Intercept Pharmaceuticals Reports First Quarter 2023 Financial Results and Provides Update on Commercial Launch Strategy for NASH

April 27, 2023

Ocaliva® net sales of $68.0 million, representing 15% growth over the prior year quarter

Gastrointestinal Drugs Advisory Committee (GIDAC) Meeting set for May 19, 2023, to review obeticholic acid (OCA) as a treatment for pre-cirrhotic fibrosis due to NASH; PDUFA Target Action Date set for June 22, 2023

Company updates progress of OCA-bezafibrate fixed-dose combination development program in PBC, including acceptance of new Phase 2 data at EASL Congress 2023

Company to host conference call today from 8:00 a.m. – 9:30 a.m. ET; call to include information about commercial launch strategy for OCA in NASH

MORRISTOWN, N.J., April 27, 2023 (GLOBE NEWSWIRE) -- Intercept Pharmaceuticals, Inc. (Nasdaq: ICPT), a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases, today announced its financial results for the quarter ended on March 31, 2023.

“We are confident in the strength of Ocaliva’s market position and the long-term opportunity with our foundational PBC business, as evidenced by double-digit sales growth for the third consecutive quarter and clinical development progress for the OCA-bezafibrate fixed-dose combination,” said Jerry Durso, President and Chief Executive Officer of Intercept. “In NASH, we are very focused on the upcoming Advisory Committee Meeting to review our new drug application in pre-cirrhotic fibrosis due to NASH. We look forward to this important step to discuss the strong and confirmed antifibrotic effect of OCA, as well as its monitorable and manageable safety profile. In parallel, we continue to make significant progress as we prepare to successfully launch a potential first-to-market therapy for NASH.”

“Our strong financial position gives us the optionality to execute on upcoming milestones, drive long-term growth and develop innovative new medicines such as the OCA-bezafibrate combination, which we believe has the potential to establish new best-in-class clinical benefits for patients living with PBC,” Durso continued.

Company Highlights

Nonalcoholic Steatohepatitis (NASH)

- In March 2023, Intercept announced that the Gastrointestinal Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) will review Intercept’s new drug application (NDA) for OCA as a treatment for pre-cirrhotic fibrosis due to NASH on May 19, 2023. FDA has assigned a Prescription Drug User Fee Act (PDUFA) Target Action Date of June 22, 2023, for the application. The timeline for review of the NDA by FDA remains subject to change.

- The Company is actively progressing its launch readiness activities for OCA for the treatment of patients with pre-cirrhotic fibrosis due to NASH. Further information on the Company’s commercial launch strategy for NASH will be shared during a conference call and webcast presentation 8:00 a.m. to 9:30 a.m. ET. Registration for the event can be found on the investor page of our website at http://ir.interceptpharma.com.

Primary Biliary Cholangitis (PBC)

- Intercept’s fixed-dose combination development program for OCA and bezafibrate, a peroxisome proliferator-activated receptor agonist (PPAR), is progressing. Intercept has completed a Phase 1 clinical study in healthy adult subjects that assessed multiple dose combinations of OCA and bezafibrate. The company has two ongoing Phase 2 studies (747-213 / NCT04594694, 747-214 / NCT05239468) that are exploring a range of therapeutic doses for the combination of OCA and bezafibrate. Intercept expects to complete planned interim analyses from both ongoing Phase 2 studies this year, with the first data being presented at the 2023 European Association for the Study of the Liver (EASL) Congress. The planned interim analyses from these Phase 2 studies, in addition to Phase 1 and preclinical data, will serve as the basis for an end-of-phase 2 meeting with FDA.

- Seven abstracts in PBC and NASH have been accepted for presentation at the 2023 EASL Congress. The congress will be held from June 21-24, 2023, in Vienna, Austria. Among the accepted abstracts is a podium presentation of new data from a planned interim analysis of an ongoing Phase 2 study evaluating the effects of the investigational combination of OCA and bezafibrate on serum biomarkers in PBC.

- Intercept remains on track for a regulatory submission to FDA this year in support of fulfilling post-marketing requirements for Ocaliva® in PBC. This submission will include data from our post-marketing study, COBALT, and supplementary

real-world evidence from large datasets in the U.S. and Europe.

Pipeline

- Intercept has completed the Phase 1 program for INT-787, a next-generation farnesoid X receptor (FXR) agonist. The company continues to progress its FRESH (FXR Effect on Severe Alcohol-Associated Hepatitis) study, a Phase 2a trial evaluating the safety, tolerability, efficacy and pharmacokinetics of INT-787 in patients with severe alcohol-associated hepatitis (sAH).

Selected First Quarter 2023 Financial Results

Revenue

- Intercept recognized $68.0 million in net sales in the first quarter 2023 compared to $59.2 million in net sales in the prior year quarter.

Operating Expenses

- In the quarter ended March 31, 2023, Intercept recorded $99.6 million in total operating expenses and $93.6 million in non-GAAP adjusted operating expenses, which excludes non-cash stock-based compensation expense of $5.9 million and depreciation expense of $0.1 million. This compares to the quarter ended on March 31, 2022, where Intercept recorded $85.6 million in total operating expenses and $79.9 million in non-GAAP adjusted operating expenses, which excluded non-cash stock-based compensation expense of $5.4 million and depreciation expense of $0.3 million.

- Selling, general and administrative expenses increased to $57.7 million in the first quarter of 2023, from $37.8 million in the prior year quarter. The increase was primarily driven by investment in NASH launch preparation and costs related to our ANDA litigation which was settled prior to trial.

- Research and development expenses decreased to $41.7 million in the first quarter of 2023, from $47.6 million in the prior year quarter. The decrease was primarily driven by the wind down of the REVERSE program and R&D cost-sharing reimbursements.

- References in this press release to “non-GAAP adjusted operating expenses” mean our total operating expenses, as calculated and presented in accordance with U.S. Generally Accepted Accounting Principles (“GAAP”), adjusted for the effects of two non-cash items: stock-based compensation and depreciation. See “Non-GAAP Financial Measures” below. A reconciliation of non-GAAP adjusted operating expenses to total operating expenses for all historical periods presented is included below under the heading “Reconciliation of Non-GAAP Adjusted Operating Expenses to Total Operating Expenses.”

Interest Expense

- Interest expense in the quarters ended March 31, 2023, and 2022 was $2.8 million and $6.7 million, respectively. For the quarters ended March 31, 2023 and 2022, interest expense was related to our Convertible Notes.

Net Loss

- In the first quarter 2023, Intercept reported a net loss from continuing operations of $31.9 million, a decrease compared to a net loss from continuing operations of $33.4 million in the first quarter 2022.

Cash Position

- As of March 31, 2023, Intercept had cash, cash equivalents, restricted cash, and investment debt securities available for sale of $435.2 million. As of December 31, 2022, Intercept had cash, cash equivalents, restricted cash, and investment debt securities available for sale of approximately $490.9 million. As anticipated, the company experienced revenue seasonality and higher cash utilization in the first quarter of 2023 relative to what is seen in other quarters.

Conference Call on April 27, 2023, at 8:00 a.m. ET
The conference call and webcast discussing the Company’s first quarter 2023 financial results and commercial launch strategy for NASH will take place on April 27, 2023, at 8:00 a.m. ET. The conference call will be available via a listen-only webcast on the investor page of our website at http://ir.interceptpharma.com. Participants who wish to ask a question may register here to receive dial-in numbers and a unique pin to join the call. A replay of the call will be available on our website shortly following the completion of the call and will be available for one year.

About Intercept
Intercept is a biopharmaceutical company 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). For more information, please visit www.interceptpharma.com or connect with the Company on Twitter and LinkedIn.

Non-GAAP Financial Measures
This press release presents non-GAAP adjusted operating expenses on a historical and projected basis. For the periods presented, non-GAAP adjusted operating expenses exclude from total operating expenses, as calculated and presented in accordance with GAAP, the effects of two non-cash items: stock-based compensation and depreciation. Non-GAAP adjusted operating expenses is a financial measure that has not been prepared in accordance with GAAP. Accordingly, investors should consider non-GAAP adjusted operating expenses in addition to, but not as a substitute for, total operating expenses that we calculate and present in accordance with GAAP. Among other things, our management uses non-GAAP adjusted operating expenses to establish budgets and operational goals and to manage our business. Other companies may define or use this measure in different ways. We believe that the presentation of non-GAAP adjusted operating expenses provides investors and management with helpful supplemental information relating to operating performance and trends. A table reconciling non-GAAP adjusted operating expenses to total operating expenses for all historical periods presented is included below under the heading “Reconciliation of Non-GAAP Adjusted Operating Expenses to Total Operating Expenses”. A quantitative reconciliation of projected non-GAAP adjusted operating expenses to total operating expenses is not available without unreasonable effort primarily due to our inability to predict with reasonable certainty the amount of future stock-based compensation expense.

About the Investigational OCA-Bezafibrate Fixed-Dose Combination
Intercept is investigating a fixed-dose combination of OCA and bezafibrate for the potential treatment of individuals with PBC. OCA, a farnesoid X receptor (FXR) agonist, is marketed by Intercept as Ocaliva in the United States for the treatment of PBC (see below for full indication and Important Safety Information). Bezafibrate, a pan-peroxisome proliferator-activated receptor (pan-PPAR) agonist, is not approved in the United States for any indication.

FXR and PPAR are distinct pathways that each play a role in PBC. Simultaneously targeting both pathways may offer the greatest potential to impact bile acid synthesis, metabolism, and clearance that underly cholestatic liver diseases. Published studies establish a clinical proof-of-concept that suggests that the combination of OCA and bezafibrate may provide additive clinical efficacy and tolerability benefits in the treatment of PBC. OCA-bezafibrate combination therapy is investigational; safety and efficacy have not been established.

About Liver Fibrosis due to NASH
Nonalcoholic steatohepatitis (NASH) is a serious progressive liver disease caused by excessive fat accumulation in the liver that induces chronic inflammation, resulting in progressive fibrosis (scarring) that can lead to cirrhosis, eventual liver failure, cancer and death. Advanced fibrosis is associated with a substantially higher risk of liver-related morbidity and mortality in patients with NASH. There are currently no medications approved for the treatment of NASH.

About Primary Biliary Cholangitis
Primary biliary cholangitis (PBC) is a rare, progressive and chronic autoimmune disease that affects the bile ducts in the liver and is most prevalent (approximately 1 in 10,000) in women over the age of 40. PBC causes bile acid to build up in the liver, resulting in inflammation and scarring (fibrosis), which, if left untreated, can lead to cirrhosis, a liver transplant, or death.

About Ocaliva® (obeticholic acid)
OCALIVA, a farnesoid X receptor (FXR) agonist, is indicated for the treatment of adult patients with primary biliary cholangitis (PBC)

- without cirrhosis or
- with compensated cirrhosis who do not have evidence of portal hypertension, either in combination with ursodeoxycholic acid (UDCA) with an inadequate response to UDCA or as monotherapy in patients unable to tolerate UDCA.

This indication is approved under accelerated approval based on a reduction in alkaline phosphatase (ALP). An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

IMPORTANT SAFETY INFORMATION

WARNING: HEPATIC DECOMPENSATION AND FAILURE IN PRIMARY BILIARY CHOLANGITIS PATIENTS WITH CIRRHOSIS

- **Hepatic decompensation and failure, sometimes fatal or resulting in liver transplant, have been reported with OCALIVA treatment in primary biliary cholangitis (PBC) patients with either compensated or decompensated cirrhosis.**
- **OCALIVA is contraindicated in PBC patients with decompensated cirrhosis, a prior decompensation event, or with compensated cirrhosis who have evidence of portal hypertension.**
- **Permanently discontinue OCALIVA in patients who develop laboratory or clinical evidence of hepatic decompensation; have compensated cirrhosis and develop evidence of portal hypertension, or experience clinically significant hepatic adverse reactions while on treatment.**

Contraindications

OCALIVA is contraindicated in patients with:

- decompensated cirrhosis (e.g., Child-Pugh Class B or C) or a prior decompensation event
- compensated cirrhosis who have evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia)
- complete biliary obstruction

Warnings and Precautions

Hepatic Decompensation and Failure in PBC Patients with Cirrhosis
Hepatic decompensation and failure, sometimes fatal or resulting in liver transplant, have been reported with OCALIVA treatment in PBC patients with cirrhosis, either compensated or decompensated. Among post-marketing cases reporting it, median time to hepatic decompensation (e.g., new onset ascites) was 4 months for patients with compensated cirrhosis; median time to a new decompensation event (e.g., hepatic encephalopathy) was 2.5 months for patients with decompensated cirrhosis.

Some of these cases occurred in patients with decompensated cirrhosis when they were treated with higher than the recommended dosage for that patient population; however, cases of hepatic decompensation and failure have continued to be reported in patients with decompensated cirrhosis even when they received the recommended dosage.

Hepatotoxicity was observed in the OCALIVA clinical trials. A dose-response relationship was observed for the occurrence of hepatic adverse reactions including jaundice, worsening ascites, and primary biliary cholangitis flare with dosages of OCALIVA of 10 mg once daily to 50 mg once daily (up to 5-times the highest recommended dosage), as early as one month after starting treatment with OCALIVA in two 3-month, placebo-controlled clinical trials in patients with primarily early stage PBC.

Routinely monitor patients for progression of PBC, including hepatic adverse reactions, with laboratory and clinical assessments to determine whether drug discontinuation is needed. Closely monitor patients with compensated cirrhosis, concomitant hepatic disease (e.g., autoimmune hepatitis, alcoholic liver disease), and/or with severe intercurrent illness for new evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia), or increases above the upper limit of normal in total bilirubin, direct bilirubin, or prothrombin time to determine whether drug discontinuation is needed. Permanently discontinue OCALIVA in patients who develop laboratory or clinical evidence of hepatic decompensation (e.g., ascites, jaundice, variceal bleeding, hepatic encephalopathy), have compensated cirrhosis and develop evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia), experience clinically significant hepatic adverse reactions, or develop complete biliary obstruction. If severe intercurrent illness occurs, interrupt treatment with OCALIVA and monitor the patient's liver function. After resolution of the intercurrent illness, consider the potential risks and benefits of restarting OCALIVA treatment.

Severe Pruritus
Severe pruritus was reported in 23% of patients in the OCALIVA 10 mg arm, 19% of patients in the OCALIVA titration arm, and 7% of patients in the placebo arm in a 12-month double-blind randomized controlled clinical trial of 216 patients. Severe pruritus was defined as intense or widespread itching, interfering with activities of daily living, or causing severe sleep disturbance, or intolerable discomfort, and typically requiring medical interventions. Consider clinical evaluation of patients with new onset or worsening severe pruritus. Management strategies include the addition of bile acid binding resins or antihistamines, OCALIVA dosage reduction, and/or temporary interruption of OCALIVA dosing.

Reduction in HDL-C
Patients with PBC generally exhibit hyperlipidemia characterized by a significant elevation in total cholesterol primarily due to increased levels of high-density lipoprotein-cholesterol (HDL-C). Dose-dependent reductions from baseline in mean HDL-C levels were observed at 2 weeks in OCALIVA-treated patients, 20% and 9% in the 10 mg and titration arms, respectively, compared to 2% in the placebo arm. Monitor patients for changes in serum lipid levels during treatment. For patients who do not respond to OCALIVA after 1 year at the highest recommended dosage that can be tolerated (maximum of 10 mg once daily), and who experience a reduction in HDL-C, weigh the potential risks against the benefits of continuing treatment.

Adverse Reactions
The most common adverse reactions (≥5%) are: pruritus, fatigue, abdominal pain and discomfort, rash, oropharyngeal pain, dizziness, constipation, arthralgia, thyroid function abnormality, and eczema.

Drug Interactions

- Bile Acid Binding Resins
  Bile acid binding resins such as cholestyramine, colestipol, or colesevelam adsorb and reduce bile acid absorption and may reduce the absorption, systemic exposure, and efficacy of OCALIVA. If taking a bile acid binding resin, take OCALIVA at least 4 hours before or 4 hours after taking the bile acid binding resin, or at as great an interval as possible.
- Warfarin
  The International Normalized Ratio (INR) decreased following coadministration of warfarin and OCALIVA. Monitor INR and adjust the dose of warfarin, as needed, to maintain the target INR range when co-administering OCALIVA and warfarin.
- CYP1A2 Substrates with Narrow Therapeutic Index
  Obeticholic acid may increase the exposure to concomitant drugs that are CYP1A2 substrates. Therapeutic monitoring of CYP1A2 substrates with a narrow therapeutic index (e.g., theophylline and tizanidine) is recommended when co-administered with OCALIVA.
- Inhibitors of Bile Salt Efflux Pump
  Avoid concomitant use of inhibitors of the bile salt efflux pump (BSEP) such as cyclosporine. Concomitant medications that inhibit canalicular membrane bile acid transporters such as the BSEP may exacerbate accumulation of conjugated bile salts including taurine conjugate of obeticholic acid in the liver and result in clinical symptoms. If concomitant use is deemed necessary, monitor serum transaminases and bilirubin.

Please click here for Full Prescribing Information, including Boxed WARNING.
To report SUSPECTED ADVERSE REACTIONS, contact Intercept Pharmaceuticals, Inc. at 1-844-782-ICPT or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Cautionary Note Regarding Forward-Looking Statements
This press release 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, and
- our strategy, future operations, future financial position, future revenue, projected costs, financial guidance, prospects, plans and objectives.

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

These forward-looking statements are based on estimates and assumptions by our management that, although believed to be reasonable, are inherently uncertain and subject to a number of risks.

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

- the success of our existing business and operations, including Ocaliva for PBC;
- our ability to successfully commercialize Ocaliva for PBC and, if approved, OCA for NASH;
- our ability to maintain our regulatory approval of Ocaliva for PBC;
- our ability to timely and cost-effectively file for and obtain regulatory approval of our product candidates on an accelerated basis or at all, including OCA for liver fibrosis due to NASH;
- our ability to address the issues raised in the complete response letter (“CRL”) received in June 2020 with respect to OCA for NASH;
- any advisory committee recommendation or dispute resolution determination that our product candidates, including OCA for liver fibrosis due to NASH, should not be approved or approved only under certain conditions;
- any future determination that the regulatory applications and subsequent information we submit for our product candidates, including OCA for liver fibrosis due to NASH, do not contain adequate clinical or other data or meet applicable regulatory requirements for approval;
- the progress, timing, and results of our REGENERATE clinical trial, including the safety and efficacy of OCA for liver fibrosis due to NASH, and the use of a consensus panel approach to histology reads;
- our pre-submission meeting with the FDA in July 2022 in which we reviewed with the FDA the planned content and the timing of the submission of our NDA for OCA for liver fibrosis due to NASH;
- our resubmission of an NDA to the FDA for OCA for liver fibrosis due to NASH, and the potential timing, review, acceptance, and approval of the NDA;
- conditions that may be imposed by regulatory authorities on our marketing approvals for our products and product candidates, including OCA for liver fibrosis due to NASH, such as the need for clinical outcomes data (and not just results based on achievement of a surrogate endpoint), any risk mitigation programs such as a Risk Evaluation and Mitigation Strategies (“REMS”) program, and any related restrictions, limitations and/or warnings contained in the label of any of our products or product candidates;
- any potential side effects associated with Ocaliva for PBC, OCA for liver fibrosis due to NASH or our other product candidates that could delay or prevent approval, require that an approved product be taken off the market, require the inclusion of safety warnings or precautions, or otherwise limit the sale of such product or product candidate, including in connection with our update to the Ocaliva prescribing information in May 2021 contraindicating Ocaliva for patients with PBC and decompensated cirrhosis, a prior decompensation event, or compensated cirrhosis with evidence of portal hypertension;
- the initiation, timing, cost, conduct, progress and results of our research and development activities, preclinical studies and clinical trials, including any issues, delays or failures in identifying patients, enrolling patients, treating patients, retaining patients, meeting specific endpoints, or completing and timely reporting the results of our NASH or PBC clinical trials;
- the outcomes of interactions with regulators including the FDA regarding our clinical trials;
- our ability to establish and maintain relationships with, and the performance of, third-party manufacturers, contract research organizations and other vendors upon whom we are substantially dependent for, among other things, the manufacture and supply of our products, including Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH, and our clinical trial activities;
- our ability to identify, develop and successfully commercialize our products and product candidates, including our ability to

successfully launch OCA for liver fibrosis due to NASH, if approved;
- our ability to obtain and maintain intellectual property protection for our products and product candidates, including our ability to cost-effectively file, prosecute, defend and enforce any patent claims or other intellectual property rights;
- the size and growth of the markets for our products and product candidates and our ability to serve those markets;
- the degree of market acceptance of Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH or our other product candidates among physicians, patients and healthcare payors;
- the availability of adequate coverage and reimbursement from governmental and private healthcare payors for our products, including Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH, and our ability to obtain adequate pricing for such products;
- our ability to establish and maintain effective sales, marketing and distribution capabilities, either directly or through collaborations with third parties;
- competition from existing drugs or new drugs that become available;
- our ability to attract and retain key personnel to manage our business effectively;
- our ability to prevent or defend against system failures or security or data breaches due to cyber-attacks, or cyber intrusions, including ransomware, phishing attacks and other malicious intrusions;
- our ability to comply with data protection laws;
- costs and outcomes relating to any disputes, governmental inquiries or investigations, regulatory proceedings, legal proceedings or litigation, including any securities, intellectual property, employment, product liability or other litigation;
- our collaborators' election to pursue research, development and commercialization activities;
- our ability to establish and maintain relationships with collaborators with development, regulatory and commercialization expertise;
- our need for and ability to generate or obtain additional financing;
- our estimates regarding future expenses, revenues and capital requirements and the accuracy thereof;
- our use of cash, cash equivalents and short-term investments;
- our ability to acquire, license and invest in businesses, technologies, product candidates and products;
- our ability to manage the growth of our operations, infrastructure, personnel, systems and controls;
- our ability to obtain and maintain adequate insurance coverage;
- continuing threats from COVID-19, including additional waves of infections, and their impacts including quarantines and other government actions; delays relating to our regulatory applications; disruptions relating to our ongoing clinical trials or involving our contract research organizations, study sites or other clinical partners; disruptions relating to our supply chain or involving our third-party manufacturers, distributors or other distribution partners; and facility closures or other restrictions; and the impact of the foregoing on our results of operations and financial position;
- the impact of general economic, industry, market, regulatory or political conditions;
- how we use the funds received from the sale of our ex-U.S. business to Advanz Pharma;
- disagreements or legal, operational, or other business problems arising from our ongoing relationship with Advanz Pharma, including the licensing of the ex-U.S. rights to Ocaliva for PBC and, if approved, OCA for NASH, our operational separation from our former ex-U.S. commercial operations, and our agreement to supply Advanz Pharma with OCA;
- unexpected tax, regulatory, litigation, or other liabilities;
- whether we receive any future earn-outs or royalties under the Advanz Pharma transaction documents; and
- the other risks and uncertainties identified in our periodic filings filed with the U.S. Securities and Exchange Commission (the "SEC"), including our latest Annual Report on Form 10-K and/or Quarterly Report on Form 10-Q.

Contact

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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 income (expense):		
Interest expense	(2,809)	(6,673)
Other income (expense), net	2,560	(334)
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:		
Net loss from continuing operations	$ (0.77)	$ (1.13)
Net 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

Condensed Consolidated Balance Sheet Information
(Unaudited)
(In thousands)

	March 31, 2023	December 31, 2022 (1)
Cash, cash equivalents, restricted cash and investment debt securities, available for sale	$ 435,215	$ 490,909
Total assets	$ 504,085	$ 553,711
Total liabilities (2)	$ 436,900	$ 460,634
Stockholders' equity	$ 67,185	$ 93,077

(1) Derived from the financial statements included in Intercept's Annual Report on Form 10-K for the period ended December 31, 2022.

(2) Includes $333.0 million and $332.7 million related to the 2023 Convertible Notes, 2026 Convertible Notes and the 2026 Secured Convertible Notes (together, the "Convertible Notes") as of March 31, 2023 and December 31, 2022, respectively. The aggregate outstanding principal amount of the Convertible Notes was $336.3 million as of March 31, 2023 and December 31, 2022, respectively.

Reconciliation of Non-GAAP Adjusted Operating Expenses to Total Operating Expenses
(Unaudited)
(In thousands)

	Three Months Ended March 31,	
	2023	2022
Total operating expenses	$ 99,590	$ 85,574
Adjustments:		
Stock-based compensation	5,864	5,381
Depreciation	89	341
Non-GAAP adjusted operating expenses	$ 93,637	$ 79,852

Source: Intercept Pharmaceuticals, Inc.