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 March 31, 2023

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 March 31, 2023 was 41,687,084.

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 CRL received in June 2020 with respect to OCA for NASH;
- any advisory committee recommendation or dispute resolution determination that any of our product candidates should not be approved or approved only under certain conditions, including, for example, the advisory committee meeting scheduled on May 19, 2023 for OCA for liver fibrosis due to NASH;
- 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 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 and its affiliates (collectively, "Advanz");
- disagreements or legal, operational, or other business problems arising from our ongoing relationship with Advanz, 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 with OCA;
- unexpected tax, regulatory, litigation, or other liabilities;
- whether we receive any future earn-outs or royalties under the transaction documents with Advanz; 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").

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)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 61,404	$ 50,517
Restricted cash	1,620	5,343
Investment debt securities, available-for-sale	372,191	435,049
Accounts receivable, net of allowance for credit losses of $58 and $54, respectively	28,745	26,862
Prepaid expenses and other current assets	26,497	22,356
Total current assets	490,457	540,127
Fixed assets, net	899	987
Inventory	6,461	6,462
Security deposits	1,025	1,013
Other assets	5,243	5,122
Total assets	$ 504,085	$ 553,711
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses and other liabilities	$ 95,185	$ 116,977
Short-term interest payable	2,244	3,531
Current portion of long-term debt	109,688	109,569
Total current liabilities	207,117	230,077
Long-term liabilities:		
Long-term debt	223,352	223,104
Long-term other liabilities	6,431	7,453
Total liabilities	$ 436,900	$ 460,634
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Common stock par value $0.001 per share; 90,000,000 shares authorized; 41,687,084 and 41,523,337 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	42	42
Additional paid-in capital	2,243,789	2,238,179
Accumulated other comprehensive loss, net	(7,623)	(8,256)
Accumulated deficit	(2,169,023)	(2,136,888)
Total stockholders' equity	67,185	93,077
Total liabilities and stockholders' equity	$ 504,085	$ 553,711

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 March 31,	
	2023	2022
Revenue:		
Product revenue, net	$ 67,958	$ 59,146
Total revenue	67,958	59,146
Operating expenses:		
Cost of sales	222	223
Selling, general and administrative	57,657	37,768
Research and development	41,711	47,583
Total operating expenses	99,590	85,574
Operating loss	(31,632)	(26,428)
Other (expense) income:		
Interest expense	(2,809)	(6,673)
Other income (expense), net	2,560	(334)
Total other expense, net	(249)	(7,007)
Loss from continuing operations	$ (31,881)	$ (33,435)
(Loss) income from discontinued operations	$ (254)	$ 16,151
Net loss	$ (32,135)	$ (17,284)
Net income (loss) per common and potential common share (basic and diluted):		
Net loss from continuing operations	$ (0.77)	$ (1.13)
Net (loss) income from discontinued operations	$ (0.01)	$ 0.54
Net loss	$ (0.77)	$ (0.58)
Weighted average common and potential common shares outstanding:		
Basic and diluted	41,670	29,696

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2023	2022
Net loss	$ (32,135)	$ (17,284)
Other comprehensive income (loss):		
Unrealized gains (losses) on investment debt securities	729	(1,020)
Foreign currency translation (losses) gains	(96)	406
Other comprehensive income (loss)	$ 633	$ (614)
Comprehensive loss	$ (31,502)	$ (17,898)

See accompanying notes to the condensed consolidated financial statements.

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

Three months ended March 31, 2023

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss, Net	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance - December 31, 2022	41,523	$ 42	$ 2,238,179	$ (8,256)	$ (2,136,888)	$ 93,077
Stock-based compensation	—	—	5,864	—	—	5,864
Issuance of common stock under equity plan	180	—	—	—	—	—
Employee withholding taxes related to stock-based awards	(17)	—	(269)	—	—	(269)
Net proceeds from exercise of stock options	1	—	15	—	—	15
Other comprehensive income	—	—	—	633	—	633
Net loss	—	—	—	—	(32,135)	(32,135)
Balance - March 31, 2023	41,687	$ 42	$ 2,243,789	$ (7,623)	$ (2,169,023)	$ 67,185

Three months ended March 31, 2022

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss, Net	Accumulated Deficit	Total Stockholders' (Deficit)
	Shares	Amount				
Balance - December 31, 2021	29,573	30	2,308,653	(2,873)	(2,489,772)	(183,962)
Stock-based compensation	—	—	6,720	—	—	6,720
Issuance of common stock under equity plan	156	—	—	—	—	—
Employee withholding taxes related to stock-based awards	(20)	—	(318)	—	—	(318)
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	—	—	—	(614)	—	(614)
Net loss	—	—	—	—	(17,284)	(17,284)
Balance - March 31, 2022	29,709	$ 30	$ 2,007,684	$ (3,487)	$ (2,375,988)	$ (371,761)

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (32,135)	$ (17,284)
Less: (Loss) income from operations of discontinued operations	(254)	16,151
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	5,864	5,381
(Accretion) amortization of (discount) premium on investment debt securities	(1,965)	791
Amortization of deferred financing costs	368	797
Depreciation	89	341
Non-cash operating lease cost	258	1,035
Provision for allowance on credit losses	4	(5)
Changes in operating assets:		
Accounts receivable	(1,883)	2,937
Prepaid expenses and other current assets	(3,505)	1,253
Inventory	95	61
Security deposits	(12)	(357)
Changes in operating liabilities:		
Accounts payable, accrued expenses and other current liabilities	(17,232)	(9,782)
Operating lease liabilities	(256)	(1,427)
Interest payable	(1,287)	(4,625)
Net cash used in operating activities - continuing operations	(51,343)	(37,035)
Net cash (used in) provided by operating activities - discontinued operations	(254)	16,911
Net cash used in operating activities	(51,597)	(20,124)
Cash flows from investing activities:		
Purchases of investment debt securities	(55,629)	(142,789)
Sales and maturities of investment debt securities	121,181	128,576
Purchases of equipment, leasehold improvements, and furniture and fixtures	—	(7)
Net cash provided by (used in) investing activities - continuing operations	65,552	(14,220)
Net cash used in investing activities - discontinued operations	(6,229)	—
Net cash provided by (used in) investing activities	59,323	(14,220)
Cash flows from financing activities:		
Proceeds from exercise of options, net	15	—
Payments of employee withholding taxes related to stock-based awards	(269)	(318)
Net cash used in financing activities - continuing operations	(254)	(318)
Net cash (used in) provided by financing activities - discontinued operations	—	—
Net cash used in financing activities	(254)	(318)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(308)	(274)
Net increase (decrease) in cash, cash equivalents and restricted cash	7,164	(34,936)
Cash, cash equivalents and restricted cash at beginning of period	55,860	94,409
Cash, cash equivalents and restricted cash at end of period	63,024	59,473
Less: Cash, cash equivalents and restricted cash of discontinued operations	—	1,549
Cash, cash equivalents and restricted cash of continuing operations	$ 63,024	$ 57,924
Supplemental disclosure of non-cash transactions:		
Right-of-use asset obtained in exchange for new operating lease obligations	$ (374)	$ (3,173)
Non-cash investing and financing activities		
Net increase in accrued fixed assets	$ —	$ (52)
Reconciliation of cash, cash equivalents and restricted cash included in the condensed consolidated balance sheets:		
Cash and cash equivalents	$ 61,404	$ 48,320
Restricted cash	1,620	9,604
Total cash, cash equivalents and restricted cash	$ 63,024	$ 57,924

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"), nonalcoholic steatohepatitis ("NASH") and severe alcohol-associated hepatitis ("sAH"). The Company currently has one marketed product, Ocaliva (obeticholic acid or "OCA").

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 months ended March 31, 2023 are not necessarily indicative of the results that may be expected for any future period or for the year ending December 31, 2023. 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, 2022, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 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 Form 10-K for the year ended December 31, 2022. 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.

4. Discontinued Operations

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 (the "Disposition Transaction") to Advanz Pharma and its affiliates (collectively, "Advanz"). 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 for Ocaliva from the European Medicines Agency ("EMA") and

Medicines and Healthcare products Regulatory Agency (“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, the Company 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. Total cash consideration received upon closing was $366.5 million. Additional consideration of $38.5 million under the Share Purchase Agreement (the “SPA”) was settled in connection with the completion statements (the post-closing statements completing and adjusting the flow of funds from the closing of the Disposition Transaction), which included adjustments for cash, working capital, and assumed liabilities, resulting in a $6.2 million cash payment to Advanz during the quarter ended March 31, 2023.

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 $1.6 million for the three months ended March 31, 2023. Cash inflows were $1.1 million for the three months ended March 31, 2023 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.

As of March 31, 2023 and December 31, 2022, respectively, 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 months ended March 31, 2023 and 2022 respectively:

	Three Months Ended March 31,	
	2023	2022
Product revenue, net	$ —	$ 29,436
Cost of sales	—	535
Selling, general and administrative	—	12,239
Research and development	—	506
Other expense, net	—	(5)
Income from discontinued operations	$ —	$ 16,151
Loss on the sale of the ex-U.S. commercial operations and sublicense	(254)	—
Net (loss) income from discontinued operations	$ (254)	$ 16,151

Stock-based compensation expense recognized under discontinued operations, included in net income from discontinued operations, was $1.3 million for the three months ended March 31, 2022.

The following table presents the net cash provided by operating activities for the assets and liabilities classified as discontinued operations for the three months ended March 31, 2023 and 2022 respectively:

	Three Months Ended March 31,	
	2023	2022
Net (loss) income from discontinued operations	$ (254)	$ 16,151
Adjustment of non-cash activities	—	1,606
Increase in accounts receivable	—	(1,813)
Increase in prepaid expenses and other current assets	—	(621)
Decrease in inventory	—	81
Decrease in other assets	—	176
Decrease in operating lease liabilities	—	(263)
Increase in accounts payable, accrued expenses and other current liabilities	—	1,594
Net cash (used in) provided by operating activities	$ (254)	$ 16,911
Payment of purchase price adjustment for Disposition Transaction	(6,229)	—
Net cash used in investing activities	$ (6,229)	$ —

5. Cash, Cash Equivalents and Investment Debt Securities

The following table summarizes the Company's cash, cash equivalents and investment debt securities as of March 31, 2023 and December 31, 2022:

	As of March 31, 2023				
	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	$ 56,455	$ —	$ —	$ —	$ 56,455
Commercial paper	4,950	—	—	(1)	4,949
Total cash and cash equivalents	61,405	—	—	(1)	61,404
Investment debt securities:					
Commercial paper	126,242	—	—	(150)	126,092
Corporate debt securities	222,776	—	63	(779)	222,060
U.S. government agency bonds	24,100	—	1	(62)	24,039
Total investment debt securities	373,118	—	64	(991)	372,191
Total cash, cash equivalents and investment debt securities	$ 434,523	$ —	$ 64	$ (992)	$ 433,595

	As of December 31, 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	$ 50,517	$ —	$ —	$ —	$ 50,517
Total cash and cash equivalents	50,517	—	—	—	50,517
Investment debt securities:					
Commercial paper	102,379	—	7	(183)	102,203
Corporate debt securities	304,234	—	33	(1,390)	302,877
U.S. government agency bonds	24,100	—	4	(109)	23,995
U.S. Treasury securities	5,993	—	—	(19)	5,974
Total investment debt securities	436,706	—	44	(1,701)	435,049
Total cash, cash equivalents and investment debt securities	$ 487,223	$ —	$ 44	$ (1,701)	$ 485,566

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 March 31, 2023					
	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	$ 122,621	$ (150)	$ —	$ —	$ 122,621	$ (150)
Corporate debt securities	181,596	(737)	18,062	(42)	199,658	(779)
U.S. government agency bonds	18,548	(51)	3,489	(11)	22,037	(62)
Total	$ 322,765	$ (938)	$ 21,551	$ (53)	$ 344,316	$ (991)

	As of December 31, 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	$ 93,659	$ (183)	$ —	$ —	$ 93,659	$ (183)
Corporate debt securities	256,918	(1,174)	27,494	(216)	284,412	(1,390)
U.S. government agency bonds	17,866	(109)	—	—	17,866	(109)
U.S. Treasury securities	5,974	(19)	—	—	5,974	(19)
Total	$ 374,417	$ (1,485)	$ 27,494	$ (216)	$ 401,911	$ (1,701)

At March 31, 2023 and December 31, 2022, respectively the Company had 99 and 122 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 totaling $2.0 million and $2.4 million at March 31, 2023 and December 31, 2022, 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:

	Total	Fair Value Measurements Using Level 1	Level 2	Level 3
		(in thousands)		
March 31, 2023				
Assets				
Cash and cash equivalents:				
Money market funds	$ 42,701	$ 42,701	$ —	$ —
Commercial paper	4,949	—	4,949	—
Available-for-sale investment debt securities:				
Commercial paper	126,092	—	126,092	—
Corporate debt securities	222,060	—	222,060	—
U.S. government agency bonds	24,039	—	24,039	—
Total financial assets	$ 419,841	$ 42,701	$ 377,140	$ —
December 31, 2022				
Assets				
Cash and cash equivalents:				
Money market funds	$ 27,035	$ 27,035	$ —	$ —
Available-for-sale investment debt securities:				
Commercial paper	102,203	—	102,203	—
Corporate debt securities	302,877	—	302,877	—
U.S. government agency bonds	23,995	—	23,995	—
U.S. Treasury securities	5,974	5,974	—	—
Total financial assets	$ 462,084	$ 33,009	$ 429,075	$ —

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 March 31, 2023	December 31, 2022
	(in thousands)	
Due in one year or less	$ 353,710	$ 391,488
Due after one year through two years	18,481	43,561
Total investment debt securities	$ 372,191	$ 435,049

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)	March 31, 2023	December 31, 2022
		(in thousands)	
Office equipment and software	3	$ 3,113	$ 3,112
Leasehold improvements	Shorter of remaining lease term or useful life	395	395
Furniture and fixtures	7	1,280	1,280
Subtotal		4,788	4,787
Less: accumulated depreciation		(3,889)	(3,800)
Fixed assets, net		$ 899	$ 987

8. Inventory

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

	March 31, 2023	December 31, 2022
	(in thousands)	
Work-in-process	$ 6,258	$ 6,230
Finished goods	203	232
Inventory	$ 6,461	$ 6,462

9. Accounts Payable, Accrued Expenses and Other Liabilities

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

	March 31, 2023	December 31, 2022
	(in thousands)	
Accounts payable	$ 12,744	$ 14,234
Accrued employee compensation	13,025	24,737
Accrued contracted services	46,586	58,875
Accrued rebates, returns, discounts and other incentives	17,803	14,460
Accrued income taxes payable	3,204	3,144
Other liabilities	1,823	1,527
Accounts payable, accrued expenses and other liabilities	$ 95,185	$ 116,977

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 through 2021 calendar years.

With respect to the 2019 RDEC claim, in February 2022, the Company received a payment of $3.8 million from His Majesty's Revenue and Customs, or HMRC. Given the claim review has not been finalized for the 2019 year, the $3.8 million credit received, which has been reduced by $0.2 million due to foreign currency translation, has not yet been recognized in income and is 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:

	March 31, 2023				
	2026 Convertible Secured Notes	2026 Convertible Notes	2023 Convertible Notes	Total Current Portion of Long-Term Debt	Total Long-Term Debt
	(in thousands)				
Principal	$ 111,143	$ 115,349	$ 109,808	$ 109,808	$ 226,492
Unamortized debt issuance costs	(1,598)	(1,542)	(120)	(120)	(3,140)
Net carrying amount	$ 109,545	$ 113,807	$ 109,688	$ 109,688	$ 223,352

	December 31, 2022				
	2026 Convertible Secured Notes	2026 Convertible Notes	2023 Convertible Notes	Total Current Portion of Long-Term Debt	Total Long-Term Debt
	(in thousands)				
Principal	$ 111,143	$ 115,349	$ 109,808	$ 109,808	$ 226,492
Unamortized debt issuance costs	(1,728)	(1,660)	(239)	(239)	(3,388)
Net carrying amount	$ 109,415	$ 113,689	$ 109,569	$ 109,569	$ 223,104

As of March 31, 2023 and December 31, 2022, the net carrying amount of the 2023 Convertible Notes was 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 $116.7 million, net of $0.9 million in issuance costs. 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.

In September 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.

In June 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.

In August and September 2022, the Company entered into privately negotiated agreements to repurchase $388.9 million of 2026 Convertible Secured Notes, using a combination of cash and equity. The Company exchanged the existing 2026 Convertible Secured Notes for $258.1 million in cash and 11,329,399 shares 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, the aggregate shares were worth $219.5 million.

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

	March 31, 2023	December 31, 2022
	(in thousands)	
2026 Convertible Secured Notes	$ 114,492	$ 108,012
2026 Convertible Notes	$ 95,891	$ 87,307
2023 Convertible Notes	$ 108,797	$ 107,680

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.

Interest Expense on Convertible Notes

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

	Three Months Ended March 31, 2023			
	2026 Convertible Secured Notes	2026 Convertible Notes	2023 Convertible Notes	Total
	(in thousands)			
Contractual interest expense	$ 973	$ 577	$ 892	$ 2,442
Amortization of debt issuance costs	130	118	119	367
Total interest expense	$ 1,103	$ 695	$ 1,011	$ 2,809

	Three Months Ended March 31, 2022			
	2026 Convertible Secured Notes	2026 Convertible Notes	2023 Convertible Notes	Total
	(in thousands)			
Contractual interest expense	$ 4,375	577	924	$ 5,876
Amortization of debt issuance costs	563	115	119	797
Total interest expense	$ 4,938	$ 692	$ 1,043	$ 6,673

The effective interest rates during the three months ended March 31, 2023 and March 31, 2022 for the 2026 Convertible Secured Notes, 2026 Convertible Notes and 2023 Convertible Notes are 4.03%, 2.44% and 3.69%, respectively.

Accrued interest on the Convertible Notes was approximately $2.2 million and $3.5 million as of March 31, 2023 and December 31, 2022, 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 March 31, 2023 and December 31, 2022, respectively, $0.1 million and $0.2 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 March 31, 2023 and December 31, 2022, respectively, $3.1 million and $3.4 million of debt issuance costs for the 2026 Convertible Secured Notes and 2026 Convertible Notes are unamortized on the condensed consolidated balance sheets in Long-term debt.

Cash payments for interest were $3.7 million and $10.5 million for the three months ended March 31, 2023 and 2022, respectively.

11. Stock Compensation

Under the Company's Amended and Restated Equity Incentive Plan (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 2022 Plan will remain effective for a ten-year term, expiring in 2032.

The estimated fair value of the stock options granted in the three months ended March 31, 2023 was determined utilizing a Black-Scholes option-pricing model at the date of grant. The fair value of the RSUs granted in the three months ended March 31, 2023 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 three months ended March 31, 2023 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 three months ended March 31, 2023:

	Number of Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	2,087	$ 43.51	7.1	$ 4
Granted	517	$ 18.35	—	$ —
Exercised	(1)	$ 15.15	—	$ 5
Cancelled/forfeited	(38)	$ 19.32	—	$ —
Expired	(11)	$ 58.85	—	$ —
Outstanding at March 31, 2023	2,554	$ 38.72	7.4	$ 44
Expected to vest	1,285	$ 19.82	8.9	$ 44
Exercisable	1,269	$ 57.86	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 March 31, 2023, the total compensation cost related to non-vested option awards not yet recognized is approximately $14.9 million with a weighted average remaining vesting period of 1.37 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:

	Three Months Ended March 31,			
	2023		2022	
Volatility	69.5 - 69.8	%	66.4 - 67.1	%
Expected term (in years)	6.0		6.0	
Risk-free rate	3.6 - 4.3	%	1.3 - 1.7	%
Expected dividend yield	—	%	—	%

The following table summarizes the aggregate RSU and PRSU activity during the three months ended March 31, 2023:

	Number of Awards (in thousands)		Weighted Average Grant Date Fair Value
Non-vested awards at December 31, 2022	1,051	$	23.90
Granted	1,074	$	19.59
Vested	(25)	$	29.33
Forfeited	(52)	$	41.81
Non-vested awards at March 31, 2023	2,048	$	21.12

As of March 31, 2023, there is approximately $34.6 million of total unrecognized compensation expense related to unvested RSUs and PRSUs which is expected to be recognized over a weighted average vesting period of 1.86 years.

During the three months ended March 31, 2023, the Company granted a total of 224,700 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 $0.5 million of stock-based compensation related to such PRSUs granted during the three months ended March 31, 2023.

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

	Three Months Ended March 31,			
	2023		2022	
Selling, general and administrative	$	4,421	$	4,010
Research and development		1,443		1,371
Total stock-based compensation	$	5,864	$	5,381

12. 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-month periods ended March 31, 2023 and 2022, 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-month periods ended March 31, 2023 and 2022, as the inclusion thereof would have been anti-dilutive:

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
Shares issuable upon conversion of Convertible Notes	6,923	25,513
Options	2,432	2,431
Unvested restricted stock units	1,777	1,392
Total	11,132	29,336

13. 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 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. On February 7, 2023, the court marked the case as disposed of due to the discontinuance.

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.

We have entered into settlement agreements with Apotex, Lupin, Amneal, Optimus, MSN and Dr. Reddy’s. Those settlements fully resolved the patent infringement case in the United States District Court for the District of Delaware that was scheduled for trial on February 27, 2023, and the case was terminated by the District Court. Separate patent litigation against Zenara remains pending in the District of Delaware, with trial scheduled for July 22, 2024. Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”), the FDA cannot grant final approval of the Zenara ANDA before the earlier of February 8, 2025 or a court decision in its favor. Under the terms of the six settlement agreements, the Company granted each of the manufacturers a non-exclusive, non-sublicensable, non-transferable, royalty-free license to commercialize a generic version of Ocaliva in the United States commencing on a specified date, or earlier under certain circumstances. The earliest such specified date agreed to is September 1, 2031 (for Apotex).

These patent proceedings are costly and time-consuming, and successful challenges to the Company’s patents 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 patent lawsuits such as the Zenara lawsuit 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 without license from the Company.

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, 2022 (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, the United Kingdom, the European Union and several other jurisdictions 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 (the "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. Ocaliva received conditional approval for PBC from the European Commission in December 2016. Since January 2017, Ocaliva has also received regulatory approval in several markets outside the United States and Europe, including (but not limited to) Canada, Israel and Australia. Ocaliva received orphan drug designation in both the United States and the European Union for the treatment of PBC. 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 and HEROES-US study. 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 as 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 the previously granted marketing approvals 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 could 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 have held a productive dialogue with the 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 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 ($p=0.0002$). Based on the results of the New Interim Analysis, in December 2022 we re-submitted our NDA for OCA in pre-cirrhotic 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 had an ongoing dialogue as we prepared to re-submit. 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 $\geq$ 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 November 2022, we announced plans to focus development of our next-generation FXR agonist, INT-787, in severe alcohol-associated hepatitis (sAH).

In December 2022, we re-submitted an NDA to the FDA for OCA for the treatment of patients with pre-cirrhotic liver fibrosis due to NASH. The resubmission is supported by a robust body of evidence from the OCA NASH clinical development program, including two positive interim 18-month analyses from the pivotal Phase 3 REGENERATE study in patients with pre-cirrhotic liver fibrosis due to NASH. In both REGENERATE analyses, treatment with OCA 25 mg demonstrated a statistically significant improvement in liver fibrosis by at least one stage without worsening of NASH—an improvement that was more pronounced in individuals with more advanced disease at baseline.

In January 2023, we announced that the FDA accepted our NDA for OCA seeking accelerated approval for the treatment of patients with pre-cirrhotic liver fibrosis due to NASH. The FDA indicated that it considers this a complete, Class 2 resubmission and has assigned a PDUFA target action date of June 22, 2023, for the NDA. The timeline for the review of the NDA by the FDA remains subject to change.

In March 2023, we announced that the Gastrointestinal Drugs Advisory Committee ("GIDAC") of the FDA will discuss our NDA for OCA as a treatment for pre-cirrhotic liver fibrosis due to NASH on May 19, 2023. GIDAC will host this discussion as a virtual meeting.

As part of our product development activities, we expect to continue to invest in evaluating the potential of OCA in progressive non-viral liver diseases.

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 that has completed enrollment. 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 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. We expect to complete planned interim analyses from both of these ongoing Phase 2 studies in 2023. The planned interim analyses from these Phase 2 studies, in addition to Phase 1 and

preclinical data, would serve as the basis for an end-of-phase 2 meeting with the FDA. 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 submitted an IND for INT-787 in the first half of 2022, which is now active, and we announced plans to focus development of INT-787 in severe alcohol-associated hepatitis (sAH). We initiated a Phase 2a trial evaluating the safety, tolerability, efficacy and pharmacokinetics of INT-787 in subjects with sAH.

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

The sale of our ex-U.S. commercial operations to Advanz Pharma and affiliates (collectively, "Advanz") and sublicense of the right to commercialize Ocaliva for PBC and, if approved, OCA for NASH, outside of the United States for $405 million (subject to adjustments including for cash, working capital, and assumed liabilities) plus a potential $45 million earnout allowed us to capitalize on an opportunity supporting multiple pathways for the future and strengthened our balance sheet. The terms of this transaction allow us to focus our resources on the United States, 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 represented a strategic shift in business that would 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 for all prior periods presented herein. Applicable amounts in prior periods 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

In March 2023, the Company entered into a Sales Agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen") with respect to an at the market offering program ("ATM"), under which the Company may, from time to time in its sole discretion, issue and sell through Cowen shares of the Company's common stock. The Sales Agreement contemplates the sale of shares of our common stock having an aggregate offering price of up to an initial amount of $100.0 million, which could be supplemented in the future. We did not sell any shares under our ATM during the three months ended March 31, 2023.

Financial Overview

Revenue

We commenced our commercial launch of Ocaliva for the treatment of PBC in the United States in June 2016. In December 2016, the European Commission granted conditional approval for Ocaliva for the treatment of PBC. Since January 2017, Ocaliva has also received regulatory approval in several markets outside the United States and Europe, including (but not limited to) Canada, Israel, and Australia. 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 a single performance obligation — to deliver products upon receipt of a customer order — and this obligation is 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 calculate gross product revenues based on the wholesale acquisition cost that we charge our customers for Ocaliva, and then estimate 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 $68.0 million and $59.2 million for the three months ended March 31, 2023 and 2022, respectively.

Selling, General and Administrative Expenses

We have incurred and expect to continue to incur significant selling, general and administrative 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 incremental 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.

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 March 31, 2023 and 2022

The following table summarizes our results of operations for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
Revenue:		
Product revenue, net	$ 67,958	$ 59,146
Total revenue	67,958	59,146
Operating expenses:		
Cost of sales	222	223
Selling, general and administrative	57,657	37,768
Research and development	41,711	47,583
Total operating expenses	99,590	85,574
Other (expense) income:		
Interest expense	(2,809)	(6,673)
Other income (expense), net	2,560	(334)
Total other expense, net	(249)	(7,007)
Loss from continuing operations	$ (31,881)	$ (33,435)
(Loss) income from discontinued operations	$ (254)	$ 16,151
Net loss	$ (32,135)	$ (17,284)

Revenues

Product revenue, net was $68.0 million and $59.2 million for the three months ended March 31, 2023 and 2022, respectively. For the three months ended March 31, 2023 and 2022, 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 $0.2 million and $0.2 million for the three months ended March 31, 2023 and 2022, respectively. Our cost of sales for the three months ended March 31, 2023 and 2022 consisted primarily of packaging, labeling, materials and related expenses.

Selling, general and administrative expenses

Selling, general and administrative expenses were $57.7 million and $37.8 million for the three months ended March 31, 2023 and 2022, respectively. The $19.9 million net increase between periods was primarily driven by personnel costs due to higher headcount, costs for NASH launch preparation and costs related to our patent litigation.

Research and development expenses

Research and development expenses were $41.7 million and $47.6 million for the three months ended March 31, 2023 and 2022, respectively. The $5.9 million net decrease between periods was primarily driven by lower costs for NASH and cholestasis related R&D activities, mainly the wind down of REVERSE, along with R&D cost-sharing reimbursements from Advanz.

Interest expense

Interest expense was $2.8 million and $6.7 million for the three months ended March 31, 2023 and 2022, respectively. The decrease was driven by lower contractual interest expense due to the reduction of principal debt outstanding. For the quarters ended March 31, 2023 and 2022, interest expense related to the principal amounts outstanding for the 2023 Convertible Notes, 2026 Convertible Notes and 2026 Convertible Secured Notes.

Other income (expense), net

Other income (expense), net was $2.6 million and $(0.3) million for the three months ended March 31, 2023 and 2022, respectively. Such income is primarily attributable to interest income earned on cash, cash equivalents and investment debt securities.

(Loss) income from discontinued operations

(Loss) income from discontinued operations was $(0.3) million and $16.2 million for the three months ended March 31, 2023 and 2022, respectively. The decrease in (loss) income from discontinued operations was a result of no product revenues realized or operating expenses incurred after the completion of the sale in 2022.

Income taxes

For the three months ended March 31, 2023 and 2022, no income tax expense or benefit was recognized for continuing or discontinued 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 we do not expect them 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 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:

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
Net cash from continuing operations (used in) provided by:		
Operating activities	$ (51,343)	$ (37,035)
Investing activities	65,552	(14,220)
Financing activities	(254)	(318)
Effect of exchange rate changes	(308)	(274)
Net (decrease) increase in cash, cash equivalents and restricted cash classified as discontinued operations	(6,483)	16,911
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 7,164	$ (34,936)

Operating Activities. Net cash used in operating activities for continuing operations of approximately $51.3 million during the three months ended March 31, 2023 was primarily a result of our $31.9 million net loss from continuing

operations, a net decrease in operating assets and operating liabilities of $24.1 million, partially offset by $5.9 million in stock-based compensation.

Net cash used in operating activities for continuing operations of approximately $37.0 million during the three months ended March 31, 2022 was primarily a result of our $33.4 million net loss from continuing operations, a net decrease in operating assets and operating liabilities of $11.9 million, partially offset by $5.4 million in stock-based compensation, and $1.0 million for non-cash operating lease costs. Cash flows for the three months ended March 31, 2022 include cash receipts of $3.8 million reflecting payments from the HMRC for the U.K. R&D tax credit claims.

Investing Activities. For the three months ended March 31, 2023, net cash provided by investing activities for continuing operations of approximately $65.6 million primarily reflects the sales and maturities of investment debt securities of $121.2 million, partially offset by the purchase of investment debt securities of $55.6 million.

For the three months ended March 31, 2022, net cash used in investing activities for continuing operations of approximately $14.2 million primarily reflects the purchase of investment debt securities of $142.8 million, partially offset by the sales and maturities of investment debt securities of $128.6 million.

Financing Activities. Net cash used in financing activities for continuing operations of approximately $0.3 million in the three months ended March 31, 2023 primarily consisted of payments of $0.3 million for employee withholding taxes related to stock-based awards.

Net cash used in financing activities for continuing operations of approximately $0.3 million in the three months ended March 31, 2022 primarily consisted of payments of $0.3 million for employee withholding taxes related to stock-based awards.

Net change in cash, cash equivalents and restricted cash – discontinued operations. Net decrease in cash, cash equivalents and restricted cash for discontinued operations in the three months ended March 31, 2023 consisted of approximately $6.2 million of cash used in investing activities for payments made to Advanz and $0.3 million of cash used in operating activities, primarily a result of $0.3 million net loss from discontinued operations.

Net increase in cash, cash equivalents and restricted cash for discontinued operations in the three months ended March 31, 2022 consisted of net cash provided by operating activities of approximately $16.9 million, primarily a result of $16.2 million net income from discontinued operations and $1.3 million in stock-based compensation partially offset by a decrease in operating assets and operating liabilities of $0.8 million.

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 March 31, 2023, we had $435.2 million in cash, cash equivalents, restricted cash and investment debt securities. We expect to continue to incur significant operating expenses in the fiscal year ending December 31, 2023. 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, and repay the remaining balance of the 2023 Convertible Notes, 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 March 31, 2023, our funds are primarily held in U.S. government agency bonds, corporate bonds, commercial paper and money market accounts.

In the prior year, we 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. On March 24, 2023, the Company entered into the Sales Agreement, pursuant to which the Company may, from time to time, sell shares of the Company's common stock through Cowen, in an ATM, up to an initial amount of $100.0 million. 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.

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

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, 2022.

Off-Balance Sheet Arrangements

As of March 31, 2023, 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 13 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.

In addition to the other information set forth in this Form 10-Q, including under the heading "Cautionary Note Regarding Forward-Looking Statements", the risks and uncertainties that we believe are most important for you to consider are discussed in "Part II, Item 1A—Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC, which could adversely affect our business, financial condition, results of operations and future growth prospects. The risks described in our Annual Report on Form 10-K for the year ended December 31, 2022 are not the only risks we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. There are no material changes to the Risk Factors described in our Annual Report on Form 10-K for the year ended December 31, 2022.

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

Recent Sales of Unregistered Securities

We did not sell any unregistered securities during the three months ended March 31, 2023.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the three months ended March 31, 2023.

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#	2023 Cash Incentive Plan (previously filed, and incorporated by reference from Exhibit 10.1 to Form 8-K filed on February 2, 2023, File No. 001-35668).
10.2#	2023 Cash Incentive Plan – Form of Performance-Based Award Agreement (previously filed, and incorporated by reference from Exhibit 10.2 to Form 8-K filed on February 2, 2023, File No. 001-35668).
10.3	Sales Agreement, dated March 24, 2023, between Intercept Pharmaceuticals, Inc., and Cowen and Company, LLC (previously field, and incorporated by reference from Exhibit 1.1 to Form 8-K filed on March 24, 2023, 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 March 31, 2023, formatted in Inline XBRL (Inline eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at March 31, 2023 and December 31, 2022 (unaudited), (ii) Condensed Consolidated Statements of Operations for the three-month periods ended March 31, 2023 and 2022 (unaudited), (iii) Condensed Consolidated Statements of Comprehensive Loss for the three-month periods ended March 31, 2023 and 2022 (unaudited), (iv) Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the three-month periods ended March 31, 2023 and 2022 (unaudited), (v) Condensed Consolidated Statements of Cash Flows for the three-month periods ended March 31, 2023 and 2022 (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).

# Indicates a management contract or compensatory plan or arrangement.

(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: April 27, 2023

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

Date: April 27, 2023

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: April 27, 2023

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: April 27, 2023

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 March 31, 2023, 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: April 27, 2023

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

Date: April 27, 2023

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.