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: 001-35668

INTERCEPT PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**22-3868459**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

305 Madison Avenue,
Morristown, NJ 07960
(Address of Principal Executive Offices and Zip Code)
(646) 747-1000
(Registrant's Telephone Number, Including Area Code)

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 $0.001 per share	ICPT	Nasdaq Global Select Market

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

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

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

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

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

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

The number of shares of the registrant's common stock outstanding as of September 30, 2022 was 41,417,127.

Intercept Pharmaceuticals, Inc.

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Unless the context otherwise requires, references in this Quarterly Report on Form 10-Q to "we," "our," "us" and the "Company" refer, collectively, to Intercept Pharmaceuticals, Inc., a Delaware corporation, and its consolidated subsidiaries.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements, including, but not limited to, statements regarding the progress, timing and results of our clinical trials, including our clinical trials for the treatment of nonalcoholic steatohepatitis ("NASH"), the safety and efficacy of our approved product, Ocaliva (obeticholic acid or "OCA") for primary biliary cholangitis ("PBC"), and our product candidates, including OCA for liver fibrosis due to NASH, the timing and acceptance of our regulatory filings and the potential approval of OCA for liver fibrosis due to NASH, the review of our New Drug Application ("NDA") for OCA for the treatment of liver fibrosis due to NASH by the U.S. Food and Drug Administration (the "FDA"), our intent to work with the FDA to address the issues raised in a complete response letter ("CRL"), the potential commercial success of OCA, as well as our strategy, future operations, future financial position, future revenue, projected costs, financial guidance, prospects, plans and objectives.

These statements constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "possible," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of their dates, and we undertake no obligation to update any forward-looking statement except as required by law. These forward-looking statements are based on estimates and assumptions by our management that, although believed to be reasonable, are inherently uncertain and subject to a number of risks.

The following represent some, but not necessarily all, of the factors that could cause actual results to differ materially from historical results or those anticipated or predicted by our forward-looking statements:

- the success of our existing business and operations, including Ocaliva for PBC;
- our ability to successfully commercialize Ocaliva for PBC and, if approved, OCA for NASH;
- our ability to maintain our regulatory approval of Ocaliva for PBC;
- our ability to timely and cost-effectively file for and obtain regulatory approval of our product candidates on an accelerated basis or at all, including OCA for liver fibrosis due to NASH;
- our ability to address the issues raised in the complete response letter ("CRL") received in June 2020 with respect to OCA for NASH;
- any advisory committee recommendation or dispute resolution determination that our product candidates, including OCA for liver fibrosis due to NASH, should not be approved or approved only under certain conditions;
- any future determination that the regulatory applications and subsequent information we submit for our product candidates, including OCA for liver fibrosis due to NASH, do not contain adequate clinical or other data or meet applicable regulatory requirements for approval;
- the progress, timing, and results of our REGENERATE clinical trial, including the safety and efficacy of OCA for liver fibrosis due to NASH, and the use of a consensus panel approach to histology reads;
- our pre-submission meeting with the FDA in July 2022 in which we reviewed with the FDA the planned content and the timing of the submission of our NDA for OCA for liver fibrosis due to NASH;
- our planned resubmission of an NDA to the FDA for OCA for liver fibrosis due to NASH, and the potential timing, review, acceptance, and approval of the NDA;
- conditions that may be imposed by regulatory authorities on our marketing approvals for our products and product candidates, including OCA for liver fibrosis due to NASH, such as the need for clinical outcomes data (and not just results based on achievement of a surrogate endpoint), any risk mitigation programs such as a Risk Evaluation and Mitigation Strategies ("REMS") program, and any related restrictions, limitations and/or warnings contained in the label of any of our products or product candidates;
- any potential side effects associated with Ocaliva for PBC, OCA for liver fibrosis due to NASH or our other product candidates that could delay or prevent approval, require that an approved product be taken off the market, require the inclusion of safety warnings or precautions, or otherwise limit the sale of such product or product candidate, including in connection with our update to the Ocaliva prescribing information in May 2021 contraindicating Ocaliva for

patients with PBC and decompensated cirrhosis, a prior decompensation event, or compensated cirrhosis with evidence of portal hypertension;

- the initiation, timing, cost, conduct, progress and results of our research and development activities, preclinical studies and clinical trials, including any issues, delays or failures in identifying patients, enrolling patients, treating patients, retaining patients, meeting specific endpoints, or completing and timely reporting the results of our NASH or PBC clinical trials;
- the outcomes of interactions with regulators, including the FDA regarding our clinical trials;
- our ability to establish and maintain relationships with, and the performance of, third-party manufacturers, contract research organizations and other vendors upon whom we are substantially dependent for, among other things, the manufacture and supply of our products, including Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH, and our clinical trial activities;
- our ability to identify, develop and successfully commercialize our products and product candidates, including our ability to successfully launch OCA for liver fibrosis due to NASH, if approved;
- our ability to obtain and maintain intellectual property protection for our products and product candidates, including our ability to cost-effectively file, prosecute, defend and enforce any patent claims or other intellectual property rights;
- the size and growth of the markets for our products and product candidates and our ability to serve those markets;
- the degree of market acceptance of Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH or our other product candidates among physicians, patients and healthcare payors;
- the availability of adequate coverage and reimbursement from governmental and private healthcare payors for our products, including Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH, and our ability to obtain adequate pricing for such products;
- our ability to establish and maintain effective sales, marketing and distribution capabilities, either directly or through collaborations with third parties;
- competition from existing drugs or new drugs that become available;
- our ability to attract and retain key personnel to manage our business effectively;
- our ability to prevent or defend against system failures or security or data breaches due to cyber-attacks, or cyber intrusions, including ransomware, phishing attacks and other malicious intrusions;
- our ability to comply with data protection laws;
- costs and outcomes relating to any disputes, governmental inquiries or investigations, regulatory proceedings, legal proceedings or litigation, including any securities, intellectual property, employment, product liability or other litigation;
- our collaborators' election to pursue research, development and commercialization activities;
- our ability to establish and maintain relationships with collaborators with development, regulatory and commercialization expertise;
- our need for and ability to generate or obtain additional financing;
- our estimates regarding future expenses, revenues and capital requirements and the accuracy thereof;
- our use of cash, cash equivalents and short-term investments;
- our ability to acquire, license and invest in businesses, technologies, product candidates and products;
- our ability to manage the growth of our operations, infrastructure, personnel, systems and controls;
- our ability to obtain and maintain adequate insurance coverage;
- continuing threats from COVID-19, including additional waves of infections, and their impacts including quarantines and other government actions; delays relating to our regulatory applications; disruptions relating to our ongoing clinical trials or involving our contract research organizations, study sites or other clinical partners; disruptions relating to our supply chain or involving our third-party manufacturers, distributors or other distribution partners; and facility closures or other restrictions; and the impact of the foregoing on our results of operations and financial position;
- the impact of general economic, industry, market, regulatory or political conditions;

- how we use the funds received from the sale of our ex-U.S. business to Advanz Pharma;
- disagreements or legal, operational, or other business problems arising from our ongoing relationship with Advanz Pharma, including the licensing of the ex-U.S. rights to Ocaliva for PBC and, if approved, OCA for NASH, our operational separation from our former ex-U.S. commercial operations, and our agreement to supply Advanz Pharma with OCA;
- unexpected tax, regulatory, litigation, or other liabilities;
- whether we receive any future earn-outs or royalties under the Advanz Pharma transaction documents; and
- the other risks and uncertainties identified under the captions “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Quarterly Report on Form 10-Q and in our other periodic filings filed with the U.S. Securities and Exchange Commission (the “SEC”), including our most recent Annual Report.

NOTE REGARDING TRADEMARKS

The Intercept Pharmaceuticals® name and logo and the Ocaliva® name and logo are either registered or unregistered trademarks or trade names of the Company in the United States and/or other countries. All other trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this Quarterly Report on Form 10-Q may appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights to these trademarks and trade names.

PART I

Item 1. Financial Statements.

INTERCEPT PHARMACEUTICALS, INC.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands, except share and per share data)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 113,195	$ 84,709
Restricted cash	6,981	8,119
Investment debt securities, available-for-sale	377,656	334,980
Accounts receivable, net of allowance for credit losses of $58 and $58, respectively	26,168	28,337
Prepaid expenses and other current assets	21,370	21,735
Current assets of discontinued operations	—	30,138
Total current assets	545,370	508,018
Fixed assets, net	1,276	3,281
Inventory	6,274	7,883
Security deposits	1,125	4,284
Other assets	5,359	3,557
Total assets	$ 559,404	$ 527,023
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable, accrued expenses and other liabilities	$ 109,888	$ 103,780
Short-term interest payable	2,244	8,601
Current portion of long-term debt	109,452	—
Current liabilities of discontinued operations	—	55,780
Total current liabilities	221,584	168,161
Long-term liabilities:		
Long-term debt	222,856	539,782
Long-term other liabilities	7,288	3,042
Total liabilities	$ 451,728	$ 710,985
Commitments and contingencies (Note 16)		
Stockholders' equity (deficit):		
Common stock par value $0.001 per share; 90,000,000 shares authorized; 41,417,127 and 29,572,953 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	41	30
Additional paid-in capital	2,231,667	2,308,653
Accumulated other comprehensive loss, net	(7,969)	(2,873)
Accumulated deficit	(2,116,063)	(2,489,772)
Total stockholders' equity (deficit)	107,676	(183,962)
Total liabilities and stockholders' equity (deficit)	$ 559,404	$ 527,023

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue:				
Product revenue, net	$ 77,588	$ 66,640	$ 208,491	$ 192,117
Total revenue	77,588	66,640	208,491	192,117
Operating expenses:				
Cost of sales	424	224	956	771
Selling, general and administrative	43,274	41,271	121,013	130,255
Research and development	44,034	44,712	136,753	132,991
Restructuring	—	—	—	(284)
Total operating expenses	87,732	86,207	258,722	263,733
Operating loss	(10,144)	(19,567)	(50,231)	(71,616)
Other (expense) income:				
Interest expense	(5,237)	(14,095)	(18,579)	(39,103)
(Loss) gain on extinguishment of debt	(91,759)	16,511	(91,739)	16,511
Other income, net	3,053	210	2,691	2,389
Total other (expense) income, net	(93,943)	2,626	(107,627)	(20,203)
Loss from continuing operations	$ (104,087)	$ (16,941)	$ (157,858)	$ (91,819)
Income from discontinued operations, net of income taxes	$ 371,540	$ 13,309	$ 400,499	$ 36,673
Net income (loss)	$ 267,453	$ (3,632)	$ 242,641	$ (55,146)
Net income (loss) per common and potential common share (basic and diluted):				
Net loss from continuing operations	$ (3.04)	$ (0.53)	$ (5.05)	$ (2.81)
Net income from discontinued operations	$ 10.83	$ 0.42	$ 12.81	$ 1.12
Net income (loss)	$ 7.80	$ (0.11)	$ 7.76	$ (1.69)
Weighted average common and potential common shares outstanding:				
Basic and diluted	34,293	31,736	31,262	32,679

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Comprehensive Income (Loss)
(Unaudited)
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net income (loss)	$ 267,453	$ (3,632)	$ 242,641	$ (55,146)
Other comprehensive loss:				
Net changes related to available-for-sale investment debt securities:				
Unrealized losses on investment debt securities	(670)	(171)	(2,196)	(538)
Reclassification adjustment for realized gains on investment debt securities included in other income, net	—	—	—	2
Net unrealized losses on investment debt securities	$ (670)	$ (171)	$ (2,196)	$ (536)
Foreign currency translation and other				
Release of currency translation adjustments associated with sale of business	(7,319)	—	(7,319)	—
Foreign currency translation gains	2,568	72	4,419	49
Other comprehensive loss	$ (5,421)	$ (99)	$ (5,096)	$ (487)
Comprehensive income (loss)	$ 262,032	$ (3,731)	$ 237,545	$ (55,633)

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit)
(Unaudited)
(In thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss, Net	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount				
Balance - June 30, 2022	29,798	$ 30	$ 2,016,201	$ (2,548)	$ (2,383,516)	$ (369,833)
Stock-based compensation	—	—	5,788	—	—	5,788
Issuance of common stock under equity plan	269	—	—	—	—	—
Employee withholding taxes related to stock-based awards	(9)	—	(135)	—	—	(135)
Net proceeds from exercise of stock options	29	—	433	—	—	433
Issuance of common stock for repurchase of convertible notes	11,330	11	209,380	—	—	209,391
Other comprehensive loss	—	—	—	(5,421)	—	(5,421)
Net income	—	—	—	—	267,453	267,453
Balance - September 30, 2022	41,417	$ 41	$ 2,231,667	$ (7,969)	$ (2,116,063)	$ 107,676

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss, Net	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount				
Balance - December 31, 2021	29,573	$ 30	$ 2,308,653	$ (2,873)	$ (2,489,772)	$ (183,962)
Stock-based compensation	—	—	21,052	—	—	21,052
Issuance of common stock under equity plan	520	—	—	—	—	—
Employee withholding taxes related to stock-based awards	(35)	—	(480)	—	—	(480)
Net proceeds from exercise of stock options	29	—	433	—	—	433
Issuance of common stock for repurchase of convertible notes	11,330	11	209,380	—	—	209,391
Reclassification of the equity components of the Convertible Notes to liability upon adoption of ASU 2020-06	—	—	(307,371)	—	131,068	(176,303)
Other comprehensive loss	—	—	—	(5,096)	—	(5,096)
Net income	—	—	—	—	242,641	242,641
Balance - September 30, 2022	41,417	$ 41	$ 2,231,667	$ (7,969)	$ (2,116,063)	$ 107,676

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss, Net	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount				
Balance - June 30, 2021	33,201	$ 33	$ 2,249,497	$ (2,865)	$ (2,449,860)	$ (203,195)
Stock-based compensation	—	—	8,616	—	—	8,616
Repurchase of common stock	(4,522)	(4)	(75,821)	—	—	(75,825)
Extinguishment of allocated costs related to exchange of convertible notes	—	—	(37,213)	—	—	(37,213)
Extinguishment of allocated costs related to repurchase of convertible notes	—	—	(1,933)	—	—	(1,933)
Bifurcation of conversion option upon issuance of convertible notes, net of issuance costs	—	—	147,458	—	—	147,458
Issuance of common stock for services	770	1	9,999	—	—	10,000
Proceeds from capped call transactions	—	—	57	—	—	57
Issuance of common stock under equity plan	112	—	—	—	—	—
Employee withholding taxes related to stock-based awards	(14)	—	(264)	—	—	(264)
Other comprehensive loss	—	—	—	(99)	—	(99)
Net loss	—	—	—	—	(3,632)	(3,632)
Balance - September 30, 2021	29,547	$ 30	$ 2,300,396	$ (2,964)	$ (2,453,492)	$ (156,030)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss, Net	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount				
Balance - December 31, 2020	33,016	$ 33	$ 2,233,937	$ (2,477)	$ (2,398,346)	$ (166,853)
Stock-based compensation	—	—	25,483	—	—	25,483
Repurchase of common stock	(4,522)	(4)	(75,821)	—	—	(75,825)
Extinguishment of allocated costs related to exchange of convertible notes	—	—	(37,213)	—	—	(37,213)
Extinguishment of allocated costs related to repurchase of convertible notes	—	—	(1,933)	—	—	(1,933)
Bifurcation of conversion option upon issuance of convertible notes, net of issuance costs	—	—	147,458	—	—	147,458
Issuance of common stock for services	770	1	9,999	—	—	10,000
Proceeds from capped call transactions	—	—	57	—	—	57
Issuance of common stock under equity plan	353	—	18	—	—	18
Employee withholding taxes related to stock-based awards	(70)	—	(1,589)	—	—	(1,589)
Other comprehensive loss	—	—	—	(487)	—	(487)
Net loss	—	—	—	—	(55,146)	(55,146)
Balance - September 30, 2021	29,547	$ 30	$ 2,300,396	$ (2,964)	$ (2,453,492)	$ (156,030)

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net income (loss)	$ 242,641	$ (55,146)
Less: Income from operations of discontinued operations, net of tax	400,499	36,673
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation	16,658	20,881
Amortization of premium on investment debt securities	716	3,384
Amortization of deferred financing costs	2,242	1,990
Write-off of fixed assets	2,400	—
Depreciation	491	2,430
Non-cash operating lease cost	1,435	3,541
Accretion of debt discount	—	21,885
Loss (gain) on early extinguishment of debt	91,739	(16,511)
Gain on lease termination	(1,101)	—
Provision for allowance on credit losses	—	(8)
Changes in operating assets:		
Accounts receivable	2,169	(518)
Prepaid expenses and other current assets	442	648
Inventory	232	190
Security deposits	3,157	345
Other assets	32	—
Changes in operating liabilities:		
Accounts payable, accrued expenses and other current liabilities	13,791	(26,003)
Operating lease liabilities	(1,479)	(4,550)
Interest payable	(6,357)	(2,021)
Net cash used in operating activities - continuing operations	(31,291)	(86,136)
Net cash provided by operating activities - discontinued operations	9,317	39,895
Net cash used in operating activities	(21,974)	(46,241)
Cash flows from investing activities:		
Purchases of investment debt securities	(401,069)	(278,438)
Sales and maturities of investment debt securities	355,485	334,233
Purchases of equipment, leasehold improvements, and furniture and fixtures	(865)	(397)
Net cash (used in) provided by investing activities - continuing operations	(46,449)	55,398
Net cash provided by investing activities - discontinued operations	363,233	—
Net cash provided by investing activities	316,784	55,398
Cash flows from financing activities:		
Payments for repurchases of convertible senior notes	(261,562)	57
Proceeds from exercise of options, net	433	18
Payments of employee withholding taxes related to stock-based awards	(480)	(1,589)
Payments of debt issuance costs	(35)	—
Payments for repurchase of common stock	—	(75,825)
Proceeds from issuance of Notes	—	117,551
Proceeds from terminations of capped call options	—	(38,129)
Net cash (used in) provided by financing activities - continuing operations	(261,644)	2,083
Net cash (used in) provided by financing activities - discontinued operations	—	—
Net cash (used in) provided by financing activities	(261,644)	2,083
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(7,399)	71
Net increase in cash, cash equivalents and restricted cash	25,767	11,311
Cash, cash equivalents and restricted cash at beginning of period	94,409	65,654
Cash, cash equivalents and restricted cash at end of period	120,176	76,965
Less: Cash, cash equivalents and restricted cash of discontinued operations	—	1,622
Cash, cash equivalents and restricted cash of continuing operations	$ 120,176	$ 75,343

Supplemental disclosure of non-cash transactions:				
Right-of-use asset obtained in exchange for new operating lease obligations	$	(5,654)	$	—
Non-cash investing and financing activities				
Net increase in accrued fixed assets	$	21	$	—
Reconciliation of cash, cash equivalents and restricted cash included in the condensed consolidated balance sheets:				
Cash and cash equivalents	$	113,195	$	68,329
Restricted cash		6,981		7,014
Total cash, cash equivalents and restricted cash	$	120,176	$	75,343
Supplemental non-cash disclosure:				
Issuance of common stock to noteholders in connection with repurchase of convertible notes	$	209,391	$	—
Exchange for existing 2023 and 2026 convertible notes	$	—	$	(421,200)
Exchange for new 2026 secured convertible notes	$	—	$	382,400
Issuance of common stock to financial advisor in connection with convertible notes exchange	$	—	$	10,000
Recognition of conversion option upon issuance of 2026 secured convertible notes	$	—	$	150,704
Extinguishment of conversion options upon exchange and repurchase of 2023 convertible notes and exchange of 2026 convertible notes	$	—	$	(39,146)
Supplementary cash flow data:				
Income taxes paid	$	455	$	—

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Overview of Business

Intercept Pharmaceuticals, Inc. (the "Company") is a biopharmaceutical company founded in 2002 and focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases, including primary biliary cholangitis ("PBC") and nonalcoholic steatohepatitis ("NASH"). The Company currently has one marketed product, Ocaliva (obeticholic acid or "OCA").

On May 5, 2022, the Company entered into a series of agreements to sell the Company's ex-U.S. commercial operations and sublicense the right to commercialize Ocaliva for PBC and, if approved, OCA for NASH outside of the United States to Advanz Pharma and its affiliates (collectively, "Advanz") (the "Disposition Transaction"). Consideration under the agreements totaled $405 million up front, subject to adjustments including for cash, working capital, and assumed liabilities. On July 1, 2022, the Company completed the Disposition Transaction.

The Company is entitled to receive an additional $45 million from Advanz contingent upon receipt of extensions of orphan exclusivity for Ocaliva from the European Medicines Agency ("EMA") and Medicines and Healthcare products Regulatory Agency ("MHRA").

2. Basis of Presentation

The Company's financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). All intercompany balances and transactions have been eliminated in consolidation. Certain information that is normally required by U.S. GAAP has been condensed or omitted in accordance with rules and regulations of the U.S. Securities and Exchange Commission ("SEC"). Operating results for the three and nine months ended September 30, 2022 are not necessarily indicative of the results that may be expected for any future period or for the year ending December 31, 2022. In the opinion of management, these unaudited condensed consolidated financial statements include all normal and recurring adjustments considered necessary for a fair presentation of these interim unaudited condensed consolidated financial statements.

These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2021, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC.

Reclassifications

Certain amounts in prior periods have been reclassified to reflect the impact of the discontinued operations treatment in order to conform to the current period presentation.

Use of Estimates

The preparation of these unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and judgments that affect the reported amounts of assets and liabilities, the disclosure of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from these estimates.

3. Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2 of Notes to Consolidated Financial Statements included in its Annual Report on 10-K for the year ended December 31, 2021. With the exception of the accounting for

held for sale assets and liabilities and discontinued operations under ASC 205-20, *Presentation of Financial Statements: Discontinued Operations* ("ASC 205"), as discussed below, and the related impacts under ASC 260, *Earnings per Share* ("ASC 260)" as discussed in Note 15, there have been no material changes in the Company's significant accounting policies as compared to the significant accounting policies described in the Annual Report, other than the adoption of the accounting pronouncements below.

Held for Sale and Discontinued Operations

Assets and liabilities of a group of components of an entity are classified as held for sale when all of the following criteria for a plan of sale have been met: (1) management, having the authority to approve the action, commits to a plan to sell the entities to be sold; (2) the entities to be sold are available for immediate sale, in their present condition, subject only to terms that are usual and customary for sales of such entities to be sold; (3) an active program to locate a buyer and other actions required to complete the plan to sell the entities have been initiated; (4) the sale of the entities is probable and is expected to be completed within one year; (5) the entities are being actively marketed for a price that is reasonable in relation to their current fair value; and (6) actions required to complete the plan indicate that it is unlikely that significant changes to the plan will be made or the plan will be withdrawn.

Components of an entity that are classified as held for sale and have operations and cash flows that can be clearly distinguished from the rest of the entity are required to be reported as assets and liabilities held for sale. A disposal of a group of components that is classified as held for sale is reported as discontinued operations if the disposal represents a strategic shift that has and will have a major effect on our operations and financial results.

In the period in which the components meet held-for-sale or discontinued operations criteria, the major current assets, other assets, current liabilities, and noncurrent liabilities shall be reported as components of total assets and liabilities separate from those balances of the continuing operations. Assets classified as held for sale are reported at the lower of their carrying value or fair value less costs to sell. Depreciation and amortization of assets ceases upon designation as held for sale. For components that meet the discontinued operations criteria, the results of operations for the discontinued operation are reclassified into separate line items in the condensed consolidated statements of operations, net of income taxes for all periods presented.

The Company accounts for contingent consideration received as a gain contingency, and recognizes such contingent consideration when it is realized or realizable, once the contingency is resolved.

Additional details surrounding the Company's assets and liabilities classified as discontinued operations are included in Note 4.

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06, "Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"), which simplifies the accounting for convertible instruments by eliminating the requirement to separately account for embedded conversion features as an equity component in certain circumstances. A convertible debt instrument will be reported as a single liability instrument with no separate accounting for an embedded conversion feature unless separate accounting is required for an embedded conversion feature as a derivative or under the substantial premium model. The ASU simplifies the diluted earnings per share calculation by requiring that an entity use the if-converted method and that the effect of potential share settlement be included in diluted earnings per share calculations. Further, the ASU requires enhanced disclosures about convertible instruments. The Company adopted ASU 2020-06 on January 1, 2022 using the modified retrospective method. Upon adoption at January 1, 2022, the Company made certain adjustments in its condensed consolidated balance sheets which consisted of an increase of $176.3 million in Long-term debt, a net decrease of $307.4 million in Additional paid-in capital and a net decrease of $131.1 million in Accumulated deficit resulting from the reversal of previously recognized non-cash interest expense.

After adoption, the Company accounts for the Convertible Notes entirely as liabilities measured at amortized cost. The Company did not elect the fair value option. Additionally, the Company will no longer incur non-cash interest expense for the amortization of debt discount related to the previously separated equity components. The Company will apply the if-converted methodology in computing diluted earnings per share if and when profitability is achieved.

The following table summarizes the adjustments made to the Company's condensed consolidated balance sheet as of January 1, 2022 as a result of applying the modified retrospective method in adopting ASU 2020-06:

	As Reported December 31, 2021	ASU 2020-06 Adjustments	As Adjusted January 1, 2022
		(in thousands)	
Convertible Notes	$ 539,782	$ 176,303	$ 716,085
Additional paid-in capital	$ 2,308,653	$ (307,371)	$ 2,001,282
Accumulated deficit	$ (2,489,772)	$ 131,068	$ (2,358,704)

Under the modified retrospective method, comparative prior periods are not adjusted.

4. Discontinued Operations

On May 5, 2022, the Company entered into the Disposition Transaction. Consideration under the agreements totaled $405 million up front, subject to adjustments including for cash, working capital, and assumed liabilities. The Company is entitled to receive an additional cumulative $45 million from Advanz contingent upon receipt of extensions of orphan drug exclusivity from the EMA and MHRA. The Company will also receive royalties on any future net sales of OCA in NASH outside of the U.S., should Advanz obtain marketing authorization for this indication in ex-U.S. regions. The Company continues to be responsible for the manufacturing and supply of OCA globally while Advanz is responsible for packaging, distribution and commercialization of the therapy in all markets outside of the U.S. In addition, the Company will be responsible for any difference between the cumulative rebate estimated for France for periods prior to July 1, 2022 and the amount agreed through final negotiations with the French government. Under the Sublicense Agreement, we agreed to continue to conduct certain post-marketing work and other activities with respect to Ocaliva for PBC, including continuing to conduct certain PBC studies (the "PBC Post-Marketing Work"). The Company will be reimbursed by Advanz for a portion of the total R&D costs related to the PBC Post-Marketing Work.

On July 1, 2022, the Company completed the previously announced Disposition Transaction. As a result of this transaction, the Company's international business has been divested and its international commercial and medical infrastructure have transitioned to Advanz. Consideration totaled $405.0 million up front. Total cash consideration received upon closing was $366.5 million. Additional consideration of $38.5 million under the Share Purchase Agreement (the "SPA") will be settled in connection with the completion statements, which will also include adjustments including for cash, working capital, and assumed liabilities.

The Company recognized a gain of $372.4 million, net of taxes on the sale of the ex-U.S. commercial operations upon closing.

Income for performing services under the Transitional Services Agreement (the "TSA"), recorded within Other income, net was $1.9 million for the three and nine months ended September 30, 2022. The total amount recognized as a reduction to Research & development expenses for a portion of the total R&D costs to be reimbursed by Advanz in relation to the PBC Post-Marketing Work was $3.1 million for the three and nine months ended September 30, 2022. Cash inflows were $1.4 million for the three and nine months ended September 30, 2022 under the TSA and Sublicense Agreement.

Amounts applicable to prior years have been recast to conform to the discontinued operations presentation. All amounts included in the notes to the unaudited condensed consolidated financial statements relate to continuing operations unless otherwise noted.

The following table presents the carrying amounts of the classes of assets and liabilities related to the discontinued operations as of September 30, 2022 and December 31, 2021:

	September 30, 2022	December 31, 2021
Restricted cash	$ —	$ 1,581
Accounts receivable, net of allowance for credit losses	—	19,280
Prepaid expenses and other current assets	—	3,551
Fixed assets, net	—	96
Inventory	—	736
Security deposits	—	2,332
Other assets	—	2,562
Total assets classified as discontinued operations in condensed consolidated balance sheets	$ —	$ 30,138
Accounts payable, accrued expenses and other liabilities	$ —	$ 54,436
Long-term other liabilities	—	1,344
Total liabilities classified as discontinued operations in condensed consolidated balance sheets	$ —	$ 55,780

As of September 30, 2022, there were no assets or liabilities classified as discontinued operations.

The following table presents the results of operations related to the discontinued operations for the three and nine months ended September 30, 2022 and 2021 respectively:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Product revenue, net	$ —	$ 26,187	$ 58,065	$ 78,947
Cost of sales	169	434	1,194	1,315
Selling, general and administrative	636	12,068	28,083	40,011
Research and development	4	335	255	614
Restructuring	—	3	—	198
Other (expense) income, net	(7)	(38)	(390)	(136)
(Loss) income from discontinued operations	$ (816)	$ 13,309	$ 28,143	$ 36,673
Gain on the sale of the ex-U.S. commercial operations and sublicense	380,356	—	380,356	—
Income from discontinued operations, pre-tax	$ 379,540	$ 13,309	$ 408,499	$ 36,673
Income tax expense	(8,000)	—	(8,000)	—
Income from discontinued operations, net of tax	$ 371,540	$ 13,309	$ 400,499	$ 36,673

The following table presents the calculation of the gain on sale related to the discontinued operations for the three and nine months ended September 30, 2022.

	September 30, 2022
Proceeds from sale of business	$ 366,500
Transaction costs	(9,901)
Carrying value of net liabilities sold	25,918
Working capital adjustments	(7,153)
Release of accumulated currency translation adjustments for disposed subsidiaries	7,319
Supply & manufacturing agreement liability	(2,327)
Gain on sale, pre-tax	380,356
Income tax expense	(8,000)
Gain on sale, net of tax	$ 372,356

The following table presents the net cash provided by operating activities for the assets and liabilities classified as discontinued operations for the nine months ended September 30, 2022 and 2021 respectively:

	Nine Months Ended September 30,	
	2022	2021
Net income from discontinued operations	$ 400,499	$ 36,673
Adjustment of non-cash activities	4,937	5,562
Decrease (increase) in accounts receivable	18,235	(4,881)
Decrease in prepaid expenses and other current assets	3,746	2,003
Decrease (increase) in inventory	242	(23)
Decrease in security deposits	2,191	—
Decrease in operating lease liabilities	(386)	(802)
(Decrease) increase in accounts payable, accrued expenses and other current liabilities	(53,647)	1,363
Reclassification of cash proceeds from sale of business to investing activities	(366,500)	—
Net cash provided by operating activities	$ 9,317	$ 39,895
Proceeds from sale of business, net of cash	363,233	—
Net cash provided by investing activities	$ 363,233	$ —

5. Cash, Cash Equivalents and Investment Debt Securities

The following table summarizes the Company's cash, cash equivalents and investment debt securities as of September 30, 2022 and December 31, 2021:

	As of September 30, 2022				
	Amortized Cost	Allowance for Credit Losses	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
			(in thousands)		
Cash and cash equivalents:					
Cash and money market funds	$ 95,225	$ —	$ —	$ —	$ 95,225
Commercial paper	13,977	—	—	(4)	13,973
Corporate debt securities	3,997	—	—	—	3,997
Total cash and cash equivalents	113,199	—	—	(4)	113,195
Investment debt securities:					
Commercial paper	108,091	—	—	(254)	107,837
Corporate debt securities	245,321	—	—	(2,018)	243,303
U.S. government agency bonds	11,751	—	1	(117)	11,635
U.S. Treasury securities	14,965	—	—	(84)	14,881
Total investment debt securities	380,128	—	1	(2,473)	377,656
Total cash, cash equivalents and investment debt securities	$ 493,327	$ —	$ 1	$ (2,477)	$ 490,851

	As of December 31, 2021				
	Amortized Cost	Allowance for Credit Losses	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
			(in thousands)		
Cash and cash equivalents:					
Cash and money market funds	$ 76,709	$ —	$ —	$ —	$ 76,709
Commercial paper	8,000	—	—	—	8,000
Total cash and cash equivalents	84,709	—	—	—	84,709
Investment debt securities:					
Commercial paper	84,513	—	—	(49)	84,464
Corporate debt securities	232,721	—	16	(245)	232,492
Municipal bonds	5,028	—	—	(1)	5,027
U.S. Treasury securities	12,998	—	—	(1)	12,997
Total investment debt securities	335,260	—	16	(296)	334,980
Total cash, cash equivalents and investment debt securities	$ 419,969	$ —	$ 16	$ (296)	$ 419,689

The aggregate fair value of the Company's available-for-sale investment debt securities that have been in a continuous unrealized loss position for less than twelve months or twelve months or longer is as follows:

	As of September 30, 2022					
	Less than 12 months		12 months or longer		Total	
	(in thousands)					
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
Commercial paper	$ 107,837	$ (254)	$ —	$ —	$ 107,837	$ (254)
Corporate debt securities	224,195	(1,906)	19,110	(111)	243,305	(2,017)
U.S. government agency bonds	10,383	(118)	—	—	10,383	(118)
U.S. Treasury securities	14,881	(84)	—	—	14,881	(84)
Total	$ 357,296	$ (2,362)	$ 19,110	$ (111)	$ 376,406	$ (2,473)

	As of December 31, 2021					
	Less than 12 months		12 months or longer		Total	
	(in thousands)					
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
Commercial paper	$ 81,464	$ (49)	$ —	$ —	$ 81,464	$ (49)
Corporate debt securities	196,120	(245)	—	—	196,120	(245)
Municipal bonds	5,027	(1)	—	—	5,027	(1)
U.S. Treasury securities	12,997	(1)	—	—	12,997	(1)
Total	$ 295,608	$ (296)	$ —	$ —	$ 295,608	$ (296)

At September 30, 2022 and December 31, 2021, respectively the Company had 117 and 97 available-for-sale investment debt securities in an unrealized loss position without an allowance for credit losses. Unrealized losses on corporate debt securities have not been recognized into income because the issuers' bonds are of high credit quality (rated A3/A- or higher) and the decline in fair value is largely due to market conditions and/or changes in interest rates. Management does not intend to sell and it is likely that management will not be required to sell the securities prior to the anticipated recovery of their amortized cost basis. The issuers continue to make timely interest payments on the bonds. The fair value is expected to recover as the bonds approach maturity.

Accrued interest receivable on available-for-sale investment debt securities totaled $1.4 million and $1.3 million at September 30, 2022 and December 31, 2021, respectively, is excluded from the estimate of credit losses and is included in Prepaid expenses and other current assets.

6. Fair Value Measurements

The carrying amounts of the Company's receivables and payables approximate their fair value due to their short maturities.

Accounting principles provide guidance for using fair value to measure assets and liabilities. The guidance includes a three-level hierarchy of valuation techniques used to measure fair value, defined as follows:

- Unadjusted Quoted Prices — The fair value of an asset or liability is based on unadjusted quoted prices in active markets for identical assets or liabilities (Level 1).

- Pricing Models with Significant Observable Inputs — The fair value of an asset or liability is based on information derived from either an active market quoted price, which may require further adjustment based on the attributes of the financial asset or liability being measured, or an inactive market transaction (Level 2).

- Pricing Models with Significant Unobservable Inputs — The fair value of an asset or liability is primarily based on internally derived assumptions surrounding the timing and amount of expected cash flows for the financial instrument. Therefore, these assumptions are unobservable in either an active or inactive market (Level 3).

The Company considers an active market as one in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis. Conversely, the Company views an inactive market as one in which there are few transactions for the asset or liability, the prices are not current, or price quotations vary substantially either over time or among market makers. Where appropriate, non-performance risk, or that of a counterparty, is considered in determining the fair values of liabilities and assets, respectively.

The Company's cash deposits, money market funds and U.S. Treasury securities are classified within Level 1 of the fair value hierarchy because they are valued using bank balances or quoted prices from active markets. Commercial paper, corporate debt securities, and U.S. government agency bonds are classified as Level 2 instruments based on market pricing and other observable inputs.

Financial assets carried at fair value are classified in the tables below in one of the three categories described above:

		Fair Value Measurements Using		
	Total	Level 1	Level 2	Level 3
		(in thousands)		
September 30, 2022				
Assets				
Cash and cash equivalents:				
Money market funds	$ 80,977	$ 80,977	$ —	$ —
Commercial paper	13,973	—	13,973	—
Corporate debt securities	3,997	—	3,997	—
Available-for-sale investment debt securities:				
Commercial paper	107,837	—	107,837	—
Corporate debt securities	243,303	—	243,303	—
U.S. government agency bonds	11,635	—	11,635	—
U.S. Treasury securities	14,881	14,881	—	—
Total financial assets	$ 476,603	$ 95,858	$ 380,745	$ —
December 31, 2021				
Assets				
Cash and cash equivalents:				
Money market funds	$ 39,287	$ 39,287	$ —	$ —
Commercial paper	8,000	—	8,000	—
Available-for-sale investment debt securities:				
Commercial paper	84,464	—	84,464	—
Corporate debt securities	232,492	—	232,492	—
Municipal bonds	5,027	—	5,027	—
U.S. Treasury securities	12,997	12,997	—	—
Total financial assets	$ 382,267	$ 52,284	$ 329,983	$ —

See Note 10 for the carrying amounts and estimated fair values of the Company's 3.50% Convertible Senior Secured Notes due 2026 ("2026 Convertible Secured Notes"), 2.00% Convertible Senior Notes due 2026 ("2026 Convertible Notes") and 3.25% Convertible Senior Notes due 2023 ("2023 Convertible Notes").

The aggregate fair value of all available-for-sale investment debt securities (commercial paper, corporate debt securities, U.S. government agency bonds, municipal bonds and U.S. Treasury securities), by contractual maturity, are as follows:

	Fair Value as of	
	September 30, 2022	December 31, 2021
	(in thousands)	
Due in one year or less	$ 336,422	$ 305,914
Due after one year through two years	41,234	29,066
Total investment debt securities	$ 377,656	$ 334,980

Actual maturities may differ from contractual maturities because issuers may have the right to call or prepay obligations without call or prepayment penalties.

7. Fixed Assets, Net

Fixed assets are stated at cost and depreciated or amortized using the straight-line method based on useful lives as follows:

	Useful lives (Years)	September 30, 2022	December 31, 2021
		(in thousands)	
Office equipment and software	3	$ 3,036	$ 4,751
Leasehold improvements	Shorter of remaining lease term or useful life	669	12,884
Furniture and fixtures	7	1,280	3,772
Subtotal		4,985	21,407
Less: accumulated depreciation		(3,709)	(18,126)
Fixed assets, net		$ 1,276	$ 3,281

8. Inventory

Inventories are stated at the lower of cost or market. Inventories consisted of the following:

	September 30, 2022	December 31, 2021
	(in thousands)	
Work-in-process	$ 6,113	$ 7,801
Finished goods	161	82
Inventory	$ 6,274	$ 7,883

9. Accounts Payable, Accrued Expenses and Other Liabilities

Accounts payable, accrued expenses and other liabilities consisted of the following:

	September 30, 2022	December 31, 2021
	(in thousands)	
Accounts payable	$ 21,303	$ 17,598
Accrued employee compensation	19,533	20,845
Accrued contracted services	45,745	51,136
Accrued rebates, returns, discounts and other incentives	14,491	11,626
Accrued income taxes payable (see Note 14)	7,380	—
Other liabilities	1,436	2,575
Accounts payable, accrued expenses and other liabilities	$ 109,888	$ 103,780

Research & Development Tax Credit

The Company has benefited from the U.K. Small and Medium-sized Enterprise R&D Tax Credit scheme, or the SME scheme, under which it can obtain a tax credit of up to 33.4% of eligible research and development expenses incurred by the Company in the U.K. Eligible expenses generally include employment costs for research staff, consumables, software and certain internal overhead costs incurred as part of research projects.

The Company has started to benefit from the U.K. Research and Development Expenditure Scheme, or the RDEC scheme, under which it can obtain a tax credit of 12% of eligible research and development expenses incurred by the Company in the U.K. The RDEC scheme is more restrictive than the SME scheme, and generally applies where qualifying R&D expenditure is not eligible for relief under the SME scheme.

The Company has submitted claims seeking to obtain tax credits for qualifying R&D expenses incurred in the 2015, 2016, 2017, 2018 and 2019 calendar years. As described further in Note 12, the 2018 RDEC claim was finalized during the quarter ended June 30, 2022, and therefore the $4.0 million net payment received, which was previously deferred, was released into income as a reduction to research & development expenses.

With respect to the 2019 RDEC claim, in February 2022, the Company received a payment of $3.8 million from HMRC. Given the claim review has not been finalized for the 2019 year, the $3.8 million credit received along with an additional $0.6 million due to foreign currency translation are recorded as a deferred liability within Accounts payable, accrued expenses, and other liabilities. The Company will be entitled to this benefit based on the terms of the Disposition Transaction.

10. Current and Long-Term Debt

Debt, net of debt issuance costs and discounts, consisted of the following:

	September 30, 2022			December 31, 2021		
	2026 Convertible Secured Notes	2026 Convertible Notes	2023 Convertible Notes	2026 Convertible Secured Notes	2026 Convertible Notes	2023 Convertible Notes
	(in thousands)					
Liability component						
Principal	$ 111,143	$ 115,349	$ 109,808	$ 500,000	$ 115,349	$ 113,655
Unamortized debt issuance costs	(1,857)	(1,778)	(356)	(7,132)	(2,313)	(816)
Unamortized debt discount	—	—	—	(141,303)	(30,228)	(7,430)
Net carrying amount	$ 109,286	$ 113,571	$ 109,452	$ 351,565	$ 82,808	105,409
Equity component, net of issuance costs*	—	—	—	$ 147,458	$ 62,841	$ 97,072

*Recorded as a reduction of Additional paid-in capital upon the adoption of ASU 2020-06.

As of September 30, 2022, the net carrying amount of the 2023 Convertible Notes is recorded in Current portion of long-term debt.

The Company has three series of convertible notes outstanding (together, the “Convertible Notes”). All three series are convertible under certain circumstances into cash, shares of the Company’s common stock, or a combination thereof, at the Company’s election.

The 2023 Convertible Notes were issued on July 6, 2016, in the amount of $460.0 million principal, at an interest rate of 3.25%. The Company received net proceeds from their sale of $447.6 million, net of $12.4 million in underwriting discounts, commissions, and estimated offering expenses.

The 2026 Convertible Notes were issued on May 14, 2019, in the amount of $230.0 million principal, at an interest rate of 2.00%. The Company received net proceeds from their sale of $223.4 million, net of $6.6 million in underwriting discounts, commissions, and estimated offering expenses.

On August 10, 2021, the Company entered into privately negotiated exchange and subscription agreements with a limited number of existing “accredited investors” and “qualified institutional buyers” (as defined under Securities Act rules) holding 2023 Convertible Notes and 2026 Convertible Notes to (1) exchange $306.5 million principal of 2023 Convertible Notes for $292.4 million principal of new notes, (2) exchange $114.7 million principal of 2026 Convertible Notes for $90.0 million principal of new notes, and (3) sell $117.6 million principal of new notes for cash. On August 17, 2021, these new notes were issued as 2026 Convertible Secured Notes in the amount of $500.0 million principal, at an interest rate of 3.50%. The Company received cash proceeds from the sale of notes of approximately $117.6 million. The Company also paid its financial advisor $10.0 million in stock for services rendered, in the amount of 769,823 shares, based on the closing price of $12.99 per share on August 20, 2021.

On September 9, 2021, the Company entered into privately negotiated agreements with certain holders of 2023 Convertible Notes to repurchase $39.9 million principal for $38.1 million in cash, which purchase closed on September 14, 2021.

On June 1, 2022, the Company entered into an agreement with a certain holder of 2023 Convertible Notes to repurchase $3.8 million principal for $3.8 million in cash, which purchase closed on June 3, 2022.

On August 18, September 1, and September 6, 2022, the Company entered into privately negotiated agreements to repurchase $327.9 million, $44.5 million, and $9.3 million of 2026 Convertible Secured Notes, using a combination of cash and equity, which purchases closed on August 25, September 6, and September 8, 2022, respectively.

The Company exchanged the existing 2026 Convertible Secured Notes for $222.0 million, $22.7 million, and $5.2 million in cash, respectively, and 9,358,269, 1,653,130, and 318,000 shares, respectively, of newly issued common stock, par value $0.001 per share.

Based on the Company's closing stock price on the dates of the agreements of $19.70, $18.06, and $16.32, respectively, the shares were worth $184.4 million, $29.9 million, and $5.2 million, respectively.

On September 9, 2022, the Company entered into a privately negotiated agreement to repurchase $7.1 million of 2026 Convertible Secured Notes using cash, which purchase closed on September 19, 2022. The Company exchanged the existing 2026 Convertible Secured Notes for $8.2 million in cash.

In accordance with Accounting Standards Codification ("ASC") Subtopic 470-20, "Debt with Conversion and Other Options" ("ASC 470-20") the repurchases of the 2026 Convertible Secured Notes were all treated as extinguishments of debt. The differences between the reacquisition prices of the debt and the net carrying amounts, resulted in losses on extinguishment of $91.8 million.

The approximate fair value of the Convertible Notes was determined as follows using Level 2 inputs based on quoted market values:

	September 30, 2022	December 31, 2021
	(in thousands)	
2026 Convertible Secured Notes	$ 116,112	$ 543,370
2026 Convertible Notes	$ 87,125	$ 69,492
2023 Convertible Notes	$ 106,963	$ 107,727

The Note Indentures

The 2023 Convertible Notes, and the 2026 Convertible Notes, were each issued pursuant to a Base Indenture, dated as of July 6, 2016, between the Company and U.S. Bank National Association ("U.S. Bank"), as trustee, and a First Supplemental Indenture (with respect to the 2023 Convertible Notes) and Second Supplemental Indenture (with respect to the 2026 Convertible Notes), dated July 6, 2016, and May 14, 2019, respectively, each between the Company and U.S. Bank as trustee. The 2026 Convertible Secured Notes were issued pursuant to a Base Indenture and a First Supplemental Indenture, each dated as of August 17, 2021, between the Company and U.S. Bank as trustee and collateral agent. In connection with the issuance of the 2026 Convertible Secured Notes, the Company also entered into a Security Agreement, dated as of August 17, 2021, with U.S. Bank as collateral agent.

Pursuant to these indentures, the 2023 Convertible Notes and 2026 Convertible Notes are senior unsecured obligations, and the 2026 Convertible Secured Notes are senior secured obligations, of the Company. Each indenture provides for customary events of default.

Each series of notes bears a fixed rate of interest as identified above, payable semi-annually in arrears:

	Semi-annual payment dates			
	First payment date	First	Second	Maturity date*
2026 Convertible Secured Notes	February 15, 2022	February 15	August 15	February 15, 2026
2026 Convertible Notes	November 15, 2019	May 15	November 15	May 15, 2026
2023 Convertible Notes	January 1, 2017	January 1	July 1	July 1, 2023

* Unless earlier repurchased, redeemed, or converted.

Each of the three series of notes is convertible under certain circumstances. Prior to January 1, 2023 (for the 2023 Convertible Notes), February 15, 2026 (for the 2026 Convertible Notes), and November 15, 2025 (for the 2026 Convertible Secured Notes), holders may convert their notes only under any of the following circumstances:

(i) During any calendar quarter commencing after the calendar quarter ended on September 30, 2016 (for the 2023 Convertible Notes), June 30, 2019 (for the 2026 Convertible Notes), or December 31, 2021 (for the 2026 Convertible Secured Notes), if the last reported sale price of the Company's common stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is at least 130% of the applicable conversion price (as defined in the applicable indenture) on each applicable trading day (the "Stock Price Conversion Condition").

(ii) During the five business day period after any five consecutive trading day period in which the trading price (as defined in the applicable indenture) per $1,000 principal amount for each trading day was less than 98% of the product of the last reported sale price of the Company's common stock and the applicable conversion rate (as defined in the applicable indenture) on each such trading day.

(iii) If the Company calls any or all of the applicable series of notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date.

(iv) Upon the occurrence of specified corporate events.

After those dates, holders may convert their notes, regardless of the foregoing circumstances, at any time until immediately preceding the applicable maturity date.

Upon conversion of notes, the Company will pay or deliver cash, shares of common stock (or cash in lieu of fractional shares), or a combination of cash and common stock, at the Company's election.

The initial conversion rates of the Convertible Notes per $1,000 principal amount, and the approximate conversion price, are as follows:

	Initial conversion rate	Approximate conversion price
2026 Convertible Secured Notes	47.7612	$20.94
2026 Convertible Notes	9.2123	$108.55
2023 Convertible Notes	5.0358	$198.58

These conversion rates are subject to adjustment upon occurrence of certain events but will not be adjusted for accrued and unpaid interest. Also, if certain specified events occur, the conversion rate will be increased for notes converted in connection with such events.

The Convertible Notes are redeemable by the Company in certain circumstances starting July 6, 2021 (for the 2023 Convertible Notes), May 20, 2023 (for the 2026 Convertible Notes), and February 20, 2024 (for the 2026 Convertible Secured Notes). After such dates, the Company may redeem for cash all or any part of the applicable Convertible Notes, at its option, if the last reported sale price of the common stock has been at least 130% of the applicable conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on and including the trading day immediately preceding the date of the applicable notice of redemption. The redemption price is equal to 100% of the principal amount redeemed, plus accrued and unpaid interest to (but excluding) the redemption date.

No sinking fund is provided for any of the Convertible Notes.

If the Company undergoes a fundamental change (as defined in the applicable indenture), noteholders may require the Company to repurchase for cash all or any portion of their notes at a fundamental change repurchase price equal to 100%

of the principal amount of the notes to be repurchased, plus accrued and unpaid interest to (but excluding) the fundamental change repurchase date.

Upon the occurrence of certain corporate events (i.e., a "make-whole fundamental change", as defined in the applicable indenture), the Company will, under certain circumstances, increase the conversion rate for holders of the Convertible Notes who elect to convert in connection with such corporate events. In addition, with respect to the 2026 Convertible Secured Notes, (1) if the Company elects to redeem all or part of such notes and provides notice of redemption to the holders or (2) if the Stock Price Conversion Condition is satisfied with respect to any calendar quarter commencing after the quarter ended September 30, 2022, the Company will, under certain circumstances, increase the conversion rate for holders who elect to convert (1) during the related redemption period, or (2) in connection with such Stock Price Conversion Condition. Upon a Company redemption of the 2026 Convertible Secured Notes, holders of notes called for redemption may be eligible to receive a make-whole premium. The Company, at its option, will satisfy the conversion obligation through cash, shares of common stock, or a combination of cash and common stock. The right to redeem the 2026 Convertible Secured Notes requires the Company to specify a date of redemption no earlier than 60 days and no later than 90 days after the notice of redemption is sent. If a holder elects to convert its 2026 Convertible Secured Notes prior to the effective date of a make-whole fundamental change or the date of the redemption notice, then it is not entitled to the increased conversion rate in connection with such make-whole fundamental change or redemption.

Upon certain events of default occurring and continuing, either the indenture trustee or holders of at least 25% in aggregate principal amount of a series of notes then outstanding may declare the entire principal amount of that series of notes, and accrued interest, if any, to be immediately due and payable. Upon events of default involving specified bankruptcy events involving the Company, the Convertible Notes are due and payable immediately.

The 2026 Convertible Secured Notes indenture and security agreement include (1) customary covenants, (2) guarantor provisions, and (3) collateral provisions. The 2026 Convertible Secured Notes may become guaranteed in the future by subsidiaries of the Company that meet certain threshold requirements, with the 2026 Convertible Secured Notes becoming senior obligations of such guarantor. The 2026 Convertible Secured Notes are secured by a first priority security interest in substantially all assets of the Company, and of any guarantors, subject to certain exceptions.

The Capped Call Transactions

On June 30, 2016, in connection with the pricing of the 2023 Convertible Notes, the Company entered into privately-negotiated capped call agreements (the "Base Capped Calls") with each of Royal Bank of Canada, UBS AG, London Branch, and Credit Suisse Capital LLC. On July 1, 2016, in connection with the underwriters' exercise of their over-allotment option in full, the Company entered into additional capped call agreements (the "Additional Capped Calls" and, together with the Base Capped Calls, the "Capped Calls") with same counterparties.

The Capped Calls are considered to be instruments indexed to the Company's own shares and met the criteria to be classified within equity. Therefore, they are not remeasured.

In August 2021, in connection with the exchange of 2023 Convertible Notes, of the 460,000 Capped Call options outstanding (400,000 Base Capped Call options and 60,000 Additional Capped Call Options), 306,486 options were terminated (246,486 Base Capped Call options and 60,000 Additional Capped Call options), equivalent to approximately 1.5 million shares.

In September 2021, in connection with the additional repurchase of $39.9 million of 2023 Convertible Notes, 39,859 more Capped Call options were terminated, equivalent to approximately 0.2 million shares, with 113,655 Base Capped Call options remaining, equivalent to approximately 0.6 million shares.

Interest Expense on Convertible Notes

The table summarizes the total interest expense recognized in the periods presented:

	Three Months Ended September 30, 2022				Nine Months Ended September 30, 2022			
	2026 Convertible Secured Notes	2026 Convertible Notes	2023 Convertible Notes	Total	2026 Convertible Secured Notes	2026 Convertible Notes	2023 Convertible Notes	Total
	(in thousands)							
Contractual interest expense	$ 3,127	$ 577	$ 892	$ 4,596	$ 11,877	$ 1,731	$ 2,729	$ 16,337
Amortization of debt issuance costs	407	117	117	641	1,540	349	353	2,242
Accretion of debt discount	—	—	—	—	—	—	—	—
Total interest expense	$ 3,534	$ 694	$ 1,009	$ 5,237	$ 13,417	$ 2,080	$ 3,082	$ 18,579

	Three Months Ended September 30, 2021				Nine Months Ended September 30, 2021			
	2026 Convertible Secured Notes	2026 Convertible Notes	2023 Convertible Notes	Total	2026 Convertible Secured Notes	2026 Convertible Notes	2023 Convertible Notes	Total
	(in thousands)							
Contractual interest expense	$ 2,090	$ 876	$ 2,487	$ 5,453	$ 2,090	$ 3,176	$ 9,962	$ 15,228
Amortization of debt issuance costs	149	152	333	634	149	538	1,303	1,990
Accretion of debt discount	2,993	1,990	3,025	8,008	2,993	7,033	11,859	21,885
Total interest expense	$ 5,232	$ 3,018	$ 5,845	$ 14,095	$ 5,232	$ 10,747	$ 23,124	$ 39,103

The effective interest rates during the three and nine months ended September 30, 2022 for the 2026 Convertible Secured Notes, 2026 Convertible Notes and 2023 Convertible Notes are 4.03%, 2.44% and 3.69%, respectively. The effective interest rates during the three and nine months ended September 30, 2021 for the 2026 Convertible Secured Notes, 2026 Convertible Notes and 2023 Convertible Notes were 12.80%, 9.90% and 8.42%, respectively. Accrued interest on the Convertible Notes was approximately $2.2 million and $8.6 million as of September 30, 2022 and December 31, 2021, respectively.

The Company's total recorded debt issuance costs are $8.7 million, which are being amortized using the effective interest method through the date of maturity. As of September 30, 2022, $0.4 million of debt issuance costs for the 2023 Convertible Notes are unamortized on the condensed consolidated balance sheets in Current portion of long-term debt. As of September 30, 2022 and December 31, 2021, $3.6 million of debt issuance costs for the 2026 Convertible Secured Notes and 2026 Convertible Notes and $10.3 million of debt issuance costs for the 2026 Convertible Secured Notes, 2026 Convertible Notes and 2023 Convertible Notes, respectively, are unamortized on the condensed consolidated balance sheets in Long-term debt. Cash payments for interest were $22.7 million and $17.3 million for the nine months ended September 30, 2022 and 2021, respectively.

11. Product Revenue, Net

The Company recognized U.S. Ocaliva net sales of $77.6 million and $66.6 million for the three months ended September 30, 2022 and 2021, respectively and $208.5 million and $192.1 million for the nine months ended September 30, 2022 and 2021, respectively.

Credit Losses

The following table summarizes the allowance for credit losses activity on the Company's trade receivables for the nine-month period ended September 30, 2022 (in thousands):

Balance at December 31, 2021	$	58
Provision for credit losses		—
Write-offs		—
Balance at September 30, 2022	$	58

12. Research and Development Tax Credit

The Company has benefited from the U.K. Small and Medium-sized Enterprise R&D Tax Credit scheme, or the SME scheme, under which it can obtain a tax credit of up to 33.4% of eligible research and development expenses incurred by the Company in the U.K. Eligible expenses generally include employment costs for research staff, consumables, software and certain internal overhead costs incurred as part of research projects.

The Company submitted a claim seeking to obtain tax credits for qualifying R&D expenses incurred in the years ended December 31, 2018 and 2019. In June 2021, the Company received a payment of $4.2 million from HMRC and made a cash repayment of $0.2 million to the HMRC due to submission of an amended claim.

Given the finalization and approval of the claims for 2018, the Company recorded the net U.K. research and development tax credit payments received of $4.0 million (less $0.5 million due to foreign currency translation) as a reduction of research and development expense in the condensed consolidated statements of operations for the nine months ended September 30, 2022. In the nine months ended September 30, 2021, the Company recorded U.K. research and development tax credits of $10.7 million as a reduction of research and development expense.

13. Stock Compensation

In April 2022, the Company's Compensation Committee and Board of Directors approved the Amended and Restated Equity Incentive Plan ("2022 Plan"), which became effective upon stockholder approval at the annual meeting of stockholders on May 25, 2022, and which replaced the Company's 2012 Stock Incentive Plan ("2012 Plan"). Under the 2022 Plan, the Company may grant stock options, which include incentive stock options ("ISOs") and non-qualified stock options ("NSOs"), stock grants, which include unrestricted shares, restricted shares ("RSAs") and performance restricted shares ("PSAs") along with stock-based awards, which include restricted stock unit awards ("RSUs") and performance restricted stock unit awards ("PRSUs"). The pool of available shares under the 2022 Plan consists of those shares which remained unallocated under the 2012 Plan, plus any shares subject to previously issued awards which are forfeited. The 2022 Plan does not contain an evergreen share replenishment clause and prohibits the repricing of stock options. The 2022 Plan will remain effective for a ten-year term, expiring in 2032.

The estimated fair value of the stock options granted in the nine months ended September 30, 2022 was determined utilizing a Black-Scholes option-pricing model at the date of grant. The fair value of the RSUs granted in the nine months ended September 30, 2022 was determined utilizing the closing price of the Company's common stock on the date of grant. The fair value of the PRSUs granted in the nine months ended September 30, 2022 was determined utilizing the Monte Carlo simulation method. The Company accounts for all forfeitures when they occur. Ultimately, the actual expense recognized over the vesting period will be for only those shares that vest and are not forfeited.

The following table summarizes stock option activity during the nine months ended September 30, 2022 (under both the 2012 Plan and the 2022 Plan):

	Number of Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	2,252	$ 50.28	7.2	$ 408
Granted	493	$ 15.04	—	$ —
Exercised	(29)	$ 15.01	—	$ 93
Cancelled/forfeited	(164)	$ 27.60	—	$ —
Expired	(105)	$ 99.54	—	$ —
Outstanding at September 30, 2022	2,447	$ 43.00	7.0	$ 45
Expected to vest	954	$ 21.97	8.7	$ 45
Exercisable	1,493	$ 56.45	5.9	$ —

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the underlying options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock. As of September 30, 2022, the total compensation cost related to non-vested option awards not yet recognized is approximately $13.2 million with a weighted average remaining vesting period of 1.23 years.

The Company estimated the fair value of stock options granted in the periods presented utilizing a Black-Scholes option-pricing model utilizing the following assumptions:

	Nine Months Ended September 30,	
	2022	2021
Volatility	66.4 - 67.7 %	65.2 - 69.3 %
Expected term (in years)	5.5 - 6.0	3.75 - 6.0
Risk-free rate	1.3 - 2.8 %	0.4 - 0.9 %
Expected dividend yield	— %	— %

The following table summarizes the aggregate RSU, RSA and PRSU activity during the nine months ended September 30, 2022 (under both the 2012 Plan and the 2022 Plan):

	Number of Awards (in thousands)	Weighted Average Grant Date Fair Value
Non-vested awards at December 31, 2021	968	$ 39.58
Granted	819	$ 15.69
Vested	(411)	$ 30.74
Forfeited	(193)	$ 38.72
Non-vested awards at September 30, 2022	1,183	$ 26.23

As of September 30, 2022, there is approximately $20.8 million of total unrecognized compensation expense related to unvested RSUs, RSAs and PRSUs, which is expected to be recognized over a weighted average vesting period of 1.54 years.

During the nine months ended September 30, 2022, the Company granted a total of 168,600 PRSUs to certain of the Company's executive officers. The performance criterion for such PRSUs is based on the Total Shareholder Return ("TSR") of the Company's common stock relative to the TSR of the companies comprising the S&P Biotechnology Select Industry Index (the "TSR Peer Group") over a 3-year performance period and is accounted for as a market condition under ASC Topic 718, *Compensation – Stock Compensation.* The TSR for the Company or a member of the TSR Peer Group is

calculated by dividing (a) the difference of the ending average stock price minus the beginning average stock price by (b) the beginning average stock price. The beginning average stock price equals the average closing stock price over the one calendar month period prior to the beginning of the performance period, after adjusting for dividends, as applicable. The ending average stock price equals the average closing price over the one calendar month period ending on the last day of the performance period, after adjusting for dividends, as applicable. The Company's relative TSR is then used to calculate the payout percentage, which may range from zero percent (0%) to one hundred and fifty percent (150%) of the target award. The Company utilized a Monte Carlo simulation to determine the grant date fair value of such PRSUs.

The Company recorded approximately $0.2 million and $0.7 million of stock-based compensation related to such PRSUs granted during the three and nine months ended September 30, 2022.

The Company modified certain stock option, stock grant and stock-based awards to accelerate vesting in anticipation of the sale of the ex-U.S. commercial operations to Advanz. The Company accelerated the vesting of all awards held by employees of those operations being sold because those employees would have otherwise forfeited the awards. Given the sale of the ex-U.S. commercial operations was probable at the time the awards were modified and the entities met the held for sale criteria, the modification to accelerate vesting was recognized at the date of the modification. As a result, incremental compensation expense of $3.4 million was recognized based on the fair value of the modified awards for the nine months ended September 30, 2022.

Stock-based compensation expense has been reported in the Company's condensed consolidated statements of operations as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
			(in thousands)	
Selling, general and administrative	$ 4,411	$ 5,737	$ 12,485	$ 16,255
Research and development	1,377	1,451	4,173	4,626
Restructuring	—	—	—	—
Total stock-based compensation	$ 5,788	$ 7,188	$ 16,658	$ 20,881

Stock-based compensation expense recognized under discontinued operations, included in net income from discontinued operations, was $0 and $1.4 million for the three months ended September 30, 2022 and 2021, respectively and $4.4 million and $4.6 million for the nine months ended September 30, 2022 and 2021, respectively.

14. Income Taxes

The Company recorded a provision for income taxes of $8.0 million for the three and nine months ended September 30, 2022, respectively. No income tax provision was recorded for the three and nine months ended September 30, 2021. The tax provision has been recorded within discontinued operations as it relates to the income tax impact on the sale of the international business to Advanz. The Company expects to utilize net operating loss carryforwards ("NOLs") to offset the income tax impact on the sale, however, primarily due to limitations on the amount of NOLs which can be used, the Company recorded an income tax provision in the United Kingdom and certain U.S. state jurisdictions of $6.5 million and $1.5 million, respectively. There is no income tax expense recorded in continuing operations for the three and nine months ended September 30, 2022 and 2021, respectively.

15. Net Loss Per Share

Basic loss per share is computed by dividing net loss attributable to common stockholders (numerator) by the weighted average number of common shares outstanding (denominator) during the period. For the three and nine-month periods ended September 30, 2022 and 2021, the diluted loss per share computations for such periods did not assume the conversion of the Convertible Notes, exercise of stock options or vesting of RSUs or PRSUs as they would have had an anti-dilutive effect on loss per share. The Company utilized the control number concept in the computation of diluted earnings per share. The control number used is net loss from continuing operations. The control number requires that the

same number of potentially dilutive securities applied in computing diluted earnings per share from continuing operations be applied to all other categories of income or loss. Since the Company had a net loss from continuing operations for all periods presented, no dilutive effect has been recognized in the calculation of income from discontinued operations per share.

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding for the three and nine-month periods ended September 30, 2022 and 2021, as the inclusion thereof would have been anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(in thousands)		(in thousands)	
Shares issuable upon conversion of Convertible Notes	18,462	14,806	23,169	7,930
Options	2,483	2,692	2,474	2,722
Unvested restricted stock units	1,233	1,244	1,351	1,221
Total	22,178	18,742	26,994	11,873

16. Commitments and Contingencies

Legal Proceedings

The Company is involved in various disputes, legal proceedings and litigation in the course of its business, including the matters described below and, from time to time, governmental inquiries and investigations and employment and other litigation. These matters, which could result in damages, fines or other administrative, civil or criminal remedies, liabilities or penalties, are often complex and the outcome of such matters is often uncertain. The Company may from time to time enter into settlements to resolve such matters.

Shareholder Litigation

The Company currently is involved in a derivative suit related to a purported shareholder class action lawsuit. The Company believes that it has a number of valid defenses to the claims of the litigant, and intends to vigorously defend itself. At this time, a discontinuance of the derivative suit has been agreed to by the parties, and is pending approval by the New York state court. Accordingly, the Company does not expect a material loss from this matter.

The 2017 Litigation

On September 27, 2017, a purported shareholder class action, initially styled DeSmet v. Intercept Pharmaceuticals, Inc., et al., was filed in the United States District Court for the Southern District of New York, naming the Company and certain of its officers as defendants. On June 1, 2018, the Court appointed lead plaintiffs in the lawsuit, and on July 31, 2018, the lead plaintiffs filed an amended complaint, captioned Hou Liu and Amy Fu v. Intercept Pharmaceuticals, Inc., et al., naming the Company and certain of its current and former officers as defendants. The lead plaintiffs claimed to be suing on behalf of anyone who purchased or otherwise acquired the Company's common stock between June 9, 2016 and September 20, 2017. This lawsuit alleged that material misrepresentations and/or omissions of material fact were made in the Company's public disclosures during that period, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Rule 10b-5 promulgated thereunder. The alleged improper disclosures relate to statements regarding Ocaliva dosing and use, and pharmacovigilance-related matters, as well as the Company's operations, financial performance, and prospects. The plaintiffs sought unspecified monetary damages on behalf of the putative class, an award of costs and expenses, including attorney's fees, and rescissory damages. On September 14, 2018, the Company filed a motion to dismiss the amended complaint. On March 26, 2020, the Court granted the Company's motion to dismiss the amended complaint in its entirety, and on March 27, 2020 the Court entered judgment in favor of the Company. On May 8, 2020, the plaintiffs filed a motion to set aside the judgment and grant leave to file a second amended complaint. On September 9, 2020, the Court denied the plaintiffs' motion, finding that the proposed second amended complaint did not cure the deficiencies identified in the amended complaint. On October 9, 2020, the plaintiffs

filed a notice of appeal to the United States Court of Appeals for the Second Circuit and on January 25, 2021, the plaintiffs filed an appellate brief challenging the March 27, 2020 judgment, the September 9, 2020 judgment, and other court orders. On April 23, 2021, the Company filed a response brief in the Second Circuit appellate proceeding. On May 14, 2021, the plaintiffs filed a reply brief. On December 9, 2021, oral argument was held in the Second Circuit. On June 16, 2022, the Second Circuit entered a summary order affirming the order of the District Court dated September 9, 2020.

Separately, on December 1, 2017, a purported shareholder demand was made on the Company based on substantially the same allegations as those set forth in the securities case above. Also, on January 5, 2018, a follow-on derivative suit, styled Davis v. Pruzanski, et al., was filed in New York state court by shareholder Gregg Davis based on substantially the same allegations as those set forth in the securities case above. The derivative litigation was stayed pending the exhaustion of all appeals relating to the dismissal of the securities case. Following exhaustion of such appeals, on October 7, 2022, the parties stipulated to and agreed to a discontinuance of the derivative suit. The stipulation is currently pending approval by the New York state court.

Patent Litigation

The Company has received paragraph IV certification notice letters from seven generic drug manufacturers indicating that each such manufacturer submitted to the FDA an Abbreviated New Drug Application (“ANDA”) seeking approval to manufacture and sell a generic version of the Company’s 5 mg and 10 mg dosage strengths of Ocaliva® (obeticholic acid) for PBC prior to the expiration of certain patents listed for Ocaliva in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”).

The seven generic drug manufacturers and when we received their initial paragraph IV certification notices are as follows: (1) Apotex Inc. (“Apotex”) (July 2020), (2) Lupin Limited (“Lupin”) (July 2020), (3) Amneal Pharmaceuticals of New York, LLC, as U.S. agent for Amneal EU Limited (collectively, “Amneal”) (July 2020), (4) Optimus Pharma Pvt Ltd (“Optimus”) (July 2020), (5) MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited (collectively, “MSN”) (July 2020), (6) Dr. Reddy’s Laboratories, Inc., and Dr. Reddy’s Laboratories, Ltd. (collectively, “Dr. Reddy’s”) (December 2020), and (7) Zenara Pharma Private Limited (“Zenara”) (August 2022).

Each paragraph IV certification notice alleged that the challenged Orange Book patents were invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of the generic products described in the generic manufacturer’s respective ANDA. In each case, within 45 days of receipt of the paragraph IV certification notice, the Company initiated a patent infringement suit against the generic manufacturer in the United States District Court for the District of Delaware. As a result, under the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”), the FDA cannot grant final approval of each generic manufacturer’s ANDA before the earlier of November 27, 2023 (or, for Zenara, February 8, 2025), or a court decision in their favor. The Company has since received additional paragraph IV certification notices from certain of the generic manufacturers challenging additional Ocaliva Orange Book patents, and the Company amended its complaints against the generic challengers accordingly to add infringement allegations in relation thereto.

The challenged Ocaliva Orange Book patents asserted by the Company in the ongoing patent litigations are U.S. Patents Nos. RE 48,286 (the “‘286 Patent”), 9,238,673 (the “‘673 Patent”), 10,047,117 (the “‘117 Patent”), 10,052,337 (the “‘337 Patent”), 10,174,073 (the “‘073 Patent”), 10,751,349 (the “‘349 Patent”), and 10,758,549 (the “‘549 Patent”).

On August 16, 2022, the Company entered into a settlement agreement with Dr. Reddy’s resolving the patent litigation over Dr. Reddy’s ANDA.

Under the terms of the agreement, the Company granted Dr. Reddy’s a non-exclusive, non-sublicensable, non-transferable, royalty-free license to commercialize its generic version of Ocaliva in the United States commencing on October 26, 2035, or earlier under certain circumstances. The parties filed the settlement agreement with the Federal Trade Commission and the Department of Justice pursuant to applicable law and terminated their litigation pursuant to a consent judgment that was approved by the court. Similar patent litigation by the Company against the other ANDA filers remains pending.

Trial against Amneal, Apotex, Lupin, MSN, and Optimus is scheduled for February 27, 2023. A trial date for the Zenara case, which was filed on September 16, 2022, has not been set.

These patent proceedings are costly and time-consuming, and successful challenges to the Company's patent or other intellectual property rights could result in the Company losing those rights in the relevant jurisdiction, and could allow third parties to use the Company's proprietary technologies without a license from the Company or its collaborators. While the Company intends to vigorously defend and enforce its intellectual property rights protecting Ocaliva, the Company can offer no assurances regarding when these lawsuits will be decided, which side will prevail, or whether a generic equivalent of Ocaliva could be approved and enter the market before the expiration of the Company's patents.

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

You should read the following discussion and analysis together with our condensed consolidated financial statements and accompanying notes included elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2021 (the "Annual Report"). This discussion and analysis contains forward-looking statements, which involve risks and uncertainties. As a result of many factors, such as those described under "Cautionary Note Regarding Forward-Looking Statements," "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases with high unmet medical need utilizing our proprietary bile acid chemistry. Our first marketed product, Ocaliva® (obeticholic acid or "OCA"), is a farnesoid X receptor ("FXR") agonist approved in the United States for the treatment of primary biliary cholangitis ("PBC") in combination with ursodeoxycholic acid ("UDCA") in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA.

In addition to commercializing OCA for PBC under the Ocaliva brand name, we are also currently developing OCA for additional indications, including nonalcoholic steatohepatitis ("NASH"). We are also developing product candidates in various stages of clinical and preclinical development. We believe that OCA and our other product candidates have the potential to treat orphan and other more prevalent liver diseases such as NASH for which there are currently limited therapeutic options.

Ocaliva was approved for PBC by the U.S. Food and Drug Administration ("FDA") in May 2016 under the accelerated approval pathway. We commenced sales and marketing of Ocaliva in the United States shortly after receiving approval, and Ocaliva is now available to U.S. patients primarily through a network of specialty pharmacy distributors. In addition, we continue to work to execute on our post-marketing regulatory commitments with respect to Ocaliva. In June 2022, we announced topline results from our COBALT trial. The primary endpoint, as agreed with the FDA, was time to first occurrence of any of the following clinical endpoints: all-cause death, liver transplant, hospitalization for other serious liver-related events, signs of progression to hepatic decompensation, or signs of development of portal hypertension. The study did not demonstrate a statistically significant difference between Ocaliva and placebo on the primary endpoint: 71 subjects in the Ocaliva arm progressed to clinical events compared to 80 in the placebo arm (p=0.30; HR 0.84). The safety and tolerability of Ocaliva were consistent with its known profile and adverse events were in line with expectations for patients with advanced PBC based on the natural history of the disease. In June 2022, we also announced topline results for our HEROES-US study, a retrospective real-world study that evaluated data from a U.S. claims database, to compare clinical outcomes in a pre-defined group of patients with PBC who were treated with Ocaliva and a comparable group of PBC patients who were eligible, but who were not treated with Ocaliva. The results from the HEROES-US study showed a statistically significant and clinically meaningful reduction in all-cause death, liver transplant, or hospitalization for hepatic decompensation among Ocaliva-treated patients compared to the control group. In the Ocaliva arm (n=429), 8 events were observed compared to 226 in the control group (n=4,585) with a weighted hazard ratio of 0.38 (p= 0.027). HEROES-US is one of two HEROES studies we are conducting that utilizes real-world data to assess the impact of Ocaliva on clinical outcomes in PBC patients.

In September 2022, we had a supplemental NDA ("sNDA") pre-submission meeting with the FDA in which we reviewed our post-marketing requirements with respect to Ocaliva. We intend to submit the data from the COBALT and HEROES-US studies as well additional data, including data from other real world evidence studies, as part of a broader evidence package in the sNDA in support of full approval of Ocaliva for the treatment of PBC, which we anticipate submitting to the FDA in 2023. If this data package does not support fulfillment of our post-marketing obligations, we may not be able to maintain our previously granted marketing approval of Ocaliva for PBC.

Our lead development product candidate is OCA for the potential treatment of NASH. In February 2019, we announced topline results from the planned 18-month interim analysis of our pivotal Phase 3 clinical trial of OCA in

patients with liver fibrosis due to NASH, known as the REGENERATE trial (the "Original Analysis"). The REGENERATE trial is ongoing and is expected to continue through clinical outcomes for verification and description of the clinical benefit of OCA. In June 2020, we received a complete response letter ("CRL") from the FDA stating that our NDA for OCA for the treatment of liver fibrosis due to NASH could not be approved in its present form. We had our end of review meeting with the FDA in October 2020 to discuss the FDA's risk-benefit assessment in the CRL based on its review of the available data, as well as our proposed resubmission of our NDA for the treatment of liver fibrosis due to NASH. The meeting was constructive and the FDA provided us with helpful guidance regarding supplemental data we can provide to further characterize OCA's efficacy and safety profile that could support resubmission based on our Phase 3 REGENERATE 18-month biopsy data, together with a safety assessment from our ongoing studies.

Following our end of review meeting, we had a dialogue with FDA regarding the REGENERATE study to clarify data, a new consensus read methodology for liver biopsies, and analyses required to resubmit our NDA. In connection with the potential resubmission of our NDA, we conducted a new interim analysis of our ongoing pivotal Phase 3 REGENERATE trial of OCA using a biopsy consensus read methodology in the same intent-to-treat ("ITT") population as the Original Analysis (the "New Interim Analysis").

In July 2022, we announced topline results from the New Interim Analysis. In this new interim analysis of the ITT population from REGENERATE, 22.4% of subjects randomized to once-daily oral OCA 25 mg met the primary endpoint of achieving at least one stage of fibrosis improvement with no worsening of NASH at month 18 on liver biopsy compared with 9.6% of subjects on placebo ($p<0.0001$). The results were consistent with the Original Analysis, which also showed that OCA 25 mg had a statistically significant effect on fibrosis improvement ($p=0.0002$). The New Interim Analysis used a consensus panel approach to histology reads, in line with recent FDA guidance, while the Original Analysis used individual central readers. A numerically greater proportion of individuals in the OCA 25 mg treatment group compared to placebo achieved the endpoint of resolution of NASH with no worsening of liver fibrosis but, consistent with the Original Analysis, the results for the endpoint of resolution of NASH were not statistically significant. As part of the New Interim Analysis, a safety evaluation was conducted in 2477 subjects from the REGENERATE trial who took at least one dose of study drug (placebo, OCA 10 mg, or OCA 25 mg). Topline results from this ongoing safety evaluation showed that treatment-emergent adverse events (TEAEs), treatment-emergent serious adverse events (TESAEs), and deaths were generally balanced across the OCA and placebo treatment groups in this new safety population. The most common TEAE was pruritus (24% in placebo, 33% in OCA 10 mg and 55% in OCA 25 mg) and pruritus was the most common cause for treatment discontinuation. As part of the safety review of the New Interim Analysis, independent groups of experts reviewed certain categories of safety events to provide a blinded adjudication as specifically requested by the FDA. These included events pertaining to hepatic safety (excluding clinical outcomes), cardiovascular and renal. Topline analysis through four years of treatment showed a numerically higher number of adjudicated hepatic safety events for OCA 25 mg, the majority of which were mild in severity. For adjudicated core major adverse cardiovascular events and adjudicated acute kidney injury events, frequency of events was low and balanced across treatment groups. Consistent with its mechanism of action as an FXR agonist, OCA treatment was associated with an increase in LDL at Month 1 which returned to near baseline values by Month 12. Based on the results of the New Interim Analysis, we intend to re-submit the NDA for OCA in liver fibrosis due to NASH by the end of 2022.

In July 2022, we had a pre-submission meeting with the FDA in which we reviewed the planned structure and the timing of the submission of our NDA and have had an ongoing dialogue as we prepare to re-submit. As we previously disclosed, the Company will need to overcome the risk-benefit assessment of the FDA from the prior review of the NDA for OCA for the treatment of liver fibrosis due to NASH. Although we believe that the insights we have gained from the re-analysis and from the larger and more robust safety database provide an improved risk-benefit, there can be no assurances that the FDA will change its view on risk-benefit and will approve such NDA on an accelerated basis, or at all.

In September 2022, we announced that REVERSE, a Phase 3 study evaluating the safety and efficacy of OCA in patients with compensated cirrhosis due to NASH, did not meet its primary endpoint of a ≥ 1-stage histological improvement in fibrosis with no worsening of NASH following up to 18 months of therapy. No new safety signals for OCA were observed in this population of patients with cirrhosis. In the REVERSE study of 919 randomized subjects with compensated cirrhosis due to NASH, 11.1% (p=NS) of subjects who were randomized to receive once-daily oral OCA 10 mg and 11.9% (p=NS) of subjects who were randomized to receive OCA 10 mg titrated to 25 mg (OCA 10-to-25 mg) after three months achieved a ≥1-stage improvement in fibrosis with no worsening of NASH after up to 18 months of

treatment, compared with 9.9% of subjects who received placebo. Though the REVERSE study did not succeed on the histological evaluation of the primary endpoint, a positive impact on liver stiffness as defined by transient elastography was noted in both OCA 10 mg and OCA 10-to-25 mg arms. Safety was evaluated in 916 subjects who took at least one dose of study drug (placebo, OCA 10 mg or OCA 10-to-25 mg). Treatment-emergent adverse events (TEAEs), treatment-emergent serious adverse events (TESAEs) and deaths were balanced across all treatment groups in REVERSE. The most common TEAE was pruritus (31% in placebo, 41% in OCA 10 mg and 57% in OCA 10-to-25 mg) and pruritus was the most common reason for treatment discontinuation. Serious gallbladder-related events were balanced across arms (0.6% in placebo, 1.0% in OCA 10 mg, 1.0% in OCA 10-to-25 mg). Consistent with the known mechanism of action of FXR-agonists, the OCA 10-to-25 mg arm had a higher incidence of gallstones.

We are evaluating the efficacy, safety and tolerability of OCA in combination with bezafibrate in patients with PBC in a Phase 2 study outside of the United States. In the United States, we have an ongoing Phase 1 study to better characterize the exposure response of the fixed-dose combination, which has completed enrollment, and we have an open Investigational New Drug ("IND") application with the FDA. We are also conducting a second Phase 2 study in the United States evaluating a fixed-dose combination of OCA and bezafibrate for the treatment of patients with PBC who have not achieved an adequate biochemical response to UDCA. Our longer-term goal is developing and seeking regulatory approval for a fixed dose combination regimen in PBC and potentially in other diseases.

In addition, we have other compounds in early stages of research and development in our pipeline, including our INT-787 compound, an FXR agonist. We are currently evaluating INT-787 in a Phase 1 clinical trial. We submitted an IND for INT-787 in the first half of 2022, which is now active.

Sale of our ex-U.S. commercial operations to Advanz Pharma

On July 1, 2022, we completed the sale of our ex-U.S. commercial operations to Advanz Pharma ("Advanz"), and sublicensed the right to commercialize Ocaliva outside of the United States. The transaction included a total upfront consideration of $405 million, subject to customary working capital and other adjustments, plus a $45 million earnout, payable upon Advanz's receipt of extensions of orphan drug exclusivity in Europe. We will also receive royalties on any future net sales of OCA in NASH outside of the U.S., should Advanz obtain marketing authorization for this indication in ex-U.S. regions. We continue to be responsible for the manufacturing and supply of OCA globally while Advanz is responsible for packaging, distribution and commercialization of the therapy in all markets outside of the U.S. The majority of employees outside of the U.S. were transferred to Advanz, while remaining international employees continue to manage our global supply chain, support our quality organization, and support global clinical trials.

Under the Transitional Services Agreement (the "TSA"), we agreed to provide certain transitional services for periods of up to six months to Advanz for continuity purposes.

Under the Sublicense Agreement, we agreed to continue to conduct certain post-marketing work and other activities with respect to Ocaliva for PBC, including continuing to conduct certain PBC studies (the "PBC Post-Marketing Work"). The Company will be reimbursed by Advanz for a portion of the total R&D costs related to the PBC Post-Marketing Work.

The transaction allowed us to capitalize on an opportunity that supports multiple pathways for the future and further strengthens our balance sheet for the current year and beyond. The terms of this transaction will allow us to focus our resources on the U.S., our largest market, while retaining upside from the potential NASH opportunity ex-U.S., via royalties on any future net sales of OCA, should Advanz obtain marketing authorizations for this indication in ex-U.S. regions.

The ex-U.S. commercial business operations met the criteria within Accounting Standards Codification 205-20 to be reported as discontinued operations because the transaction was held for sale and represents a strategic shift in business that will have a major effect on our operations and financial results. Therefore, we have reported the historical results of the ex-U.S. commercial business including the results of operations and cash flows as discontinued operations, and related assets and liabilities were retrospectively reclassified as assets and liabilities of discontinued operations for all prior periods presented herein. Unless otherwise noted, applicable amounts in the prior year have been recast to conform to this

discontinued operations presentation. Refer to Note 4 of our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for additional information.

Recent Developments

On August 16, we entered into a settlement agreement with Dr. Reddy's resolving the patent litigation over Dr. Reddy's ANDA seeking approval to market a generic version of Ocaliva prior to expiration of our patents.

On September 20, we announced that a key publication in *Gastroenterology* showed that people receiving OCA for PBC in a clinical trial setting had greater transplant-free survival compared to patients with PBC selected from "real-world" patient registries who did not receive OCA.

On September 30, we announced that REVERSE, a Phase 3 study evaluating the safety and efficacy of OCA in patients with compensated cirrhosis due to NASH, did not meet its primary endpoint of a ≥ 1-stage histological improvement in fibrosis with no worsening of NASH following up to 18 months of therapy. No new safety signals for OCA were observed in this population of patients with cirrhosis.

Debt Retirement

In August and September 2022, we entered into a series of exchange agreements and agreed with a limited number of existing noteholders of our 2026 Convertible Secured Notes to exchange approximately $388.9 million aggregate principal amount of existing notes for $258.2 million in cash and 11,329,399 shares of newly issued common stock (equivalent to $219.4 million), for total consideration of $477.6 million. Net of these exchanges, the principal balance of the 2026 Convertible Secured Notes was reduced by $388.9 million from $500.0 million to $111.1 million.

The result of these activities was to lower principal debt outstanding by 54% or $388.9 million to $336.3 million and decrease annual cash interest expense by 58% or $13.6 million to $9.8 million on an annual basis. In addition, these activities reduced overall potential shareholder dilution associated with the 2026 Convertible Secured Notes.

Financial Overview

Revenue

We commenced our commercial launch of Ocaliva for the treatment of PBC in the United States in June 2016. We sell Ocaliva to a limited number of specialty pharmacies which dispense the product directly to patients. The specialty pharmacies are referred to as our customers.

Product Revenue, Net

We recognize revenue upon delivery of Ocaliva to our customers, net of discounts, rebates and incentives associated with the product. We provide the right of return to our customers for unopened product for a limited time before and after its expiration date.

Under Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), we have written contracts with each of our customers that have a single performance obligation — to deliver products upon receipt of a customer order — and these obligations are satisfied when delivery occurs and the customer receives Ocaliva. We evaluate the creditworthiness of each of our customers to determine whether collection is reasonably assured. We estimate variable revenue by calculating gross product revenues based on the wholesale acquisition cost that we charge our customers for Ocaliva, and then estimating our net product revenues by deducting (i) estimated government rebates and discounts related to Medicare, Medicaid and other government programs, (ii) estimated costs of incentives offered to certain indirect customers including patients and (iii) trade allowances, such as invoice discounts for prompt payment and customer fees.

We recognized net sales of Ocaliva of $77.6 million and $66.6 million for the three months ended September 30, 2022 and 2021, respectively, and $208.5 million and $192.1 million for the nine months ended September 30, 2022 and 2021, respectively.

Selling, General and Administrative Expenses

We have incurred and expect to continue to incur significant selling, general and administrative ("SG&A") expenses as a result of, among other initiatives, the commercialization of Ocaliva for PBC in the United States. In addition, we have incurred significant selling, general and administrative expenses and may in the future incur similar expenses in connection with the preparation for the potential commercialization of OCA for liver fibrosis due to NASH, if approved, and our other future approved products, if any, and any maintenance of our general and administrative infrastructure in the United States.

Research and Development Expenses

Since our inception, we have focused significant resources on our research and development activities, including conducting preclinical studies and clinical trials, pursuing regulatory approvals and engaging in other product development activities. We recognize research and development expenses as they are incurred.

We have incurred and expect to continue to incur significant research and development expenses as a result of, among other initiatives, our clinical development programs for OCA for PBC and NASH, our other earlier stage research programs and our regulatory approval efforts.

Results of Operations

Comparison of the Three Months Ended September 30, 2022 and 2021

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

	Three Months Ended September 30,	
	2022	2021
	(in thousands)	
Revenue:		
Product revenue, net	$ 77,588	$ 66,640
Total revenue	77,588	66,640
Operating expenses:		
Cost of sales	424	224
Selling, general and administrative	43,274	41,271
Research and development	44,034	44,712
Restructuring	—	—
Total operating expenses	87,732	86,207
Other (expense) income:		
Interest expense	(5,237)	(14,095)
(Loss) gain on extinguishment of debt	(91,759)	16,511
Other income, net	3,053	210
Total other (expense) income, net	(93,943)	2,626
Loss from continuing operations	$ (104,087)	$ (16,941)
Income from discontinued operations, net of tax	$ 371,540	$ 13,309
Net income (loss)	$ 267,453	$ (3,632)

Revenues

Product revenue, net was $77.6 million and $66.6 million for the three months ended September 30, 2022 and 2021, respectively. For the three months ended September 30, 2022 and 2021, product revenue, net was solely comprised of U.S. Ocaliva net sales. The increase in product revenues was driven by operational growth, primarily due to increased unit sales volumes and higher pricing.

Cost of sales

Cost of sales was $0.4 million and $0.2 million for the three months ended September 30, 2022 and 2021, respectively. Our cost of sales for the three months ended September 30, 2022 and 2021 consisted primarily of packaging, labeling, materials and related expenses.

Selling, general and administrative expenses

Selling, general and administrative expenses were $43.3 million and $41.3 million for the three months ended September 30, 2022 and 2021, respectively. The $2.0 million net increase between periods was primarily driven by increased commercial activities and costs related to our ANDA litigation.

Research and development expenses

Research and development expenses were $44.0 million and $44.7 million for the three months ended September 30, 2022 and 2021, respectively. The $0.7 million net decrease between periods was primarily driven by lower costs for NASH and cholestasis activities, partially offset by increased costs related to pipeline compound activities as well as R&D cost-sharing reimbursements from Advanz.

Interest expense

Interest expense was $5.2 million and $14.1 million for the three months ended September 30, 2022 and 2021, respectively. For the quarter ended September 30, 2022, interest expense related to the principal amounts outstanding for the 2023 Convertible Notes, 2026 Convertible Notes and 2026 Convertible Secured Notes and no longer included any accretion of debt discounts, which was $8.0 million for the three months ended September 30, 2021, after the adoption of ASU 2020-06. For the quarter ended September 30, 2021, interest expense related to the principal amounts outstanding for the 2023 Convertible Notes, 2026 Convertible Notes and 2026 Convertible Secured Notes.

(Loss) gain on extinguishment of debt

(Loss) gain on extinguishment of debt was ($91.8) million and $16.5 million for the three months ended September 30, 2022 and 2021, respectively. For the quarter ended September 30, 2022, the loss on extinguishment of debt relates to the repurchases of the 2026 Convertible Secured Notes. For the quarter ended September 30, 2021, the gain on extinguishment of debt relates to the exchange of debt and repurchase of 2023 Convertible Notes.

Other income, net

Other income, net was $3.1 million and $0.2 million for the three months ended September 30, 2022 and 2021, respectively. Such income is primarily attributable to interest income earned on cash, cash equivalents and investment debt securities along with additional income recognized during the quarter ended September 30, 2022 for transitional services provided by us.

Income from discontinued operations, net of tax

Income from discontinued operations, net of tax was $371.5 million and $13.3 million for the three months ended September 30, 2022 and 2021, respectively. The increase in income from discontinued operations was a result of the $372.4 million gain recognized on the sale of the sale our ex-U.S. commercial operations and sublicense to Advanz offset

by a decrease in operating income associated with product revenues and operating expenses, which are no longer included after the closing of the sale during the three months ended September 30, 2022.

Income taxes

For the three months ended September 30, 2022 and 2021, no income tax expense or benefit was recognized for our continuing operations. Our deferred tax assets are comprised primarily of net operating loss carryforwards. We maintain a full valuation allowance on our deferred tax assets since we have not yet achieved sustained profitable operations. As a result, we have not recorded any income tax benefit since our inception.

Comparison of the Nine Months Ended September 30, 2022 and 2021

	Nine Months Ended September 30,	
	2022	2021
	(in thousands)	
Revenue:		
Product revenue, net	$ 208,491	$ 192,117
Total revenue	208,491	192,117
Operating expenses:		
Cost of sales	956	771
Selling, general and administrative	121,013	130,255
Research and development	136,753	132,991
Restructuring	—	(284)
Total operating expenses	258,722	263,733
Other (expense) income:		
Interest expense	(18,579)	(39,103)
(Loss) gain on extinguishment of debt	(91,739)	16,511
Other income, net	2,691	2,389
Total other (expense), net	(107,627)	(20,203)
Loss from continuing operations	$ (157,858)	$ (91,819)
Income from discontinued operations, net of tax	$ 400,499	$ 36,673
Net income (loss)	$ 242,641	$ (55,146)

Revenues

Product revenue, net was $208.5 million and $192.1 million for the nine months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, product revenue, net was solely comprised of U.S. Ocaliva net sales. The increase in product revenues was driven by operational growth, primarily due to higher pricing and increased unit sales volumes, partially offset by higher gross to net deductions.

Cost of sales

Cost of sales was $1.0 million and $0.8 million for the nine months ended September 30, 2022 and 2021, respectively. Our cost of sales for the nine months ended September 30, 2022 and 2021 consisted primarily of packaging, labeling, materials and related expenses.

Selling, general and administrative expenses

Selling, general and administrative expenses were $121.0 million and $130.3 million for the nine months ended September 30, 2022 and 2021, respectively. The $9.3 million net decrease between periods was primarily driven by lower headcount, along with a decrease in costs for commercial and medical affairs activities.

Research and development expenses

Research and development expenses were $136.8 million and $133.0 million for the nine months ended September 30, 2022 and 2021, respectively. The $3.8 million net increase between periods was primarily driven by a $7.2 million reduction in recognition of UK R&D tax credits under the SME and RDEC schemes and higher costs for INT-787 and cholestasis activities, partially offset by lower NASH development costs as well as R&D cost-sharing reimbursements of $3.1 million from Advanz.

Interest expense

Interest expense was $18.6 million and $39.1 million for the nine months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022, interest expense related to the principal amounts outstanding for the 2023 Convertible Notes, 2026 Convertible Notes and 2026 Convertible Secured Notes and no longer included any accretion of debt discounts, which was $21.9 million for the nine months ended September 30, 2021, after the adoption of ASU 2020-06. For the nine months ended September 30, 2021, interest expense related to the principal amounts outstanding for the 2023 Convertible Notes, 2026 Convertible Notes and 2026 Convertible Secured Notes.

(Loss) gain on extinguishment of debt

(Loss) gain on extinguishment of debt was ($91.7) million and $16.5 million for the three months ended September 30, 2022 and 2021, respectively. For the quarter ended September 30, 2022, the loss on extinguishment of debt relates to the repurchases of the 2026 Convertible Secured Notes. For the quarter ended September 30, 2021, the gain on extinguishment of debt relates to the exchange of debt and repurchase of 2023 Convertible Notes.

Other income, net

Other income, net was $2.7 million and $2.4 million for the nine months ended September 30, 2022 and 2021, respectively. Such income is primarily attributable to interest income earned on cash, cash equivalents and investment debt securities along with additional income recognized during the quarter ended September 30, 2022 for transitional services provided by us.

Income from discontinued operations, net of tax

Income from discontinued operations, net of tax was $400.5 million and $36.7 million for the nine months ended September 30, 2022 and 2021, respectively. The increase in income from discontinued operations was a result of the $372.4 million gain recognized on the sale of the sale our ex-U.S. commercial operations and sublicense to Advanz offset by a decrease in operating income associated with product revenues and operating expenses, given one fewer quarter of product revenues were included in the nine months ended September 30, 2022.

Income taxes

For the nine months ended September 30, 2022 and 2021, no income tax expense or benefit was recognized for our continuing operations. Our deferred tax assets are comprised primarily of net operating loss carryforwards. We maintain a full valuation allowance on our deferred tax assets since we have not yet achieved sustained profitable operations. As a result, we have not recorded any income tax benefit since our inception.

Liquidity and Capital Resources

Sources of liquidity

Since inception, we have incurred significant operating losses. Our continuing operations have never been profitable and do not expect to be profitable in the foreseeable future. To date, we have financed our operations primarily through public and private securities offerings, sales of product and payments received under our licensing and collaboration agreements and the sale of our ex-U.S. commercial operations.

Continued cash generation is highly dependent on the success of our commercial product, Ocaliva, as well as the success of our product candidates if approved. The absence of cash flows from discontinued operations are not expected to affect future liquidity and capital resources.

We have devoted substantially all of our resources to the development of our product candidates, including the conduct of our clinical trials, the launch and commercialization of Ocaliva for PBC, preparation for a potential launch of OCA for liver fibrosis due to NASH and general and administrative operations, including the protection of our intellectual property. We intend to continue to develop OCA and our other existing product candidates, alone or in combination, for non-viral liver diseases. If OCA or any of our other product candidates fails in clinical trials or does not gain or maintain regulatory approval, or if OCA or any of our other product candidates does not achieve market acceptance, we may never become profitable. Our net losses and negative operating cash flows have had, and will continue to have, an adverse effect on our stockholders' deficit and working capital.

Our executive officers and our Board of Directors periodically review our sources and potential uses of cash in connection with our annual budgeting process. Generally speaking, our principal funding source is cash from operating activities, and our principal cash requirements include operating expenses and interest payments.

We expect to continue to incur losses for the foreseeable future, and we expect these losses to be significant as we, among other things, develop and seek regulatory approval for our product candidates, including OCA for liver fibrosis due to NASH, maintain our regulatory approval and commercialize our approved products. We believe our prospects and ability to significantly grow revenues will be dependent on our ability to successfully develop and commercialize OCA for indications other than PBC, such as NASH, and to identify strategic business development opportunities to leverage our capabilities in rare diseases. As a result, we expect a significant amount of resources to continue to be devoted to our development programs for OCA and to developing our pipeline.

Cash Flows

The following table sets forth the significant sources and uses of cash for the periods indicated:

	Nine Months Ended September 30,	
	2022	2021
	(in thousands)	
Net cash from continuing operations (used in) provided by:		
Operating activities	$ (31,291)	$ (86,136)
Investing activities	(46,449)	55,398
Financing activities	(261,644)	2,083
Effect of exchange rate changes	(7,399)	71
Net increase in cash, cash equivalents and restricted cash classified as discontinued operations	372,550	39,895
Net increase in cash, cash equivalents and restricted cash	$ 25,767	$ 11,311

Operating Activities. Net cash used in operating activities for continuing operations of approximately $31.3 million during the nine months ended September 30, 2022 was primarily a result of our $157.9 million net loss from continuing operations, partially offset by a loss of $91.7 million on the extinguishments of debt, a net increase in operating assets and liabilities of $12.0 million, $16.7 million in stock-based compensation, and $2.4 million of write-offs of fixed assets. Cash flows for the nine months ended September 30, 2022 include net cash receipts of $3.8 million reflecting payments from the HMRC for the U.K. R&D tax credit claims.

Net cash provided by operating activities for discontinued operations of approximately $9.3 million during the nine months ended September 30, 2022 was primarily a result of $400.5 million net income from discontinued operations and $4.4 million in stock-based compensation, partially offset by the reclassification of $366.5 million in cash proceeds from the sale of the business to investing activities and a net decrease in operating assets and liabilities of $29.6 million.

Net cash used in operating activities for continuing operations of approximately $86.1 million during the nine months ended September 30, 2021 was primarily a result of our $91.8 million net loss from continuing operations, a net decrease in operating assets and liabilities of $31.9 million and a gain on extinguishment of debt of $16.5 million, partially offset by $20.9 million in stock-based compensation, $11.9 million for accretion of the discount on the 2023 Convertible Notes, $7.0 million for accretion of the discount on the 2026 Convertible Notes, $3.5 million for non-cash operating lease costs, $3.0 million for accretion of the discount on the 2026 Convertible Secured Notes and $2.4 million of depreciation. Cash flows for the nine months ended September 30, 2021 include cash receipts of $4.2 million reflecting payments from the HMRC for the U.K. R&D tax credit claims.

Net cash provided by operating activities for discontinued operations of approximately $39.9 million during the nine months ended September 30, 2021 was primarily a result of our $36.7 million net income from discontinued operations, and $4.6 million in stock-based compensation partially offset by a net decrease in assets and liabilities from discontinued operations of $2.3 million.

The effect of exchange rate changes on cash increased operating cash flows and comprehensive income during the nine months ended September 30, 2022 given the significant fluctuations in the rate of exchange between the U.S. dollar and the pound sterling. In particular, as a result of our sale of our ex-U.S. business, we have additional exposure to fluctuations in the pound sterling as our only remaining business operations outside of the U.S. are in the United Kingdom.

Investing Activities. For the nine months ended September 30, 2022, net cash used in investing activities for continuing operations of approximately $46.4 million primarily reflects the purchase of investment debt securities of $401.1 million, partially offset by the sales and maturities of investment debt securities of $355.5 million.

For the nine months ended September 30, 2022, net cash provided by investing activities for discontinued operations reflects the net cash proceeds of $363.2 million received from the sale of the ex-U.S. business to Advanz.

For the nine months ended September 30, 2021, net cash provided by investing activities for continuing operations of approximately $55.4 million primarily reflects the sales and maturities of investment debt securities of $334.2 million, partially offset by the purchase of investment debt securities of $278.4 million.

Financing Activities. Net cash used in financing activities for continuing operations of approximately $261.6 million in the nine months ended September 30, 2022, primarily consisted of payments of $258.2 million for the repurchase of 2026 Convertible Secured Notes and $3.9 million for the repurchase of 2023 Convertible Notes.

Net cash provided by financing activities for continuing operations of approximately $2.1 million in the nine months ended September 30, 2021 primarily consisted of $117.6 million of proceeds from the sale of 2026 Convertible Secured Notes, offset by payments of $75.8 million for the repurchase of common stock and $38.1 million for the repurchase of 2023 Convertible Notes.

Future Funding Requirements

We are currently developing OCA for additional indications, including NASH, and other product candidates through various stages of clinical and preclinical development. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. In addition, we have incurred and anticipate that we will continue to incur significant research and development, product sales, marketing, manufacturing and distribution expenses relating to the commercialization of Ocaliva for PBC. As part of our longer-term strategy, we anticipate that we will incur significant expenses in connection with our research and development efforts, the commercialization of our other products such as OCA for liver fibrosis due to NASH, if approved, and the maintenance of our general and administrative infrastructure. We may also engage in business development activities that involve potential in- or out-licensing of products or technologies or acquisitions of other products, technologies or businesses.

As of September 30, 2022, we had $497.8 million in cash, cash equivalents, restricted cash and investment debt securities. We currently expect to continue to incur significant operating expenses in the fiscal year ending December 31, 2022. These expenses are planned to support, among other initiatives, the continued commercialization of Ocaliva for

PBC, our continued clinical development of OCA for PBC and NASH and our other earlier stage research and development programs. Although we believe that our existing capital resources, together with our net sales of Ocaliva for PBC, will be sufficient to fund our anticipated operating requirements for the next twelve months following the filing of this report, we may need to raise additional capital to fund our operating requirements beyond that period. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. As of September 30, 2022, our funds are primarily held in U.S. treasuries, U.S. government agency bonds, corporate bonds, commercial paper and money market accounts.

We recently used a combination of cash proceeds received from the sale of our international business as well as common stock to fund the repurchases of the 2026 Convertible Secured Notes. Our short-term obligations include $109.8 million of 2023 Convertible Notes outstanding scheduled to mature on July 1, 2023, and $226.5 million of convertible notes scheduled to mature in 2026, all of which will need to be paid off or refinanced, if not converted. Furthermore, in light of our receipt of the CRL from the FDA in June 2020 with respect to our NDA for OCA for liver fibrosis due to NASH and the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, any delays in, or unanticipated costs associated with, our development, regulatory or commercialization efforts could significantly increase the amount of capital required by us to fund our operating requirements. Accordingly, we may seek to access the public or private capital markets whenever conditions are favorable, to issue new securities, or to refinance or repurchase existing securities, even if we do not have an immediate need for additional capital at that time.

Given the latest strategic financial moves including the sale of our international business and repurchases of our 2026 Convertible Secured Notes, we have improved our capital structure and are well-positioned for the future to grow our existing business in PBC, progress on our NASH development program and advance our pipeline products.

Our forecasts regarding the period of time that our existing capital resources will be sufficient to meet our operating requirements and the timing of our future funding requirements, both near and long-term, will depend on a variety of factors, many of which are outside of our control. Such factors include, but are not limited to, those factors listed above under “Cautionary Note Regarding Forward-Looking Statements”.

We have no committed external sources of funding and additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us, we may not be able to make scheduled debt payments on a timely basis, or at all, and may be required to delay, limit, reduce or cease our operations.

Contractual Obligations

Except as discussed above regarding Advanz Pharma and our repurchases of 2026 Convertible Secured Notes, there have been no material changes to our contractual obligations outside the ordinary course of business from those disclosed under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Future Funding Requirements—Future Contractual Obligations” in our Annual Report on Form 10-K for the year ended December 31, 2021.

Off-Balance Sheet Arrangements

As of September 30, 2022, we did not have any off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates and there have been no material changes to our market risk from that disclosed under the caption “Quantitative and Qualitative Disclosures about Market Risk” in our Annual Report.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Based on the evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")), required by Rule 13a-15(b) or 15d-15(b) of the Exchange Act, our Chief Executive Officer and Chief Financial Officer have concluded that as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II
OTHER INFORMATION

Item 1. Legal Proceedings.

For a description of our significant legal proceedings, see Note 16 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q and incorporated by reference herein.

Item 1A. Risk Factors.

As of the date of this Quarterly Report on Form 10-Q, there are no material changes to the risk factors set forth in Part I, Item 1A, Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 2, 2022, and the risk factors set forth in Part II, Item 1A, Risk Factors, in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 filed with the SEC on August 3, 2022, except for the following Risk Factors. The following set of Risk Factors does not purport to be a full list of risks relating to the business of the Company and any of these factors or others disclosed in our Annual Report on Form 10-K or Quarterly Report on Form 10-Q could result in a significant or material adverse effect on our results of operations or financial condition. Additional risk factors not presently known to us or that we currently deem immaterial may also impair our business or results of operations. We may disclose changes to such risk factors or disclose additional risk factors from time to time in our future filings with the SEC.

Risks Related to Clinical Trials

We are developing product candidates for the treatment of rare diseases or diseases for which there are no or limited therapies, such as PBC and NASH, and for some of which there is little clinical experience, and our development approach involves new endpoints and methodologies. As a result, there is a heightened risk that we will not be able to gain agreement with regulatory authorities regarding an acceptable development plan, that the outcome of our clinical trials will not be favorable or that, even if favorable, regulatory authorities may not find the results of our clinical trials to be sufficient for marketing approval.

We are focused on developing therapeutics for the treatment of rare diseases and diseases for which there are no or limited treatments. As a result, the design and conduct of our clinical trials for these indications is subject to heightened risk.

In the United States, the FDA generally requires two adequate and well-controlled pivotal clinical trials to approve a NDA. Furthermore, for full approval of a NDA, the FDA requires a demonstration of efficacy based on a clinical benefit endpoint. The FDA may grant accelerated approval based on a surrogate endpoint reasonably likely to predict clinical benefit. Even though our pivotal clinical trial for a specific indication, such as our Phase 3 REGENERATE trial of OCA in patients with liver fibrosis due to NASH, may achieve its primary endpoints and is reasonably believed by us to be likely to predict clinical benefit, the FDA may not accept the results of such trial or approve our product candidate on an accelerated basis, or at all. It is also possible that the FDA may refuse to accept for filing and review any regulatory application we submit for regulatory approval in the United States. Even if our regulatory application is accepted for review, there may be delays in the FDA's review process and the FDA may determine that such regulatory application does not contain adequate clinical or other data or support the approval of the product candidate. In such a case, the FDA may issue a CRL that may require that we conduct and/or complete additional clinical trials and preclinical studies or provide additional information or data before it will reconsider our application for approval. For example, in June 2020 we received a CRL from the FDA regarding our NDA for OCA for liver fibrosis due to NASH. The CRL indicated that, based on the data the FDA had reviewed, the FDA had determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remained uncertain and did not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH. In addition, following the results of the New Interim Analysis we intend to re-submit our NDA for OCA for liver fibrosis due to NASH with the FDA. The requirements imposed by the FDA in connection with the resubmission of our NDA may be substantial, expensive and time-consuming, and there is no guarantee that we will continue to pursue any such application or that the FDA will ultimately decide that any such application supports the approval of the product candidate on an accelerated basis, or at all. The FDA may also refer any regulatory application to an advisory committee for review and recommendation as to whether, and under what

conditions, the application should be approved. While the FDA is not bound by the recommendation of an advisory committee, it considers such recommendations carefully when making decisions.

Even if we receive accelerated approval for any of our product candidates, we may be required to conduct or complete a post-approval clinical outcomes trial to confirm the clinical benefit of such product candidates by demonstrating the correlation of the surrogate endpoint therapeutic response in patients with a significant reduction in adverse clinical outcomes over time. For example, the results of the New Interim Analysis were based on surrogate endpoints and the impact on clinical outcomes has not been confirmed. There can be no assurance that the clinical outcomes portion of our REGENERATE trial will confirm that the surrogate endpoint used as the basis of the regulatory submissions we have made or expect to make seeking approval of OCA for liver fibrosis due to NASH will eventually show an adequate correlation with clinical outcomes.

In addition, as a condition of the accelerated approval of Ocaliva for PBC in the United States, we are required to conduct a clinical outcomes study with respect to Ocaliva for PBC. Based on a review by the DMC of an unblinded pre-specified interim efficacy analysis of the COBALT trial and unblinded safety and pharmacokinetic data from both the COBALT and 401 trials, the DMC stated that it was not feasible to continue the COBALT trial as designed and noted the challenges in enrolling and maintaining placebo-controlled post-marketing studies in this rare disease setting. We notified the FDA of the DMC's recommendation and based on discussions with the FDA, which are ongoing, we closed our COBALT and 401 trials and compiled data available from these studies. In June 2022, we announced topline results from our COBALT trial. The primary endpoint, as agreed with the FDA, was time to first occurrence of any of the following clinical endpoints: all-cause death, liver transplant, hospitalization for other serious liver-related events, signs of progression to hepatic decompensation, or signs of development of portal hypertension. The study did not demonstrate a statistically significant difference between Ocaliva and placebo on the primary endpoint. The safety and tolerability of Ocaliva were consistent with its known profile and adverse events were in line with expectations for patients with advanced PBC based on the natural history of the disease. In June 2022, we also announced topline results for our HEROES-US study, a retrospective real-world study that evaluated data from a U.S. claims database, to compare clinical outcomes in a pre-defined group of patients with PBC who were treated with Ocaliva and a comparable group of PBC patients who were eligible, but who were not treated with Ocaliva. The results from the HEROES-US study showed a statistically significant and clinically meaningful reduction in all-cause death, liver transplant, or hospitalization for hepatic decompensation among Ocaliva-treated patients compared to the control group.

In September 2022, we had an sNDA pre-submission meeting with the FDA in which we reviewed our post-marketing requirements with respect to Ocaliva. We intend to submit the data from the COBALT and HEROES-US studies as well additional data, including data from other real world evidence studies, as part of a broader evidence package in the sNDA in support of full approval of Ocaliva for the treatment of PBC, which we anticipate submitting to the FDA in 2023. If this data package does not support fulfillment of our post-marketing obligations, we may not be able to maintain our previously granted marketing approval of Ocaliva for PBC.

Our lead development product candidate is OCA for the potential treatment of NASH. In February 2019, we announced the results of the REGENERATE Original Analysis. The REGENERATE trial is ongoing and is expected to continue through clinical outcomes for verification and description of the clinical benefit of OCA. In June 2020, we received a CRL from the FDA stating that our NDA for OCA for the treatment of liver fibrosis due to NASH could not be approved in its present form. The CRL indicated that, based on the data the FDA had reviewed, the FDA determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remained uncertain and did not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH. We had our end of review meeting with the FDA in October 2020 to discuss the FDA's risk-benefit assessment in the CRL based on its review of the available data, as well as our proposed resubmission of our NDA for the treatment of liver fibrosis due to NASH. The meeting with FDA provided us with helpful guidance regarding supplemental data we can provide to further characterize OCA's efficacy and safety profile that could support resubmission based on our Phase 3 REGENERATE 18-month biopsy data, together with a safety assessment from our ongoing studies.

Following our end of review meeting, we had a dialogue with FDA regarding the REGENERATE study to clarify data, a new consensus read methodology for liver biopsies, and analyses required to re-submit our NDA. In connection with the potential resubmission of our NDA, we conducted the New Interim Analysis. In the New Interim Analysis of the

ITT population from REGENERATE, 22.4% of subjects randomized to once-daily oral OCA 25 mg met the primary endpoint of achieving at least one stage of fibrosis improvement with no worsening of NASH at month 18 on liver biopsy compared with 9.6% of subjects on placebo ($p<0.0001$). These results are consistent with the Original Analysis, which also showed that OCA 25 mg had a statistically significant effect on fibrosis improvement ($p=0.0002$). The New Interim Analysis used a consensus panel approach to histology reads, in line with recent FDA guidance, while the Original Analysis used individual central readers. A numerically greater proportion of individuals in the OCA 25 mg treatment group compared to placebo achieved the endpoint of resolution of NASH with no worsening of liver fibrosis but, consistent with the Original Analysis, the results for the endpoint of resolution of NASH were not statistically significant. As part of the New Interim Analysis, a safety evaluation was conducted in 2477 subjects from the REGENERATE trial who took at least one dose of study drug (placebo, OCA 10 mg, or OCA 25 mg). Topline results from this ongoing safety evaluation showed that treatment-emergent adverse events (TEAEs), treatment-emergent serious adverse events (TESAEs), and deaths were generally balanced across the OCA and placebo treatment groups in this new safety population. The most common TEAE was pruritus (24% in placebo, 33% in OCA 10 mg and 55% in OCA 25 mg) and pruritus was the most common cause for treatment discontinuation. Serious gallbladder-related events occurred in <3% of subjects in any treatment group and, consistent with its known mechanism of action, OCA 25 mg had higher rates of biliary events including gallstones.

In July 2022, we had a pre-submission meeting with the FDA in which we reviewed the planned structure and the timing of the submission of our NDA and have had an ongoing dialogue as we prepare to re-submit. As we previously disclosed, the Company will need to overcome the risk-benefit assessment of the FDA from the prior review of the NDA for OCA for the treatment of liver fibrosis due to NASH. Although we believe that the insights we have gained from the re-analysis and from the larger and more robust safety database provide an improved risk-benefit, there can be no assurances that the FDA will change its view on risk-benefit and will approve such NDA on an accelerated basis, or at all.

In September 2022, we announced that REVERSE, a Phase 3 study evaluating the safety and efficacy of OCA in patients with compensated cirrhosis due to NASH, did not meet its primary endpoint of a ≥ 1-stage histological improvement in fibrosis with no worsening of NASH following up to 18 months of therapy. In the REVERSE study of 919 randomized subjects with compensated cirrhosis due to NASH, 11.1% (p=NS) of subjects who were randomized to receive once-daily oral OCA 10 mg and 11.9% (p=NS) of subjects who were randomized to receive OCA 10 mg titrated to 25 mg (OCA 10-to-25 mg) after three months achieved a ≥1-stage improvement in fibrosis with no worsening of NASH after up to 18 months of treatment, compared with 9.9% of subjects who received placebo. Safety was evaluated in 916 subjects who took at least one dose of study drug (placebo, OCA 10 mg or OCA 10-to-25 mg). Treatment-emergent adverse events (TEAEs), treatment-emergent serious adverse events (TESAEs) and deaths were balanced across all treatment groups in REVERSE. The most common TEAE was pruritus (31% in placebo, 41% in OCA 10 mg and 57% in OCA 10-to-25 mg) and pruritus was the most common reason for treatment discontinuation. Serious gallbladder-related events were balanced across arms (0.6% in placebo, 1.0% in OCA 10 mg, 1.0% in OCA 10-to-25 mg). Consistent with the known mechanism of action of FXR-agonists, the OCA 10-to-25 mg arm had a higher incidence of gallstones.

While OCA received breakthrough therapy designation from the FDA in January 2015 for the treatment of NASH patients with liver fibrosis and we intend to re-submit our NDA for approval of OCA for liver fibrosis due to NASH following the results from the New Interim Analysis, we do not know if this will be sufficient for marketing approval or if the FDA will approve OCA for liver fibrosis due to NASH on an accelerated or conditional basis, or at all. There may be delays in the FDA review processes and the FDA may also require that we continue our Phase 3 REGENERATE trial until completion to assess the potential benefits of OCA treatment on liver-related and other clinical outcomes for purposes of marketing approval. Our regulatory pathway for OCA for the treatment of NASH will depend upon our ongoing discussions with the FDA. As a result, we may face difficulty in establishing an acceptable registration strategy with respect to our Phase 3 REGENERATE trial, as well as other trials we may conduct in other subpopulations of NASH patients.

Delays or difficulties in the commencement, enrollment and completion of our clinical trials and studies could increase our product development costs and delay, limit or prevent us from obtaining regulatory approval for OCA and our other product candidates.

Delays or difficulties in the commencement, enrollment and completion of our clinical trials and studies could increase our product development costs and limit or prevent us from obtaining or maintaining regulatory approval for OCA and our other product candidates. The results of our clinical trials may not be available when we anticipate and we may be required to conduct additional clinical trials or studies not currently planned in order for our product candidates, including OCA for PBC and NASH, to be approved or to maintain approvals in the U.S. In addition, our clinical programs are subject to a number of risks and uncertainties, such as the results of other trials, patient enrollment, safety issues or regulatory interactions that could result in a change of trial design or timing. Any delays or difficulties in completing one of our clinical trials could increase our product development costs and limit or prevent us from obtaining or maintaining regulatory approval. Consequently, we do not know whether our current or future clinical trials or studies of OCA or our other product candidates will be completed on schedule, if at all.

For example, our Phase 3 REGENERATE trial is a large and complicated clinical trial in a disease without any approved therapies and involves serial liver biopsies over many years. While we announced the topline results from the New Interim Analysis in July 2022, there can be no assurance the FDA will approve our NDA for OCA for NASH on an accelerated or conditional basis, or at all. In September 2022, we announced that our REVERSE trial evaluating the safety and efficacy of OCA in patients with compensated cirrhosis due to NASH, did not meet its primary endpoint of a ≥ 1-stage histological improvement in fibrosis with no worsening of NASH following up to 18 months of therapy. As we engage in other large and complicated trials and trials in advanced disease populations, we may experience a number of challenges that may negatively affect or delay our plans and development programs.

Failure can occur at any stage of clinical development. The results of earlier clinical trials are not necessarily predictive of future results and any product candidate we or our collaborators advance through clinical trials, including OCA, may not have favorable results in later clinical trials or receive or maintain regulatory approval.

Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or our collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in preclinical studies and early clinical trials does not ensure that subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate the efficacy and safety of our product candidates. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in Phase 3 clinical trials and at other stages of clinical development, even after seeing promising results in earlier clinical trials. For example, in September 2022, we announced that our REVERSE trial did not meet its primary endpoint of a ≥ 1-stage histological improvement in fibrosis with no worsening of NASH following up to 18 months of therapy.

In addition, the design of clinical trials, including trial endpoints, protocols and statistical analysis plans, can determine whether such trials will support product approvals, and flaws in the design of such trials may not become apparent until such trials are well-advanced. We may be unable to design and execute clinical trials to support regulatory approval. Further, clinical trials of product candidates often reveal that it is not practical or feasible to continue development efforts. If OCA or our other product candidates are found to be unsafe or lack sufficient efficacy for any indication, we will not be able to obtain or maintain regulatory approval for them, and our prospects and business may be materially and adversely affected.

There may be significant variability in the safety and/or efficacy results we see in different trials studying OCA or our other product candidates due to numerous factors, including differences in the underlying disease being studied, changes or differences in trial protocols or statistical analysis plans, differences in the composition of the patient populations or clinical trial sites, differences in adherence to the dosing regimen and other aspects of the trial protocols and differences in the rate of dropouts among clinical trial participants. We do not know whether any Phase 2, Phase 3 or other clinical trials we or any of our collaborators may conduct on our product candidates will demonstrate consistent or adequate

efficacy and safety or result in the approval of our product candidates by regulatory authorities. If we are unable to bring any of our current or future product candidates to market, acquire any previously approved products or maintain approval for our approved products, our ability to create long-term stockholder value will be limited.

In December 2014, we received comprehensive datasets from the Phase 2b FLINT trial for the treatment of NASH, which met its primary endpoint with statistical significance. In October 2015, we announced that the Phase 2 dose ranging trial of OCA in 200 adult NASH patients in Japan conducted by our former collaborator, Sumitomo Dainippon, did not meet its primary endpoint with statistical significance. In the Sumitomo Dainippon trial, there was a dose dependent, although not statistically significant, increase in the percentage of OCA-treated patients compared to placebo who achieved the primary endpoint ($p = 0.053$). In addition, no difference was seen in fibrosis improvement in the OCA groups compared to placebo. The Sumitomo Dainippon Phase 2 trial involved different doses of OCA being administered to the trial subjects than those utilized in the Phase 2b FLINT trial. Furthermore, the baseline characteristics between the patients in the Japanese Phase 2 dose ranging trial conducted by Sumitomo Dainippon were distinct in a number of ways from those of the Western patients included in the Phase 2b FLINT trial.

In February 2019, we announced the results from the REGENERATE Original Analysis. In the primary efficacy analysis, once-daily OCA 25 mg met, with statistical significance, the primary endpoint agreed with the FDA of fibrosis improvement by at least one stage with no worsening of NASH (defined as no worsening of hepatocellular ballooning, no worsening of lobular inflammation and no worsening of steatosis) at the planned 18-month analysis. Although a numerically greater proportion of patients in both OCA treatment groups compared to placebo achieved the primary endpoint of NASH resolution with no worsening of liver fibrosis in the primary efficacy analysis, this result did not reach statistical significance. As agreed with the FDA, in order for the primary objective to be met, the study was required to achieve one of the two primary endpoints. Notwithstanding the results of the REGENERATE 18-month analysis, the CRL indicated that, based on the data the FDA had reviewed, the FDA had determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remained uncertain and did not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH. The FDA recommended that we submit additional post-interim analysis efficacy and safety data from the ongoing REGENERATE study in support of potential accelerated approval and that the long-term outcomes phase of the study should continue.

In connection with the potential resubmission of our NDA, we conducted a new interim analysis of our ongoing pivotal Phase 3 REGENERATE trial of OCA using a biopsy consensus read methodology in the same ITT population as the Original Analysis. In July 2022, we announced topline results from our New Interim Analysis. In this new interim analysis of the ITT population from REGENERATE, once-daily OCA 25 mg met, with statistical significance, the primary endpoint agreed with the FDA of fibrosis improvement by at least one stage with no worsening of NASH at month 18. The New Interim Analysis used a consensus panel approach to histology reads, in line with recent FDA guidance, while the Original Analysis used individual central readers. A numerically greater proportion of individuals in the OCA 25 mg treatment group compared to placebo achieved the endpoint of resolution of NASH with no worsening of liver fibrosis but, consistent with the Original Analysis, the results for the endpoint of resolution of NASH were not statistically significant. As part of the New Interim Analysis, a safety evaluation was conducted in 2477 subjects from the REGENERATE trial who took at least one dose of study drug (placebo, OCA 10 mg, or OCA 25 mg). Topline results from this ongoing safety evaluation showed that treatment-emergent adverse events (TEAEs), treatment-emergent serious adverse events (TESAEs), and deaths were generally balanced across the OCA and placebo treatment groups in this new safety population. The most common TEAE was pruritus (24% in placebo, 33% in OCA 10 mg and 55% in OCA 25 mg) and pruritus was the most common cause for treatment discontinuation. Serious gallbladder-related events occurred in <3% of subjects in any treatment group and, consistent with its known mechanism of action, OCA 25 mg had higher rates of biliary events including gallstones.

In September 2022, we announced that REVERSE, a Phase 3 study evaluating the safety and efficacy of OCA in patients with compensated cirrhosis due to NASH, did not meet its primary endpoint of a ≥ 1-stage histological improvement in fibrosis with no worsening of NASH following up to 18 months of therapy. In the REVERSE study of 919 randomized subjects with compensated cirrhosis due to NASH, 11.1% (p=NS) of subjects who were randomized to receive once-daily oral OCA 10 mg and 11.9% (p=NS) of subjects who were randomized to receive OCA 10 mg titrated to 25 mg (OCA 10-to-25 mg) after three months achieved a ≥1-stage improvement in fibrosis with no worsening of NASH after up to 18 months of treatment, compared with 9.9% of subjects who received placebo.

While we intend to resubmit to the FDA our NDA for approval of OCA for liver fibrosis due to NASH following the results of the New Interim Analysis, we do not know if such results will be sufficient for marketing approval or if the FDA will approve OCA for liver fibrosis due to NASH on an accelerated or conditional basis, or at all.

Our product candidates may have undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require that our products be taken off the market or include new or additional safety warnings. Any such events may limit our existing and future product sales and materially and adversely affect our business, financial condition and results of operations.

OCA has been shown to be a potent FXR agonist. With the exception of the endogenous human bile acid chenodeoxycholic acid and cholic acid, there are no approved FXR agonists and the adverse effects from long-term exposure to this drug class are unknown. Unforeseen side effects from any of our product candidates, including OCA, could arise either during clinical development or, if approved, after the approved product has been marketed. Serious adverse events, including deaths, in patients taking OCA have occurred in clinical trials and in the post-marketing setting, and we cannot assure you that additional serious adverse events in patients taking OCA in clinical trials or in the post-marketing setting will not occur.

The most common side effects observed in clinical trials of OCA for PBC were pruritus, fatigue, headaches, nausea, constipation and diarrhea. In our Phase 3 POISE trial, pruritus, generally mild to moderate, was the most frequently reported adverse event associated with OCA treatment for PBC and was observed in 38% of patients on placebo, 70% of patients in the OCA 10 mg group and 56% of patients in the OCA titration group (5 mg to 10 mg). Eight patients discontinued due to pruritus, of whom none were in the placebo group, seven (10%) were in the OCA 10 mg group and one (1%) was in the OCA titration group. Pruritus also has been observed in other clinical trials of OCA. Decreases in high density lipoprotein HDL cholesterol were also observed during treatment in our Phase 3 POISE trial. In our Phase 2 trials for OCA for PBC, a dose-response relationship was observed in the occurrence of liver-related adverse reactions, including jaundice, ascites and primary biliary cholangitis flare with dosages of OCA of 10 mg once daily to 50 mg once daily (up to 5-times the highest recommended dosage), as early as one month after starting treatment with OCA.

In the course of our post-marketing pharmacovigilance activities, deaths have been reported in PBC patients with moderate or severe hepatic impairment. In an analysis performed by us and in consultation with the FDA, we concluded that certain of these patients were prescribed once daily doses of Ocaliva, which is seven times higher than the recommended weekly dose in such patients. As a result, in September 2017, we issued a Dear Health Care Provider (“DHCP”) letter, and the FDA also subsequently issued its own drug safety communication to reinforce recommended label dosing. Both communications remind healthcare providers of the importance of the recommended reduced dosing of Ocaliva in PBC patients with moderate or severe hepatic impairment, while reiterating the importance of monitoring PBC patients for progression of their disease and the occurrence of liver-related adverse reactions. In addition to the DHCP letter, we took actions to enhance education about appropriate use of Ocaliva. These initiatives included: reeducating physicians on the label, with a focus on ensuring appropriate dosing for patients with moderate or severe hepatic impairment; enhancing monitoring of patients for liver-related adverse reactions; and adjudicating reported cases of serious liver injury, including in patients with no or mild hepatic impairment. In February 2018, we announced that the Ocaliva label in the United States had been updated by the FDA to include a boxed warning and a dosing table that reinforced the then-existing dosing schedule for patients with Child-Pugh Class B or C or decompensated cirrhosis. In addition, the FDA issued an updated drug safety communication to accompany the revised label. We remain focused on the safety of all of the patients using Ocaliva within and outside of our ongoing clinical studies and have engaged with relevant regulatory authorities to ensure that the Ocaliva label sufficiently reinforces the importance of appropriate dosing in patients with advanced cirrhosis.

In 2020 the FDA notified us that, in the course of its routine safety surveillance, in May of that year it began to evaluate a newly identified safety signal, or NISS, regarding liver disorder for Ocaliva which the FDA classified as a potential risk, focused on a subset of the cirrhotic, or more advanced, PBC patients who had taken Ocaliva. In May 2021, the NISS process was concluded and we aligned with the FDA on updated Ocaliva prescribing information in the United States, and Ocaliva is now contraindicated for patients with PBC and decompensated cirrhosis, a prior decompensation event, or compensated cirrhosis with evidence of portal hypertension, in addition to the existing contraindication for complete biliary obstruction. This issue, and any other safety concerns associated with Ocaliva, perceived or real, may

adversely affect the successful development and commercialization of our product candidates and approved products, including Ocaliva, and materially and adversely affect our business including future revenue generated by Ocaliva.

In June 2022, we announced the results of our COBALT study. The safety and tolerability of Ocaliva were consistent with its known profile and adverse events were in line with expectations for patients with advanced PBC based on the natural history of the disease.

In July 2022, we announced topline safety results from the New Interim Analysis of our REGENERATE study. Compared to the Original Analysis, the safety population in the New Interim Analysis had significantly longer exposure to study drug (median 42 months vs. 15 months), yielding more than 8,000 total patient-years and 3.4 times more exposure. As part of the New Interim Analysis, a safety evaluation was conducted in 2477 subjects from the REGENERATE trial who took at least one dose of study drug (placebo, OCA 10 mg, or OCA 25 mg). Topline results from this ongoing safety evaluation showed that treatment-emergent adverse events (TEAEs), treatment-emergent serious adverse events (TESAEs), and deaths were generally balanced across the OCA and placebo treatment groups in this new safety population. The most common TEAE was pruritus (24% in placebo, 33% in OCA 10 mg and 55% in OCA 25 mg) and pruritus was the most common cause for treatment discontinuation. Serious gallbladder-related events occurred in <3% of subjects in any treatment group and, consistent with its known mechanism of action, OCA 25 mg had higher rates of biliary events including gallstones. As part of the safety review of the New Interim Analysis, independent groups of experts reviewed certain categories of safety events to provide a blinded adjudication as specifically requested by the FDA. These included events pertaining to hepatic safety (excluding clinical outcomes), cardiovascular and renal. Topline analysis through four years of treatment showed a numerically higher number of adjudicated hepatic safety events for OCA 25 mg, the majority of which were mild in severity. For adjudicated core major adverse cardiovascular events and adjudicated acute kidney injury events, frequency of events was low and balanced across treatment groups. Consistent with its mechanism of action as an FXR agonist, OCA treatment was associated with an increase in LDL at Month 1 which returned to near baseline values by Month 12.

In September 2022, we announced topline results for REVERSE, a Phase 3 study evaluating the safety and efficacy of OCA in patients with compensated cirrhosis due to NASH. Safety was evaluated in 916 subjects who took at least one dose of study drug (placebo, OCA 10 mg or OCA 10-to-25 mg). Treatment-emergent adverse events (TEAEs), treatment-emergent serious adverse events (TESAEs) and deaths were balanced across all treatment groups in REVERSE. The most common TEAE was pruritus (31% in placebo, 41% in OCA 10 mg and 57% in OCA 10-to-25 mg) and pruritus was the most common reason for treatment discontinuation. Serious gallbladder-related events were balanced across arms (0.6% in placebo, 1.0% in OCA 10 mg, 1.0% in OCA 10-to-25 mg). Consistent with the known mechanism of action of FXR-agonists, the OCA 10-to-25 mg arm had a higher incidence of gallstones.

In the Phase 2b FLINT trial, pruritus occurred more frequently in the OCA treatment group than in the placebo treatment group (23% vs. 6%, $p < 0.0001$) and at a higher grade (predominately moderate pruritus). OCA treatment was also associated with changes in serum lipid levels, including increases in total cholesterol and LDL cholesterol and a decrease in HDL cholesterol, that were observed within 12 weeks of initiating treatment, peaked and then decreased in magnitude while on treatment, and reversed further during the 24-week post-treatment period. These changes in cholesterol levels, along with the achievement of pre-defined efficacy criteria, played a role in the decision of the FLINT data and safety monitoring board to terminate the treatment phase of the Phase 2b FLINT trial, and the publication of the FLINT results noted the need for further study of these changes. There were two patient deaths in the Phase 2b FLINT trial, and neither death was considered related to OCA treatment.

In December 2015, we initiated a Phase 2 clinical trial, known as the CONTROL trial, to characterize the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients. CONTROL enrolled 80 NASH patients who were naïve to statin therapy or had undergone a statin washout period. The study included a 16-week double-blind phase followed by an optional long-term safety extension (“LTSE”) phase of the trial. OCA treatment in the absence of statin therapy over the first four weeks resulted in an increase in LDL across all OCA treatment groups, while the placebo group was relatively unchanged. Treatment with atorvastatin beginning at week four and continuing through week 16 reversed OCA-related increases in LDL to below baseline levels in all OCA treatment groups. Dose-dependent pruritus was the most common adverse event in patients treated with OCA, occurring in 5% of patients on placebo, 5% of patients in the OCA 5 mg group, 10% of patients in the OCA 10 mg group and 55% of patients

in the OCA 25 mg group. All adverse events were mild to moderate and two patients discontinued treatment in the OCA 25 mg group due to pruritus. Over 95% of the patients completing the double-blind phase of CONTROL enrolled in the LTSE phase of the trial.

During the LTSE phase of CONTROL, there was one patient death. This patient was a 64 year-old male with a history of NASH associated liver cirrhosis, morbid obesity (BMI >40) and type 2 diabetes. At baseline, this patient had blood tests consistent with impaired liver function (e.g., low LDL and low platelets). The patient was randomized to placebo for the double-blind phase of the study. Early in the double-blind phase, the patient had serum biochemistry changes consistent with worsening hepatic impairment (e.g., albumin decline and bilirubin was increasing). Atorvastatin was started per protocol and then stopped early due to the patient's persistently low LDL levels. The patient later enrolled in the LTSE phase and began receiving OCA 25 mg treatment. Over the following four months, the patient's serum biochemistry remained consistent with ongoing hepatic impairment. Approximately five months after starting the LTSE phase, the patient developed severe protracted diarrhea, which resulted in weight loss of 30 pounds over the ensuing one-month period. Both an infectious cause and possible inflammatory bowel disease were suspected, and the patient subsequently was started on broad spectrum antibiotics and steroid therapy. Due to the diarrhea, the principal investigator stopped treatment with OCA and discontinued the patient from the study. Concurrently, the patient reported jaundice and was found to have significantly elevated serum bilirubin and ALP, while other liver enzymes remained relatively stable. Over the ensuing two-week period, various diagnostic tests and procedures were performed (e.g., magnetic resonance cholangiopancreatography to investigate possible gallstone bile duct obstruction) and the patient continued receiving a number of other medications, including the ongoing course of steroid therapy. During this time, the patient continued to deteriorate and was hospitalized with acute renal and liver failure, complicated by severe metabolic acidosis. The patient rapidly progressed to multi-organ system failure, sepsis and death. The principal investigator determined that the events leading to the patient's death were unlikely related to OCA. Despite the numerous confounding factors in this case, given the contemporaneous administration of OCA during the patient's ongoing deterioration, we determined that it could not be ruled out that these events were possibly related to treatment. Subsequent to our determination, the independent data safety monitoring committee separately evaluated the case and determined that the events leading to the patient's death were unlikely related to OCA.

Additional or unforeseen side effects relating to OCA or any of our other product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. With the approval of Ocaliva for PBC in the United States, OCA is currently used in an environment that is less rigorously controlled than in clinical studies. If new side effects are found, if known side effects are shown to be more severe than previously observed or if OCA is shown to have other unexpected characteristics, we may need to abandon our development of OCA for PBC, NASH and other potential indications. Furthermore, our commercial sales of Ocaliva for PBC may be materially and adversely affected.

The range and potential severity of possible side effects from systemic therapies is significant. The results of our current or future clinical trials may show that our product candidates, including OCA, cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, result in a delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities, result in marketing approval from the FDA and other regulatory authorities with restrictive label warnings or result in the withdrawal of previously granted marketing approvals.

In addition, our product candidates are being developed as potential treatments for severe, life-threatening diseases and, as a result, our trials will necessarily be conducted in patient populations that are more prone than the general population to exhibit certain disease states or adverse events. Ocaliva is prescribed in patients suffering from various stages of PBC, which can be life threatening, and patients may suffer from other concomitant illnesses that may increase the likelihood of certain adverse events. It may be difficult to discern whether certain events or symptoms observed during our clinical trials or by patients using our approved products are related to our product candidates or approved products or some other factor. As a result, we and our development programs may be negatively affected even if such events or symptoms are ultimately determined to be unlikely related to our product candidates or approved products. We cannot assure you that additional or more severe adverse side effects related to OCA or our other product candidates will not be observed in our clinical trials or in the commercial setting. If observed, such adverse side effects could delay or preclude regulatory approval of OCA, limit commercial use or result in the withdrawal of previously granted marketing approvals.

Risks Related to the Development and the Regulatory Review and Approval of Our Products and Product Candidates

We cannot be certain whether Ocaliva will receive full approval for PBC in the United States. Furthermore, OCA may not be approved on an accelerated basis, or at all, for NASH or any other indication beyond PBC and we may not receive regulatory approval for any other product candidate. Without regulatory approval, we will not be able to market and commercialize our product candidates.

The development, testing, manufacture, packaging, labeling, storage, approval, promotion, advertising, distribution, marketing and export and import, among other things, of our products and product candidates are subject to extensive regulation by the FDA in the United States. We are not permitted to market our product candidates in the United States until we receive approval of a NDA from the FDA. Currently, our ability to generate product sales depends on the successful marketing of Ocaliva for PBC. In the future, our ability to generate product sales in addition to those of Ocaliva for PBC will depend on whether we are successful in obtaining regulatory approval of our other product candidates, including OCA for liver fibrosis due to NASH.

Ocaliva is our only drug that has been approved for sale and it has only been approved for the treatment of PBC in combination with UDCA in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA. In the United States, Ocaliva was approved for PBC under the accelerated approval pathway. Accelerated approval was granted for Ocaliva for PBC based on a reduction in ALP; however, an improvement in survival or disease-related symptoms has not yet been established. Continued approval of Ocaliva for PBC in the United States is contingent upon the verification and description of clinical benefit in confirmatory trials and our satisfaction of our other post-marketing regulatory requirements. Any failure by us to confirm the clinical benefit of Ocaliva for PBC due to COVID-19 or other factors may jeopardize the continued approval of Ocaliva for PBC.

In addition, we continue to work to execute on our post-marketing regulatory commitments with respect to Ocaliva. Based on a review by the DMC of an unblinded pre-specified interim efficacy analysis of the COBALT trial and unblinded safety and pharmacokinetic data from both the COBALT and 401 trials, the DMC stated that it was not feasible to continue the COBALT trial as designed and noted the challenges in enrolling and maintaining placebo-controlled post-marketing studies in this rare disease setting. We notified the FDA of the DMC's recommendation and based on discussions with the FDA, which are ongoing, we closed our COBALT and 401 trials and compiled data available from these studies. In June 2022, we announced topline results from our COBALT trial. The primary endpoint, as agreed with the FDA, was time to first occurrence of any of the following clinical endpoints: all-cause death, liver transplant, hospitalization for other serious liver-related events, signs of progression to hepatic decompensation, or signs of development of portal hypertension. The study did not demonstrate a statistically significant difference between Ocaliva and placebo on the primary endpoint: 71 subjects in the Ocaliva arm progressed to clinical events compared to 80 in the placebo arm (p=0.30; HR 0.84). The safety and tolerability of Ocaliva were consistent with its known profile and adverse events were in line with expectations for patients with advanced PBC based on the natural history of the disease. In June 2022, we also announced topline results for our HEROES-US study, a retrospective real-world study that evaluated data from a U.S. claims database, to compare clinical outcomes in a pre-defined group of patients with PBC who were treated with Ocaliva and a comparable group of PBC patients who were eligible, but who were not treated with Ocaliva. The results from the HEROES-US study showed a statistically significant and clinically meaningful reduction in all-cause death, liver transplant, or hospitalization for hepatic decompensation among Ocaliva-treated patients compared to the control group. In the Ocaliva arm (n=429), 8 events were observed compared to 226 in the control group (n=4,585) with a weighted hazard ratio of 0.38 (p= 0.027). HEROES-US is one of two HEROES studies we are conducting that utilizes real-world data to assess the impact of Ocaliva on clinical outcomes in PBC patients.

In September 2022, we had an sNDA pre-submission meeting with the FDA in which we reviewed our post-marketing requirements with respect to Ocaliva. We intend to submit the data from the COBALT and HEROES-US studies as well additional data, including data from other real world evidence studies, as part of a broader evidence package in the sNDA in support of full approval of Ocaliva for the treatment of PBC, which we anticipate submitting to the FDA in 2023. If this data package does not support fulfillment of our post-marketing obligations, we may not be able to maintain our previously granted marketing approval of Ocaliva for PBC.

Ocaliva is not approved for any indication other than PBC. We currently have no other products approved for sale and we cannot guarantee that we will ever have additional marketable products or that OCA will be approved for use in additional indications such as NASH. NDAs must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. NDAs must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of a NDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA review processes can take years to complete and approval is not guaranteed. Even after the submission of a NDA, the FDA may decide not to accept the submission for filing and review or may determine that the submission does not support approval. For example, in 2020 we received a CRL from the FDA with respect our NDA for OCA for liver fibrosis due to NASH. The CRL indicated that, based on the data the FDA had reviewed, the FDA determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remained uncertain and did not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH.

In July 2022, we had a pre-submission meeting with the FDA in which we reviewed the planned structure and the timing of the submission of our NDA and have had an ongoing dialogue as we prepare to re-submit. As we previously disclosed, the Company will need to overcome the risk-benefit assessment of the FDA from the prior review of the NDA for OCA for the treatment of liver fibrosis due to NASH. Although we believe that the insights we have gained from the re-analysis and from the larger and more robust safety database provide an improved risk-benefit, there can be no assurances that the FDA will change its view on risk-benefit and will approve such NDA on an accelerated basis, or at all.

In order to obtain and/or maintain regulatory approval for OCA for indications other than PBC, we will need to complete additional clinical trials and studies. For example, we intend to re-resubmit our NDA for OCA for patients with liver fibrosis following the results of the New Interim Analysis, but we can provide no assurances that the FDA will grant approval. Our ability to obtain and maintain the regulatory approvals necessary to commercialize OCA for indications other than PBC, including NASH, will depend on our ability to successfully design, conduct and complete these trials, the efficacy, safety and risk-benefit profile of OCA demonstrated by such trials and our ability to prepare and submit complex regulatory filings in accordance with applicable regulatory requirements.

There can be no assurance that Ocaliva will receive full approval from the FDA or that OCA will receive marketing approval on an accelerated or conditional basis, or at all for NASH, or that any of our other product candidates will receive marketing approval for any indication in any jurisdiction. We cannot predict whether our clinical trials and studies for our product candidates, including OCA for NASH or any other indication, will be successful, whether regulatory authorities will agree with our conclusions relating to the clinical trials and studies we conduct, or whether such regulatory authorities will require us to conduct additional clinical trials or studies.

For example, while OCA received breakthrough therapy designation from the FDA in January 2015 for the treatment of NASH patients with liver fibrosis and we intend to resubmit our NDA for OCA for liver fibrosis due to NASH following the results of the New Interim Analysis, we do not know if the FDA will approve OCA for liver fibrosis due to NASH on an accelerated or conditional basis, or at all.

If we are unable to obtain or maintain regulatory approval for OCA for PBC or for other indications, we may not be able to generate sufficient revenue to maintain profitability or to continue our operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Recent Sales of Unregistered Securities

Except as disclosed in our filings on Form 8-K, we did not sell any unregistered securities during the three months ended September 30, 2022.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the three months ended September 30, 2022.

Item 6. Exhibits.

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth in the Exhibit Index below, which is incorporated herein by reference.

Exhibit Index

Exhibit Number	Description of Exhibit
10.1++	Amendment to Transitional Services Agreement, dated July 26, 2022, between Intercept Pharmaceuticals, Inc. ("ICPT Inc.") and Advanz Pharma Services (UK) Limited ("Advanz Services") (previously filed, and incorporated by reference from Exhibit 10.8 to Form 10-Q filed on August 3, 2022, File No. 001-35668).
10.2	Amendment to Safety Data Exchange Agreement, dated July 1, 2022, between ICPT Inc. and Mercury Pharma Group Limited ("Mercury Pharma") (previously filed, and incorporated by reference from Exhibit 10.9 to Form 10-Q filed on August 3, 2022, File No. 001-35668).
10.3	Amendment to Share Purchase Agreement, dated July 1, 2022, between ICPT Inc. and Mercury Pharma (previously filed, and incorporated by reference from Exhibit 10.10 to Form 10-Q filed on August 3, 2022, File No. 001-35668).
31.1	Certification of Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a).
31.2	Certification of Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a).
32.1(1)	Certifications required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C 1350).
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2022, formatted in Inline XBRL (Inline eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at September 30, 2022 and December 31, 2021 (unaudited), (ii) Condensed Consolidated Statements of Operations for the three and nine-month periods ended September 30, 2022 and 2021 (unaudited), (iii) Condensed Consolidated Statements of Comprehensive Income (Loss) for the three and nine-month periods ended September 30, 2022 and 2021 (unaudited), (iv) Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the three and nine-month periods ended September 30, 2022 and 2021 (unaudited), (v) Condensed Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2022 and 2021 (unaudited) and (vi) Notes to Condensed Consolidated Financial Statements (unaudited).
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

++ Portions of the exhibit have been omitted pursuant to Regulation S-K, Item 601(b)(10)(iv).

(1) The certifications attached hereto as Exhibit 32.1 are furnished to the SEC pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

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.

INTERCEPT PHARMACEUTICALS, INC.

Date: November 1, 2022

By: /s/ Jerome Durso
Jerome Durso
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 1, 2022

By: /s/ Andrew Saik
Andrew Saik
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATION

I, Jerome Durso, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Intercept Pharmaceuticals, 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 1, 2022

By: /s/ Jerome Durso
Jerome Durso
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Andrew Saik, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Intercept Pharmaceuticals, 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 1, 2022

By: /s/ Andrew Saik
Andrew Saik
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Jerome Durso, President and Chief Executive Officer of Intercept Pharmaceuticals, Inc. (the "Company"), and Andrew Saik, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

(1) The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2022, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

(2) The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 1, 2022

By: /s/ Jerome Durso
Jerome Durso
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 1, 2022

By: /s/ Andrew Saik
Andrew Saik
Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement required by Rule 13a-14(b) of the Exchange Act and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350) has been provided to Intercept Pharmaceuticals, Inc. and will be retained by Intercept Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Quarterly Report on Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Intercept Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Quarterly Report on Form 10-Q), irrespective of any general incorporation language contained in such filing.