalties—ending balance	\$
Less current portion classified within accrued expenses	\$
Long-term liability related to sale of future royalties	\$

The Company records estimated royalties due for the current period in accrued expenses until the payment is received from EA Pharma at which time it 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 obligation. 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 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. For the period ended September 30, 2022, the Company's estimate of its total interest expense resulted in an annual effective interest rate of approximately 18.0%.

The Company periodically assesses the estimated royalty payments to HCR and to the extent such payments are greater or less than its initial estimates, such payments are materially different than its original estimates, the Company will prospectively adjust the accretion of interest on the royalty obligation. 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, are not limited to, the rate of elobixibat prescriptions, the number of doses administered, the introduction of competing products, manufacturing or distribution issues, regulatory 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 the level of sales which would result in reduced royalty payments and reduced non-cash interest expense over the life of the royalty obligation. To the extent future payments are less than the liability, the Company is not obligated to fund any such shortfall.

Purchase Agreement with Sagard

In September 2022, the Company and Albireo AB entered into a purchase and sale agreement with Sagard Healthcare Partners (Delaware) (Sagard) for a revenue interest generated from Bylvay (odevixibat) (the Purchase Agreement) for an aggregate purchase price of \$115.0 million payable upon the closing of the transaction, which occurred on September 22, 2022. In consideration for the payment of such purchase price, the Company is obligated to pay to Sagard 12.5% on the worldwide annual consolidated net revenues of Bylvay (the Included Product Revenue) at a rate of (A) 12.5% for Included Product Revenue up to \$250.0 million, (B) 5% for Included Product Revenue in excess of \$250.0 million but less than or equal to \$350.0 million, and (C) prior to approval of the Marketing Application by the U.S. Food and Drug Administration of Bylvay for the treatment of biliary atresia (the Marketing Approval), 5% for Included Product Revenue up to \$350.0 million and, from and after Marketing Approval, the rate is decreased to 1% for Included Product Revenue in excess of \$350.0 million (collectively, the Revenue Interest Payments). These obligations payable to Sagard are capped at \$184.0 million, but the cap will be increased to \$230.0 million if the Company has not received aggregate Revenue Interest Payments of \$184.0 million by December 31, 2028 (the applicable cap, the Revenue Interest Cap). In addition, the amount of Revenue Interest Payments received by Sagard as of December 31, 2036 is less than \$230.0 million, the Company has agreed to pay Sagard the difference between the Revenue Interest Cap and the aggregate amount of all Revenue Interest Payments received by Sagard as of December 31, 2036 (such difference, the Put/Call Payment).

In addition, the Company has the right, but not the obligation (the Call Option), to buy out Sagard's interest in the Revenue Interest Payments (the Put/Call Payment) equal to the difference between (a) a specified amount ranging from \$149.5 million up to \$230.0 million, based on the period of the Call Option and the exercise of the Call Option, and (b) the aggregate amount of Revenue Interest Payments that have been received by Sagard. Further, Sagard has the obligation, to require the Company to make the Put/Call Payment at any time during the 180 days following the occurrence of certain specified events, which are limited to, a sale or merger of the Company resulting in a change of control, certain uncured material breaches of the Purchase Agreement by the Company or suspension of marketing approval for Bylvay, or any sale or other disposition of Bylvay by the Company within the United States. The Company's Put/Call Payment will be automatically payable upon the occurrence of a bankruptcy event.

As of September 30, 2022 \$111.6 million, was recorded as a revenue interest liability, net of issuance costs on the accompanying unaudited consolidated balance sheet. The Company imputes interest expense associated with this liability using the effective interest rate method. The effective interest rate is the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including changes in the estimated level of forecasted product sales and the amount of product sales. The Company evaluates the interest rate quarterly based on its current product sales, net forecasts utilizing the prospective method. A significant increase or decrease in product sales could result in a change in the interest rate.

will materially impact the revenue interest liability, interest expense and the time period for repayment. The Company recorded interest expense of \$0.4 million for three months ended September 30, 2022.

The Company incurred \$3.4 million of issuance costs in connection with the purchase and sale agreement with Sagard, which reduced the revenue interest liability and will be amortized to interest expense over the estimated term of the debt.

Revenue Interest Payments made as a result of the Company's product sales, net reduce the revenue interest liability.

The following table shows the activity within the revenue interest liability account for the nine-month period ended September 30, 2022:

	Sept
	(in
Revenue interest liability—beginning balance	\$
Interest expense recognized	
Revenue interest liability—ending balance	\$
Less current portion classified within accrued expenses	
Long-term revenue interest liability	\$

Trade Receivables, net

Accounts receivable, net related to product sales, which are recorded in accounts receivable, net on the consolidated balance sheets, were approximately \$3.3 million as of September 30, 2022 and December 31, 2021, respectively. As of September 30, 2022 and December 31, 2021, we had no accounts. An allowance for doubtful accounts is determined based on the Company's assessment of the credit worthiness and financial condition 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. U.S. customers are typically 31 - 36 days from receipt of invoice and for European customers are typically 45 days from receipt of invoice.

Inventory

The Company commenced capitalizing inventory for Bylvay upon FDA approval on July 20, 2021. All commercial manufacturing expenses and development expenses prior to FDA approval. Manufacturing costs incurred prior to FDA approval totaled approximately \$1.6 million and were instead were expensed as research and development expenses from 2020 to 2021. All manufacturing subsequent to FDA approval is capitalized in inventory.

Recent accounting pronouncements

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

Fair value of financial instruments

9 Months Ended
Sep. 30, 2022

[Fair value of financial instruments](#)

[Fair value of financial instruments](#)

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, 2022		
	Level 1	Level 2	Level 3
Cash Equivalents:			
Money market funds	\$214,999	\$ —	\$ —
Total	<u>\$214,999</u>	<u>\$ —</u>	<u>\$ —</u>

	December 31, 2021		
	Level 1	Level 2	Level 3
Cash Equivalents:			
Money market funds	\$243,180	\$ —	\$ —
Total	<u>\$243,180</u>	<u>\$ —</u>	<u>\$ —</u>

The Company's financial instruments consist mainly of cash, cash equivalents and restricted cash, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities. The carrying amounts of cash, cash equivalents, prepaid expenses and other current assets, accounts payable, accrued expenses, and other current liabilities approximate their estimated fair value due to their short-term maturities. The carrying amount of restricted cash as of September 30, 2022 approximates its fair value based on the contractual terms of the purchase and sale agreement with Sagard. The carrying amount of the revenue interest liability, net as of September 30, 2022 approximates its fair value and is based on the Company's contractual repayment obligation based on the current estimates of future revenues, over the life of the purchase and sale agreement with Sagard. The carrying amount of liability related to sale of future royalties as of September 30, 2022 and December 31, 2021 approximates its fair value and is based on the Company's contractual repayment obligation based on the current estimates of future revenues, over the life of the RIAA.

**Commitments and
contingencies**

**9 Months Ended
Sep. 30, 2022**

[Commitments and
contingencies](#)

[Commitments and
contingencies](#)

3. Commitments and contingencies

Agreements with CROs and CMOs

As of September 30, 2022, the Company had various agreements with CROs and CMOs for the conduct of specified research and development activities and based on the terms of the respective agreements, the Company is contractually obligated to make future payments of up to \$13.0 million upon the completion of contracted work.

Net (loss) income per share

9 Months Ended
Sep. 30, 2022

Net (loss) income per share

Net (loss) income per share

4. Net (loss) income per share

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

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Basic and Diluted net (loss) income per share:				
Numerator				
Net (loss) income	\$ (37,800)	\$ 57,086	\$ (120,183)	\$ (23,068)
Denominator				
Number of shares used for basic EPS computation	19,655,350	19,258,905	19,541,044	19,197,536
Effect of dilutive securities				
Dilutive options	—	380,934	—	—
Dilutive stock units	—	11,404	—	—
Number of shares used for diluted EPS computation	19,655,350	19,651,243	19,541,044	19,197,536
Basic net (loss) income per share	\$ (1.92)	\$ 2.96	\$ (6.15)	\$ (1.20)
Basic and Diluted net loss (income) per share	\$ (1.92)	\$ 2.90	\$ (6.15)	\$ (1.20)

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

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Options to purchase common stock, RSUs and warrants	3,593,074	2,779,257	3,593,074	3,171,596

Income taxes

**9 Months Ended
Sep. 30, 2022**

[Income taxes](#)

[Income taxes](#)

5. Income taxes

The Company did not record a tax provision or benefit for the three and nine months ended September 30, 2022. 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 maintain a full valuation allowance against its net deferred tax assets for the year.

Inventory

**9 Months Ended
Sep. 30, 2022**

[Inventory](#)
[Inventory](#)

6. Inventory

Inventory consists of the following (in thousands):

	<u>September 30, 2022</u>	<u>December 31, 2021</u>
Raw materials	\$ 953	\$ —
Work-in-process	147	—
Finished goods	2,049	194
Total inventory	<u>\$ 3,149</u>	<u>\$ 194</u>

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

Note Payable

**9 Months Ended
Sep. 30, 2022**

[Note Payable](#)

[Note Payable](#)

7. Note Payable

2020 Loan and Security Agreement

On June 8, 2020, the Company entered into a Loan and Security Agreement with several banks and other financial institutions or entities from time to time parties to the Loan and Security Agreement (the Loan and Security Agreement), as lenders, (collectively, referred to as the Lender), and Hercules Capital, Inc., in its capacity as administrative agent and collateral agent for itself and Lender (in such capacity, the Agent or Hercules), which provided for term loans up to an aggregate principal amount of \$80.0 million (the Term Loans) to the Company. The Loan and Security Agreement provided for (i) an initial term loan advance of \$10.0 million, which closed on June 8, 2020, (ii) subject to the achievement of certain initial performance milestones (Performance Milestone I), the Company had the right to request that the Lender make additional term loan advances to the Company in an aggregate principal amount of up to \$20.0 million from January 1, 2021 through December 15, 2021 in minimum increments of \$10.0 million, which Company did not exercise, and (iii) subject to the Lender's investment committee's sole discretion, the Company had the right to request that the Lender make additional term loan advances to the Company in an aggregate principal amount of up to \$45.0 million through March 31, 2022 in minimum increments of \$5.0 million, which the Company did not exercise. During the term of the Loan and Security Agreement, the Company had borrowed an aggregate principal amount of \$10.0 million. The Company was 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 had a maturity date of January 1, 2024, which was extended to July 1, 2024 upon achievement of Performance Milestone I (the Maturity Date).

The Term Loan bore interest at an annual rate equal to the greater of 10.65% and 10.65% plus the prime rate of interest minus 4.75%. Borrowings under the Loan and Security Agreement were repayable in monthly interest-only payments through January 1, 2022, which was extended to (i) July 1, 2022 upon the Company's achievement of Performance Milestone I and (ii) July 1, 2023 upon the Company's achievement of certain additional performance milestones. After the interest-only payment period, borrowings under the Loan and Security Agreement were repayable in equal monthly payments of principal and accrued interest until the Maturity Date. At the Company's option, the Company could 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 occurred 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 (the Prepayment Charge).

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.

On July 27, 2022, the Loan and Security Agreement was terminated upon the receipt by Hercules of a payoff amount of \$10.9 million from the Company; provided that the Company continues to be bound by certain indemnification obligations under the Loan and Security Agreement. The payoff amount paid by the Company in connection with the termination of the Loan and Security Agreement was pursuant to a payoff letter with Hercules and included payment of (a) \$0.7 million as an End of Term Charge and (b) \$0.1 million as a Prepayment Charge. As a result of this payoff we recognized a loss on extinguishment on the note payable, net of discount of \$0.6 million for the three and nine months ended September 30, 2022 within the condensed consolidated statements of operations.

During the three months ended September 30, 2022 and 2021, the Company recognized \$0.1 million and \$0.3 million, respectively, of interest expense related to the Loan and Security Agreement. During the nine months ended September 30, 2022 and 2021, the Company recognized \$0.7 million and \$1.0 million, respectively, of interest expense related to the Loan and Security Agreement.

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 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.

Equity Financings

**9 Months Ended
Sep. 30, 2022**

[Equity Financings](#)
[Stockholders' equity](#)

8. Equity Financings

2021 At-the-Market Offering Program Sales Agreement

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

In February 2021, the Company entered into a sales agreement with Cowen and Company, LLC (Cowen) with respect to an at-the-market offering program under which the Company may offer and sell, from time to time at the Company’s sole discretion, shares of common stock having an aggregate offering price of up to \$100.0 million (the 2021 Sales Agreement). Subsequently in July 2021, the Company sold 7,508 shares of common stock for net proceeds of approximately \$0.2 million pursuant to the 2021 Sales Agreement. Because the Company no longer qualified as a well-known seasoned issuer following the filing of the Annual Report on Form 10-K for the year ended December 31, 2021, the 2021 Form S-3 was no longer available for the Company to offer and sell securities pursuant to the 2021 Form S-3. The 2021 Sales Agreement was terminated in August 2022 in connection with the Company entering into the 2022 Sales Agreement (as defined below) with Cowen.

In August 2022, the Company filed a new universal shelf registration on Form S-3 with the SEC, which was declared effective on August 25, 2022 (the 2022 Form S-3), pursuant to which the Company registered for sale up to \$400.0 million of any combination of its common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that the Company may determine.

In August 2022, the Company entered into a new sales agreement with Cowen with respect to an at-the-market offering program under which the Company may offer and sell, from time to time at the Company’s sole discretion, shares of common stock having an aggregate offering price of up to \$100.0 million (the 2022 Sales Agreement). Subsequently in the third quarter of 2022, the Company sold 1,072,310 shares of common stock for net proceeds of approximately \$20.8 million pursuant to the 2022 Sales Agreement.

Stock-based Compensation

9 Months Ended
Sep. 30, 2022

[Stock-based Compensation](#)

[Stock-based Compensation](#)

9. Stock-based Compensation

For the nine months ended September 30, 2022, the Company granted 329,700 options at a weighted average exercise price per share of \$25.89. For the nine months ended September 30, 2022, the Company granted 688,300 RSUs.

The Company recorded the following stock-based compensation expense:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
	<u>(in thousands)</u>			
Employee awards:				
Cost of product revenue	\$ 88	\$ —	\$ 265	\$ —
Research and development expense	1,179	2,817	4,154	5,330
Selling, general and administrative expense	2,280	3,889	6,252	7,942
Total stock-based compensation expense	<u>\$ 3,547</u>	<u>\$ 6,706</u>	<u>\$ 10,671</u>	<u>\$ 13,272</u>

Summary of significant accounting policies and basis of presentation (Policies)

9 Months Ended

Sep. 30, 2022

[Summary of significant accounting policies and basis of presentation](#)

[Basis of presentation](#)

Basis of presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted (GAAP) for interim financial information, and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include footnotes required by GAAP for complete financial statements and should be read in conjunction with the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021. In the opinion of management, all adjustments (recurring adjustments) considered necessary for fair presentation have been included in the Condensed Consolidated Financial Statements. The results for the three and nine months ended September 30, 2022 and 2021 are not necessarily indicative of the results that may be expected for the full fiscal year 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](#)

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](#)

Foreign currency translation

Functional and presentation currency

Items included in the financial statements of each subsidiary are measured using the currency of the primary economic environment in which the subsidiary operates (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 at the respective transaction dates. Foreign exchange gains and losses resulting from the settlement of such transactions and from the remeasurement of monetary assets and liabilities denominated in foreign currencies are recognized within other operating expense, net except for changes in the fair value of future royalties which are recorded in interest expense, net in the Condensed Consolidated Statements of Operations.

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

- a. assets and liabilities presented are translated at the closing exchange rate as of September 30, 2022 and December 31, 2021;
- b. income and expenses for the statement of operations and comprehensive loss are translated at the average exchange rates that are relevant to the periods for which the income and expenses occur; and
- c. significant transactions use the exchange rate on the date of the transaction.

All resulting exchange differences arising from such translations are recognized directly in accumulated other comprehensive income and are a component of equity.

[Use of estimates](#)

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts of revenues and expenses reported in the financial statements and accompanying notes. Management must apply significant judgment in this process. The Company evaluates its estimates and assumptions, including but not limited to accruals, including its clinical trial accruals and revenue deduction for chargebacks and other discounts, realizability of deferred tax assets and the accretion of interest on the monetization liability. Actual results could differ from these estimates.

[Cash and cash equivalents](#)

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments that are readily convertible into cash without penalty and with original maturities of one year or less to purchase to be cash equivalents.

Restricted cash consists of deposits placed in a segregated bank account required under the terms of the Company's Purchase Agreement with the Partners (Delaware) LP ("Sagard").

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the unaudited condensed consolidated balance sheet together reflect the same amounts shown in the unaudited condensed consolidated statements of cash flows (in thousands):

	September 30, 2022	
Cash and cash equivalents	\$	222,476
Restricted cash		50,000
Total cash, cash equivalents and restricted cash	\$	272,476

Revenue recognition

Revenue recognition

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods or services in accordance with ASC 606 *Revenue from Contracts with Customers*. To determine the amount of revenue to recognize on 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 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 to which 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 each 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 up to the point the Company sells Bylvay to a limited number of specialty pharmacies and a specialty distributor in the United States which dispense the product directly to patients. 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 through 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. The Company estimates 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 payment. The performance obligations are satisfied when delivery occurs and the customer receives Bylvay. The Company evaluates creditworthiness of each of its customers and collection is reasonably assured. The wholesale acquisition cost that the Company charges its customers for Bylvay is adjusted to arrive at the Company's net product revenues by deducting components of variable consideration which include (i) estimated government rebates and discounts related to Medicare and Medicaid government programs, (ii) estimated costs of incentives offered to certain indirect customers including patients, (iii) trade allowances, such as inventory discounts, payment and customer fees, and (iv) allowance for sales returns. Product revenue, net was \$4.1 million in the United States and \$3.4 million in international markets for the three months ended September 30, 2022. Product revenue, net was \$10.4 million in the United States and \$7.7 million in international markets for the three months ended September 30, 2021. Product revenue, net was \$0.8 million in the United States and \$0.3 million in international markets for the three and nine months ended September 30, 2021.

Rebates and Discounts

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

The Company contracts with national authorities in Europe to make Bylvay available to eligible patients. In jurisdictions in which final pricing is determined through negotiations with the government, the Company estimates the rebate expected to be due and deducts these estimated amounts from its gross product revenues when the revenues are recognized. The Company's estimates of such liabilities are based on current invoice pricing and total prior units sold and assumptions based on benchmarks of Bylvay pricing approved in other relevant European jurisdictions. The Company recorded \$0.6 million and \$0.2 million in such estimates as of September 30, 2022 and December 31, 2021, respectively, in other current liabilities on the consolidated balance sheets.

Other Incentives

Other incentives that the Company offers to indirect customers include co-pay assistance cards provided by the Company for patients who receive Bylvay through 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 the 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 and the amount dispensed by the specialty pharmacies to the patients. These estimates are based on redemption information provided by third-party claims processors. The Company funds this incentive program through upfront payments. There were no upfront payments made during the quarter ended September 30, 2022. The Company recorded less than \$0.1 million in such estimates as of September 30, 2022 and December 31, 2021 in prepaid expenses on the consolidated balance sheets.

Trade Allowances

The Company provides invoice discounts on Bylvay sales to its customers for prompt payment and records these discounts as a reduction to gross product revenues. These discounts are based on contractual terms. The Company also pays fees to its distributors for their services as well as data that they provide to the Company. Prompt payment allowances are recorded in accounts receivable, net on the consolidated balance sheets. Prompt payment allowances were less than \$0.1 million in 2022 and December 31, 2021. The other distributor fees are recorded as other current liabilities on the consolidated balance sheets and was \$0.1 million in 2022 and December 31, 2021.

Milestone Payments

At the inception of each arrangement that includes development milestone payments or upfront payment, the Company evaluates whether the achievement of the milestone is considered probable of being achieved and estimates the amount to be included in the transaction price, which includes any upfront payments, using the expected amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price.

transaction price is established, the associated consideration is allocated to the performance obligations that have been identified in the respective 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 they are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve a milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue will be received by the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, based on its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings per share adjustment.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on a level of sales, and in which the license is deemed to be the 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 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 Pharma) 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 to which the Company has completed all of its performance obligations under the Agreement.

As of September 30, 2022, the Company is eligible to receive an additional regulatory-based milestone payment under the Agreement of \$4.2 million if a regulatory event is achieved for elobixibat. The cash payments and any other payments for milestones and royalties from EA Pharma are non-refundable 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 regulatory exclusivity in place for any products subject to royalties. EA Pharma may terminate the Agreement upon 180 days' prior written notice and the other 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

Monetization of Future Royalties

Royalty Interest Acquisition Agreement with HCR

In December 2017, the Company entered into a royalty interest acquisition agreement (RIAA) with HealthCare Royalty Partners III, L.P. (HCR). The Company 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 \$14.8 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 (i) the \$78.8 million cap amount and (ii) the Company's obligation to receive royalties on sales in Japan and sales milestones for elobixibat in certain other territories that may become payable by EA Pharma and (iii) the Company's obligation 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 to the extent it receives future Japanese royalties, sales milestones or other specified payments from EA Pharma. Although the Company sold its royalty interest to HCR, 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 record royalties and milestones as revenue. Upon receipt of the payments from HCR the Company recorded net cash totaling \$59.3 million as a liability for 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, 2022:

	September 30, 2022 (in thousands)
Liability related to sale of future royalties—beginning balance	\$
Accretion of interest expense on liability related to royalty monetization	\$
Repayment of the liability	\$
Liability related to sale of future royalties—ending balance	\$
Less current portion classified within accrued expenses	\$
Long-term liability related to sale of future royalties	\$

The Company records estimated royalties due for the current period in accrued expenses until the payment is received from EA Pharma at which time it 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 obligation. To determine the accretion of the royalty obligation, the Company is required to estimate the total amount of future royalty payments to be received over the life of the obligation. 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. For the period ended September 30, 2022, the Company's estimate of its total interest expense resulted in an annual effective interest rate of approximately 18.0%.

The Company periodically assesses the estimated royalty payments to HCR and to the extent such payments are greater or less than its initial estimates, such payments is materially different than its original estimates, the Company will prospectively adjust the accretion of interest on the royalty obligation. 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, are not limited to, the rate of elobixibat prescriptions, the number of doses administered, the introduction of competing products, manufacturing or distribution 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 milestones which would result in reduced royalty payments and reduced non-cash interest expense over the life of the royalty obligation. To the extent future payments are amount less than the liability, the Company is not obligated to fund any such shortfall.

Purchase Agreement with Sagard

In September 2022, the Company and Albireo AB entered into a purchase and sale agreement with Sagard Healthcare Partners (Delaware) for a revenue interest generated from Bylvay (odevixibat) (the Purchase Agreement) for an aggregate purchase price of \$115.0 million payable upon the closing of the transaction, which occurred on September 22, 2022. In consideration for the payment of such purchase price, the Company is obligated to pay to Sagard

on the worldwide annual consolidated net revenues of Bylvay (the Included Product Revenue) at a rate of (A) 12.5% for Included Product Revenue up to \$250.0 million, (B) 5% for Included Product Revenue in excess of \$250.0 million but less than or equal to \$350.0 million, and (C) prior to approval of the Marketing Application by the U.S. Food and Drug Administration of Bylvay for the treatment of biliary atresia (the Marketing Approval), 5% for Included Product Revenue up to \$350.0 million and, from and after Marketing Approval, the rate is decreased to 1% for Included Product Revenue in excess of \$350.0 million (collectively, the Revenue Interest Payments). These obligations payable to Sagard are capped at \$184.0 million, but the cap will be increased to \$230.0 million if the Company has not received aggregate Revenue Interest Payments of \$184.0 million by December 31, 2028 (the applicable cap, the Revenue Interest Cap). In addition, if the aggregate amount of Revenue Interest Payments received by Sagard as of December 31, 2036 is less than \$230.0 million, the Company has agreed to pay Sagard the difference between the Revenue Interest Cap and the aggregate amount of all Revenue Interest Payments received by Sagard as of December 31, 2036 (such difference, the Put/Call Payment).

In addition, the Company has the right, but not the obligation (the Call Option), to buy out Sagard's interest in the Revenue Interest Payments (the Put/Call Payment) equal to the difference between (a) a specified amount ranging from \$149.5 million up to \$230.0 million, based on the period of time between the end of the term of the Revenue Interest Cap and the exercise of the Call Option, and (b) the aggregate amount of Revenue Interest Payments that have been received by Sagard. Further, Sagard has the obligation, to require the Company to make the Put/Call Payment at any time during the 180 days following the occurrence of certain specified events, including, but not limited to, a sale or merger of the Company resulting in a change of control, certain uncured material breaches of the Purchase Agreement by the Company, or suspension of marketing approval for Bylvay, or any sale or other disposition of Bylvay by the Company within the United States. The Company's obligation to make the Put/Call Payment will be automatically payable upon the occurrence of a bankruptcy event.

As of September 30, 2022 \$111.6 million, was recorded as a revenue interest liability, net of issuance costs on the accompanying unaudited consolidated balance sheet. The Company imputes interest expense associated with this liability using the effective interest rate method. The effective interest rate is the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including changes in the estimated level of forecasted product sales and the amount of product sales. The Company evaluates the interest rate quarterly based on its current product sales, net forecasts utilizing the prospective method. A significant increase or decrease in product sales will materially impact the revenue interest liability, interest expense and the time period for repayment. The Company recorded interest expense of \$0.4 million for three months ended September 30, 2022.

The Company incurred \$3.4 million of issuance costs in connection with the purchase and sale agreement with Sagard, which reduced the carrying amount of the revenue interest liability and will be amortized to interest expense over the estimated term of the debt.

Revenue Interest Payments made as a result of the Company's product sales, net reduce the revenue interest liability.

The following table shows the activity within the revenue interest liability account for the nine-month period ended September 30, 2022:

	September 30, 2022 (in millions)
Revenue interest liability—beginning balance	\$ 111.6
Interest expense recognized	0.4
Revenue interest liability—ending balance	\$ 112.0
Less current portion classified within accrued expenses	(0.4)
Long-term revenue interest liability	\$ 111.6

Trade Receivables, net

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

Inventory

The Company commenced capitalizing inventory for Bylvay upon FDA approval on July 20, 2021. All commercial manufacturing expenses and development expenses prior to FDA approval. Manufacturing costs incurred prior to FDA approval totaled approximately \$1.6 million and were instead were expensed as research and development expenses from 2020 to 2021. All manufacturing subsequent to FDA approval is capitalized in inventory.

Recent accounting pronouncements

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

[Trade Receivables, net](#)

[Inventory](#)

[Recent accounting pronouncements](#)

**Summary of Significant
Accounting Policies and
Basis of Presentation
(Tables)**

9 Months Ended

Sep. 30, 2022

[Summary of significant accounting policies and basis of presentation](#)

[Schedule of cash, cash equivalents and restricted cash](#)

	<u>September 30, 2022</u>	<u>December 31, 2021</u>
Cash and cash equivalents	\$ 222,476	\$ 248,107
Restricted cash	50,000	—
Total cash, cash equivalents and restricted cash	<u>\$ 272,476</u>	<u>\$ 248,107</u>

[Schedule of Activity within Liability Account from Inception of Royalty Transaction](#)

	<u>September 30, 2022</u> (in thousands)
Liability related to sale of future royalties—beginning balance	\$ 71,667
Accretion of interest expense on liability related to royalty monetization	8,250
Repayment of the liability	<u>(15,595)</u>
Liability related to sale of future royalties—ending balance	\$ 64,322
Less current portion classified within accrued expenses	<u>(2,269)</u>
Long-term liability related to sale of future royalties	\$ 62,053

[Schedule of activity within revenue interest liability account](#)

	<u>September 30, 2022</u> (in thousands)
Revenue interest liability—beginning balance	\$ 111,327
Interest expense recognized	403
Revenue interest liability—ending balance	\$ 111,730
Less current portion classified within accrued expenses	<u>(86)</u>
Long-term revenue interest liability	\$ 111,644

**Fair value of financial
instruments (Tables)**

**9 Months Ended
Sep. 30, 2022**

Fair value of financial instruments

**Schedule of financial assets measured at
fair value on a recurring basis**

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, 2022		
	Level 1	Level 2	Level 3
Cash Equivalents:			
Money market funds	\$214,999	\$ —	\$ —
Total	<u>\$214,999</u>	<u>\$ —</u>	<u>\$ —</u>

	December 31, 2021		
	Level 1	Level 2	Level 3
Cash Equivalents:			
Money market funds	\$243,180	\$ —	\$ —
Total	<u>\$243,180</u>	<u>\$ —</u>	<u>\$ —</u>

**Net (loss) income per share
(Tables)**

**9 Months Ended
Sep. 30, 2022**

Net (loss) income per share

**Summary of Computation of Basic EPS
and Diluted EPS**

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Basic and Diluted net (loss) income per share:				
Numerator				
Net (loss) income	\$ (37,800)	\$ 57,086	\$ (120,183)	\$ (23,068)
Denominator				
Number of shares used for basic EPS computation	19,655,350	19,258,905	19,541,044	19,197,536
Effect of dilutive securities				
Dilutive options	—	380,934	—	—
Dilutive stock units	—	11,404	—	—
Number of shares used for diluted EPS computation	19,655,350	19,651,243	19,541,044	19,197,536
Basic net (loss) income per share	\$ (1.92)	\$ 2.96	\$ (6.15)	\$ (1.20)
Basic and Diluted net loss (income) per share	\$ (1.92)	\$ 2.90	\$ (6.15)	\$ (1.20)

Summary of Outstanding Shares

Excluded from Computation of Diluted EPS

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Options to purchase common stock, RSUs and warrants	3,593,074	2,779,257	3,593,074	3,171,596

Inventory (Tables)

9 Months Ended Sep. 30, 2022

Inventory

Schedule of inventory

Inventory consists of the following (in thousands):

	<u>September 30, 2022</u>	<u>December 31, 2021</u>
Raw materials	\$ 953	\$ —
Work-in-process	147	—
Finished goods	2,049	194
Total inventory	<u>\$ 3,149</u>	<u>\$ 194</u>

**Stock-based Compensation
(Tables)**

**9 Months Ended
Sep. 30, 2022**

Stock-based Compensation
Summary of stock-based
compensation expense

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
	(in thousands)			
Employee awards:				
Cost of product revenue	\$ 88	\$ —	\$ 265	\$ —
Research and development expense	1,179	2,817	4,154	5,330
Selling, general and administrative expense	2,280	3,889	6,252	7,942
Total stock-based compensation expense	<u>\$ 3,547</u>	<u>\$ 6,706</u>	<u>\$ 10,671</u>	<u>\$ 13,272</u>

Summary of significant accounting policies and basis of presentation - Organization (Details) - USD (\$) \$ in Thousands	3 Months Ended		9 Months Ended		69 Months Ended	
	Sep. 30,	Sep. 30,	Sep. 30,	Sep. 30,	Sep. 30,	Dec. 31, Dec. 31,
	2022	2021	2022	2021	2022	2021 2020
<u>Cash and cash equivalents</u>						
<u>Issuance of common stock, net of costs</u>	\$ 20,617	\$ 241			\$ 377,500	
<u>Proceeds from sale of future royalties, net</u>			\$		59,300	
			111,577			
<u>Proceeds from sale of priority review voucher, net of transaction costs</u>				\$	103,400	
				103,387		
<u>Cash and cash equivalents</u>	222,476		222,476		222,476	\$
						248,107
<u>Restricted Cash</u>	50,000		50,000		50,000	
<u>Cash, cash equivalents and restricted cash</u>	\$	\$	\$	\$	272,476	\$ \$
	272,476	262,612	272,476	262,612		248,107 251,272
<u>Loan and Security Agreement, Term Loans</u>						
<u>Cash and cash equivalents</u>						
<u>Proceeds from issuance of debt, net of issuance costs</u>					\$ 111,300	

Summary of significant accounting policies and basis of presentation - Revenue recognition (Details) - USD (\$) \$ in Thousands	3 Months Ended		9 Months Ended		12 Months Ended
	Sep. 30, 2022	Sep. 30, 2021	Sep. 30, 2022	Sep. 30, 2021	Dec. 31, 2021
<u>Revenue</u>					
<u>Revenue</u>	\$ 9,832	\$ 3,664	\$ 24,870	\$ 8,058	
<u>Upfront payments for incentive program</u>	0				
<u>Distributor fees</u>			100		\$ 100
<u>Product</u>					
<u>Revenue</u>					
<u>Revenue</u>	7,543	1,060	18,090	1,060	
<u>Maximum</u>					
<u>Revenue</u>					
<u>Prepaid amounts for incentive program</u>	100		100		100
<u>Prompt payment allowances</u>	100		100		100
<u>United States</u>					
<u>Revenue</u>					
<u>Rebates and discounts</u>	1,100		1,100		700
<u>United States Product</u>					
<u>Revenue</u>					
<u>Revenue</u>	4,100	800	10,400	800	
<u>International markets Product</u>					
<u>Revenue</u>					
<u>Revenue</u>	3,400	\$ 300	7,700	\$ 300	
<u>Europe</u>					
<u>Revenue</u>					
<u>Rebates and discounts</u>	600		600		\$ 200
<u>EA Pharma License Agreement</u>					
<u>Revenue</u>					
<u>Milestone payment receivable</u>	\$ 4,200		\$ 4,200		
<u>Period of written notice required prior to termination of agreement</u>			180 days		

Summary of significant accounting policies and basis of presentation - Monetization of future royalties (Details) - USD (\$) \$ in Thousands	1 Months Ended			9 Months Ended		30 Months Ended	69 Months Ended	Dec. 31, 2021
	Jun. 08, 2020	Jan. 31, 2018	Dec. 31, 2017	Sep. 30, 2022	Sep. 30, 2021	Jun. 08, 2020	Sep. 30, 2022	
Summary Of Significant Accounting Policies								
<u>Proceeds from sale of future royalties, net</u>				\$ 111,577			\$ 59,300	
Liability related to sale of future royalties activity								
<u>Accretion of interest expense on liability related to royalty monetization</u>				8,250	\$ 9,428			
<u>Long-term liability related to sale of future royalties</u>				62,053			62,053	\$ 60,132
<u>HCR Royalty Interest Acquisition Agreement</u>								
Summary Of Significant Accounting Policies								
<u>Maximum royalties under monetization agreement</u>				\$ 78,800				
<u>Proceeds from sale of future royalties, net</u>	\$ 14,800	\$ 44,500					\$ 59,300	
<u>Milestone payment receivable</u>	\$ 15,000						\$ 15,000	
Liability related to sale of future royalties activity								
<u>Liability related to the sale of future royalties - beginning balance</u>				71,667				
<u>Accretion of interest expense on liability related to royalty monetization</u>				8,250				
<u>Repayment of the liability</u>				(15,595)				
<u>Liability related to sale of future royalties - ending balance</u>				64,322			64,322	
<u>Less current portion classified within accrued expenses</u>				(2,269)			(2,269)	
<u>Long-term liability related to sale of future royalties</u>				\$ 62,053			\$ 62,053	
<u>Annual effective interest rate (as a percent)</u>				18.00%			18.00%	

Summary of significant accounting policies and basis of presentation - Purchase Agreement with Sagard (Details) \$ in Thousands	1 Months Ended Sep. 30, 2022 USD (\$)	3 Months Ended Sep. 30, 2022 USD (\$)	9 Months Ended Sep. 30, 2022 USD (\$)
<u>Purchase Agreement</u>			
<u>Revenue interest liability, net</u>	\$ 111,644	\$ 111,644	\$ 111,644
<u>Interest expense recognized</u>			403
<u>Purchase Agreement Sagard</u>			
<u>Purchase Agreement</u>			
<u>Aggregate purchase price</u>	115,000	115,000	115,000
<u>Royalty cap</u>	184,000	184,000	184,000
<u>Increase in royalty cap</u>	\$ 230,000		
<u>Term of put or call payment</u>	180 days		
<u>Revenue interest liability, net</u>	\$ 111,644	111,644	111,644
<u>Interest expense recognized</u>		400	403
<u>Issuance costs amortized to interest expense</u>	3,400		
<u>Purchase Agreement Sagard Minimum</u>			
<u>Purchase Agreement</u>			
<u>Specified amount of call option of royalty payments</u>	149,500	149,500	149,500
<u>Purchase Agreement Sagard Maximum</u>			
<u>Purchase Agreement</u>			
<u>Specified amount of call option of royalty payments</u>	\$ 230,000	\$ 230,000	\$ 230,000
<u>Purchase Agreement Sagard Up to \$ 250 Million</u>			
<u>Purchase Agreement</u>			
<u>Royalty rate (as a percent)</u>	12.50%	12.50%	12.50%
<u>Royalty amount</u>	\$ 250,000	\$ 250,000	\$ 250,000
<u>Purchase Agreement Sagard Greater than \$250 Million and Less than \$350 Million</u>			
<u>Purchase Agreement</u>			
<u>Royalty rate (as a percent)</u>	5.00%	5.00%	5.00%
<u>Purchase Agreement Sagard Greater than \$250 Million and Less than \$350 Million Minimum</u>			
<u>Purchase Agreement</u>			
<u>Royalty amount</u>	\$ 250,000	\$ 250,000	\$ 250,000
<u>Purchase Agreement Sagard Greater than \$250 Million and Less than \$350 Million Maximum</u>			
<u>Purchase Agreement</u>			
<u>Royalty amount</u>	\$ 350,000	\$ 350,000	\$ 350,000
<u>Purchase Agreement Sagard Greater than \$350 Million</u>			
<u>Purchase Agreement</u>			
<u>Royalty rate (as a percent)</u>	5.00%	5.00%	5.00%
<u>Royalty amount</u>	\$ 350,000	\$ 350,000	\$ 350,000

Decrease in royalty rate (as a percent)

1.00%

**Summary of significant
accounting policies and basis
of presentation - Revenue
Interest Liability (Details)
\$ in Thousands**

3 Months Ended 9 Months Ended

**Sep. 30, 2022 Sep. 30, 2022
USD (\$) USD (\$)**

Purchase Agreement

<u>Interest expense recognized</u>		\$ 403
<u>Revenue interest liability, net</u>	\$ 111,644	111,644

Purchase Agreement | Sagard

Purchase Agreement

<u>Revenue interest liability-beginning balance</u>		111,327
<u>Interest expense recognized</u>	400	403
<u>Revenue interest liability-ending balance</u>	111,730	111,730
<u>Less current portion classified within accrued expenses</u>	(86)	(86)
<u>Revenue interest liability, net</u>	\$ 111,644	\$ 111,644

Summary of significant accounting policies and basis of presentation - Trade Receivables (Details) - USD

9 Months Ended

Sep. 30, 2022 Dec. 31, 2021

(\$)

\$ in Thousands

Trade Receivables

Accounts receivable, net \$ 2,029 \$ 3,272

Allowance for doubtful accounts \$ 0 \$ 0

Europe

Trade Receivables

Payment terms 45 days

Minimum | United States

Trade Receivables

Payment terms 31 days

Maximum | United States

Trade Receivables

Payment terms 36 days

**Summary of significant
accounting policies and basis
of presentation - Inventory
(Details)
\$ in Millions**

**24 Months Ended
Dec. 31, 2021
USD (\$)**

Research and development expense

Inventory

Manufacturing costs

\$ 1.6

**Fair value of financial
instruments (Details) -
Recurring - Fair Value Level Sep. 30, 2022 Dec. 31, 2021
1 - USD (\$)
\$ in Thousands**

Fair Value

Cash Equivalents \$ 243,180

Total \$ 214,999 \$ 243,180

Money market funds

Fair Value

Cash Equivalents \$ 214,999

**Commitments and
contingencies - Agreements
with CROs (Details)
\$ in Millions**

**Sep. 30, 2022
USD (\$)**

Commitments and contingencies

Maximum future payable under agreements with CROs \$ 13.0

Net (loss) income per share - Basic and Diluted EPS (Details) - USD (\$) \$ / shares in Units, \$ in Thousands	3 Months Ended		9 Months Ended	
	Sep. 30, 2022	Sep. 30, 2021	Sep. 30, 2022	Sep. 30, 2021
<u>Basic and Diluted net (loss) income per share - Numerator</u>				
<u>Net income (loss), Basic</u>	\$ (37,800)	\$ 57,086	\$ (120,183)	\$ (23,068)
<u>Net income (loss), Diluted</u>	\$ (37,800)	\$ 57,086	\$ (120,183)	\$ (23,068)
<u>Denominator</u>				
<u>Number of shares used for basic EPS computation</u>	19,655,350	19,258,905	19,541,044	19,197,536
<u>Number of shares used for diluted EPS computation</u>	19,655,350	19,651,243	19,541,044	19,197,536
<u>Basic net income (loss) per share (in dollars per share)</u>	\$ (1.92)	\$ 2.96	\$ (6.15)	\$ (1.20)
<u>Diluted net income (loss) per share (in dollars per share)</u>	\$ (1.92)	\$ 2.90	\$ (6.15)	\$ (1.20)
<u>Employee Stock Option</u>				
<u>Denominator</u>				
<u>Dilutive options</u>		380,934		
<u>RSUs</u>				
<u>Denominator</u>				
<u>Dilutive options</u>		11,404		

Net (loss) income per share -
Anti-dilutive shares (Details)
- shares

3 Months Ended 9 Months Ended
Sep. 30, Sep. 30, Sep. 30, Sep. 30,
2022 2021 2022 2021

[Options to purchase common stock, RSUs and warrants](#)

[Antidilutive Securities](#)

[Anti-dilutive securities excluded from computation of diluted net
loss per share](#) 3,593,074 2,779,257 3,593,074 3,171,596

Income Taxes (Details) - USD (\$) \$ in Thousands	3 Months Ended		9 Months Ended	
	Sep. 30, 2022	Sep. 30, 2021	Sep. 30, 2022	Sep. 30, 2021
Income taxes				
<u>Income tax provision (benefit)</u>	\$ 0	\$ 3,789	\$ 0	\$ 3,789

Inventory (Details) - USD (\$)	3 Months Ended		9 Months Ended
\$ in Thousands	Sep. 30, 2022	Sep. 30, 2022	Dec. 31, 2021
<u>Inventory</u>			
<u>Raw materials</u>	\$ 953	\$ 953	
<u>Work-in-process</u>	147	147	
<u>Finished goods</u>	2,049	2,049	\$ 194
<u>Total inventory</u>	3,149	3,149	\$ 194
<u>Inventory write downs</u>	\$ 0	\$ 0	
<u>Finished goods inventory shelf life</u>		24 months	

**Note Payable - Loan and
Security Agreement (Details)
\$ in Millions**

**Jun. 08,
2020
USD (\$)**

Loan and Security Agreement, Term Loans

Debt instrument

Maximum borrowing capacity \$ 80.0

Amount borrowed \$ 10.0

End of term charge as a percent of principal amount 6.95%

Prepayment premium, as a percent of principal, between 9 months and 24 months following closing date 2.00%

Prepayment premium, as a percent of principal, 24 months following closing date and before maturity date 1.00%

Loan and Security Agreement, Term Loans | Minimum

Debt instrument

Interest rate percentage added to variable rate to determine minimum annual interest rate 10.65%

Loan and Security Agreement, Term Loans | Prime Rate

Debt instrument

Interest rate percentage added to variable rate to determine minimum annual interest rate 10.65%

Spread on rate (as a percent) 4.75%

Loan and Security Agreement, Term Loan, First/Initial Tranche

Debt instrument

Maximum borrowing capacity \$ 10.0

Loan and Security Agreement, Term Loan, Second Tranche

Debt instrument

Maximum borrowing capacity 20.0

Minimum borrowing increments 10.0

Loan and Security Agreement, Term Loan, Third Tranche

Debt instrument

Maximum borrowing capacity, term loan advance 45.0

Minimum borrowing increments \$ 5.0

Note Payable - Carrying Value (Details) - USD (\$) \$ in Thousands	3 Months Ended			9 Months Ended		Dec. 31, 2021
	Jul. 27, 2022	Sep. 30, 2022	Sep. 30, 2021	Sep. 30, 2022	Sep. 30, 2021	
<u>Debt Instrument [Line Items]</u>						
<u>Note payable net of discount, long-term</u>						\$ 10,004
<u>Loss on extinguishment of debt</u>		\$ (613)		\$ (613)		
<u>Loan and Security Agreement, Term Loans</u>						
<u>Debt Instrument [Line Items]</u>						
<u>Pay off amount</u>	\$ 10,900					
<u>End of term charge</u>	700					
<u>Prepayment charge</u>	\$ 100					
<u>Loss on extinguishment of debt</u>		(600)		(600)		
<u>Interest expense</u>		\$ 100	\$ 300	\$ 700	\$ 1,000	

Note Payable - Warrants (Details) \$ / shares in Units, \$ in Millions	Jun. 08, 2020 USD (\$) \$ / shares shares
<u>Loan and Security Agreement, Term Loans Warrants</u>	
<u>Number of warrants (as a percent)</u>	1.00%
<u>Number of warrants issued (in shares) shares</u>	5,311
<u>Warrant exercise period</u>	7 years
<u>Warrants exercise price (in dollars per share) \$ / shares</u>	\$ 18.83
<u>Warrant registration period</u>	60 days
<u>Loan and Security Agreement, Term Loans Maximum Warrants</u>	
<u>Warrant registration period</u>	180 days
<u>Loan and Security Agreement, Term Loan, First/Initial Tranche Warrants</u>	
<u>Fair value of warrants \$</u>	\$ 0.1

Equity Financings (Details) - USD (\$) \$ in Thousands	1 Months Ended		3 Months Ended		9 Months Ended		69 Months Ended		Aug. 31, 2022	Feb. 28, 2021
	Aug. 25, 2022	Sep. 30, 2022	Jul. 31, 2021	Sep. 30, 2022	Sep. 30, 2021	Sep. 30, 2022	Sep. 30, 2021	Sep. 30, 2022		
<u>Equity</u>										
<u>Proceeds from issuance of common stock, net of issuance costs</u>						\$ 20,633	\$ 241			
<u>Issuance of common stock, net of costs</u>				\$ 20,617	\$ 241			\$ 377,500		
<u>2021 Sales Agreement, At-the-Market Offering</u>										
<u>Equity</u>										
<u>Issuance of common stock (in shares)</u>			7,508							
<u>Proceeds from issuance of common stock, net of issuance costs</u>			\$ 200							
<u>2021 Sales Agreement, At-the-Market Offering Maximum</u>										
<u>Equity</u>										
<u>Aggregate offering price</u>									\$ 100,000	
<u>Issuance of common stock, net of costs</u>	\$ 400,000									
<u>2022 Sales Agreement, At-the-Market Offering</u>										
<u>Equity</u>										
<u>Issuance of common stock (in shares)</u>		1,072,310								
<u>Proceeds from issuance of common stock, net of issuance costs</u>		\$ 20,800								
<u>2022 Sales Agreement, At-the-Market Offering Maximum</u>										
<u>Equity</u>										
<u>Aggregate offering price</u>								\$ 100,000		

**Stock-based Compensation -
Stock-based Compensation
activity (Details)**

**9 Months Ended
Sep. 30, 2022
\$ / shares
shares**

Stock-based Compensation

Options granted (in shares) 329,700

Weighted average exercise price - Options granted (in dollars per share) | \$ / shares \$ 25.89

RSUs

Stock-based Compensation

RSUs granted during period 688,300

Stock-based Compensation - Stock-based compensation expense (Details) - USD (\$) \$ in Thousands	3 Months Ended		9 Months Ended	
	Sep. 30, 2022	Sep. 30, 2021	Sep. 30, 2022	Sep. 30, 2021
<u>Stock-based compensation</u>				
<u>Stock-based compensation expense</u>	\$ 3,547	\$ 6,706	\$ 10,671	\$ 13,272
<u>Cost of product revenue</u>				
<u>Stock-based compensation</u>				
<u>Stock-based compensation expense</u>	88		265	
<u>Research and development expense</u>				
<u>Stock-based compensation</u>				
<u>Stock-based compensation expense</u>	1,179	2,817	4,154	5,330
<u>Selling, general and administrative expense</u>				
<u>Stock-based compensation</u>				
<u>Stock-based compensation expense</u>	\$ 2,280	\$ 3,889	\$ 6,252	\$ 7,942

1. The first part of the document discusses the importance of maintaining accurate records of all transactions and activities. It emphasizes the need for transparency and accountability in financial reporting.

2. The second part of the document outlines the various methods and techniques used to collect and analyze data. It includes a detailed description of the experimental procedures and the tools used for data collection.

3. The third part of the document presents the results of the study, including a comparison of the different methods and techniques used. It discusses the strengths and weaknesses of each method and provides a summary of the findings.

4. The fourth part of the document discusses the implications of the study and provides recommendations for future research. It highlights the need for further investigation into the effectiveness of the different methods and techniques used.

5. The fifth part of the document provides a conclusion and a summary of the key findings. It reiterates the importance of maintaining accurate records and the need for transparency and accountability in financial reporting.

6. The sixth part of the document provides a list of references and a bibliography. It includes a list of all the sources used in the study and provides a detailed description of each source.

7. The seventh part of the document provides a list of appendices and a bibliography. It includes a list of all the appendices used in the study and provides a detailed description of each appendix.

8. The eighth part of the document provides a list of figures and a bibliography. It includes a list of all the figures used in the study and provides a detailed description of each figure.

9. The ninth part of the document provides a list of tables and a bibliography. It includes a list of all the tables used in the study and provides a detailed description of each table.

10. The tenth part of the document provides a list of equations and a bibliography. It includes a list of all the equations used in the study and provides a detailed description of each equation.

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3. The third part of the document presents the results of the study, showing the trends and patterns observed in the data. It includes several tables and graphs to illustrate the findings.

4. The fourth part of the document discusses the implications of the results and the potential applications of the findings. It highlights the need for further research and the development of new strategies.

5. The fifth part of the document concludes the study and provides a summary of the key findings. It also includes a list of references and a bibliography of the sources used in the research.

