Intercept Pharmaceuticals Reports Third Quarter 2022 Financial Results and Provides Business Update

November 1, 2022

U.S. Ocaliva® net sales of $77.6 million; 16.4% growth over the prior year quarter

Company increases 2022 Ocaliva non-GAAP adjusted net sales guidance to $340 million to $350 million and narrows non-GAAP adjusted operating expense guidance to $350 million to $365 million

As of September 30, 2022, Company has cash, cash equivalents, restricted cash, and investment debt securities available for sale of $497.8 million

Company remains on track to resubmit new drug application (NDA) for obeticholic acid (OCA) in liver fibrosis due to NASH by end of 2022 based on the positive Phase 3 REGENERATE study

MORRISTOWN, N.J., Nov. 01, 2022 (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 September 30, 2022.

“We drove accelerated, double-digit growth in Ocaliva this quarter, resulting in an increase to our sales guidance for this year,” said Jerry Durso, President and Chief Executive Officer of Intercept. “This quarter’s performance reinforces the underlying strength and value of our PBC business, and there is significant opportunity to grow this franchise given the number of patients who remain eligible for second-line therapy. Importantly, the long-term outcomes data we are generating reinforce the role Ocaliva can play in the future of PBC treatment.”

“In the near term, we remain on track to resubmit our NDA in liver fibrosis due to NASH by the end of this year, based on the second positive interim analysis of our Phase 3 REGENERATE study,” Durso continued. “There will also be additional data from the REGENERATE study presented in a late-breaking oral presentation at The Liver Meeting® later this month. Importantly, given the recent strategic transactions that have strengthened our capital structure, we are well-positioned financially to manage this critical time while building for the future.”

Program Highlights

Primary Biliary Cholangitis (PBC)

- *Gastroenterology* published data showing that patients receiving OCA for PBC in a clinical trial setting had greater transplant-free survival compared to patients with PBC from real-world patient registries who did not receive OCA.
- We continue to compile data from our post-marketing study, COBALT, and supplementary real-world evidence from large datasets in the U.S., UK and Europe, to be included in a regulatory submission to FDA in support of fulfilling our post-marking requirements for Ocaliva in PBC. To enable a fulsome review of our submission, we will be incorporating a greater depth of real-world analyses and adjudications of events from our Phase 4 study, COBALT, as requested by FDA, which will bring our anticipated timing for submission into 2023.
- Our OCA/bezafibrate fixed-dose combination development program is ongoing, and we continue to screen patients and add clinical sites in our two Phase 2 studies evaluating different doses of OCA and bezafibrate for the planned fixed-dose combination.

Nonalcoholic Steatohepatitis (NASH)

- We remain on track to resubmit our NDA for OCA in liver fibrosis due to NASH by the end of 2022, based on the positive new interim analysis from our Phase 3 REGENERATE study that read out earlier this year.
- Additional data from the REGENERATE study will be presented in a late-breaking oral presentation at The Liver Meeting®.
- As previously disclosed, our Phase 3 REVERSE study in patients with compensated cirrhosis due to NASH did not meet its regulatory primary endpoint. Importantly, no new safety signals for OCA were observed in this population of patients with compensated cirrhosis.

Pipeline

- Our comprehensive Phase 1 study for our next-generation FXR agonist, INT-787, has progressed to its final cohort. We look forward to sharing data from our Phase 1 studies at The Liver Meeting® as well as our lead indication and updates on our Proof-of-Concept study, FRESH, next week.

Financial Results

Revenue

- We recognized $77.6 million in U.S. net sales in the third quarter 2022 as compared to $66.6 million in U.S. net sales in the prior year quarter.

Operating Expenses

- In the quarter ended September 30, 2022, we recorded $87.7 million in total operating expenses and $82.7 million in non-GAAP adjusted operating expenses, which excludes non-cash stock-based compensation expense of $5.8 million and depreciation expense of $0.1 million and adds back ex-U.S. operating expense of $0.8 million. This compares to the quarter ended on September 30, 2021, where we recorded $86.2 million in total operating expenses and $89.6 million in non-GAAP adjusted operating expenses, which excluded non-cash stock-based compensation expense of $8.6 million and depreciation expense of $0.8 million and added back ex-U.S. operating expense of $12.8 million.

- 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 and one item for discontinued operations. 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."

Cost of Sales

- Our cost of sales were $0.4 million and $0.2 million for quarters ended September 30, 2022, and 2021, respectively. Our cost of sales for the quarters ended September 30, 2022 and 2021 consisted primarily of packaging, labeling, materials and related expenses.

Sales, General & Administrative Expenses

- Our selling, general and administrative expenses were $43.3 million in the third quarter of 2022, up from $41.3 million in the prior year quarter. The increase was primarily driven by commercial activities and costs related to our ANDA litigation.

Research & Development Expenses

- Our research and development expenses were $44.0 million in the third quarter of 2022, down from $44.7 million in the prior year quarter.

Interest Expense

- Interest expense in the quarters ended September 30, 2022 and 2021 was $5.2 million and $14.1 million, respectively. For the quarter ended September 30, 2022, interest expense is related to the principal amounts outstanding for the 2023 Convertible Notes, 2026 Convertible Notes and 2026 Convertible Secured Notes and no longer includes any accretion of debt discounts upon adoption of ASU 2020-06. For the quarter ended September 30, 2021, interest expense is related to the principal amounts outstanding for the 2023 Convertible Notes, 2026 Convertible Notes and 2026 Convertible Secured Notes.

Net Income/Loss

- In the third quarter of 2022, we reported net income of $267.5 million, an increase compared to a net loss of $3.6 million in the third quarter of 2021. The increase was driven by the gain recognized on the sale of the ex-U.S. business, partially offset by a loss on extinguishment of 2026 Convertible Secured Notes.

Cash Position

- As of September 30, 2022, we had cash, cash equivalents, restricted cash, and investment debt securities available for sale of $497.8 million. As of December 31, 2021, we had cash, cash equivalents, restricted cash, and investment debt securities available for sale of approximately $427.8 million.

Capital Structure

Convertible Secured Notes Repurchase

- In August and September 2022, we repurchased $388.9 million of 2026 Convertible Secured Notes for $258.2 million in cash and $219.4 million in equity, for a total consideration of $477.6 million. As a result of these repurchases, the principal

balance of the 2026 Convertible Secured Notes was reduced by approximately 78% to $111.1 million. As a result of these repurchases, we were able to decrease our annual cash interest expense by 58% or $13.6 million to $9.8 million on an annual basis.

2022 Financial Guidance

We are updating our full year 2022 guidance:

- Increasing Ocaliva non-GAAP adjusted net sales guidance to $340 million to $350 million from $325 million to $345 million.
- Narrowing non-GAAP adjusted operating expense guidance to $350 million to $365 million from $335 million to $365 million.

This guidance includes our international business for the first six months of the year and our ongoing U.S. business for the full year.

See “Non-GAAP Financial Measures” below. A quantitative reconciliation of projected non-GAAP adjusted net sales to total revenue is included below under the heading “Reconciliation of Non-GAAP Adjusted Net Sales to Total Revenue”. 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.

Conference Call on November 1, 2022, at 8:30 a.m. ET

We are hosting our third quarter 2022 financial results conference call and webcast on November 1, 2022, at 8:30 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) and nonalcoholic steatohepatitis (NASH). 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 net sales and non-GAAP adjusted operating expenses on a historical and projected basis. For the periods presented, non-GAAP adjusted net sales include in total revenue, as calculated and presented in GAAP, the effect of one item: total revenue from discontinued operations. 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 and one item for discontinued operations. Non-GAAP adjusted net sales and adjusted operating expenses are financial measures that have not been prepared in accordance with GAAP. Accordingly, investors should consider non-GAAP adjusted net sales and adjusted operating expenses in addition to, but not as a substitute for, total revenue and 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 net sales and 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 net sales to total revenue for all historical periods presented is included below under the heading “Reconciliation of Non-GAAP Adjusted Net Sales to Total Revenue”. 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 net sales to total revenue is included below under the heading “Reconciliation of Non-GAAP Adjusted Net Sales to Total Revenue”. 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 Liver Fibrosis and Cirrhosis due to Nonalcoholic Steatohepatitis (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. There are currently no medications approved for the treatment of NASH.

About the REGENERATE Study

REGENERATE (Randomized Global Phase 3 Study to Evaluate the Impact on NASH with Fibrosis of Obeticholic Acid Treatment) is an ongoing Phase 3, randomized, double-blind, placebo-controlled, multicenter, international study assessing the safety and efficacy of obeticholic acid (OCA) on clinical outcomes in patients with liver fibrosis due to NASH. A pre-specified 18-month interim analysis was conducted on 931 subjects who had scheduled biopsy at Month 18 to assess the effect of OCA on liver histology comparing Month 18 biopsies with baseline biopsies. REGENERATE is fully enrolled with 2,480 randomized participants and is expected to continue through clinical outcomes for verification and description of clinical benefit. The end-of-study analysis will evaluate the effect of OCA on all-cause mortality and liver-related clinical outcomes, as well as long-term safety.

About the REVERSE Study

REVERSE is a randomized, double-blind, placebo-controlled, multicenter Phase 3 study evaluating the safety and efficacy of OCA in NASH patients with compensated cirrhosis. The primary endpoint is the percentage of patients with histological improvement in fibrosis by at least one stage with no worsening of NASH using the NASH Clinical Research Network (CRN) scoring system after 18 months of treatment. Over 900 patients have been randomized in a 1:1:1 ratio to the three treatment arms: once-daily OCA 10 mg, once-daily OCA 10 mg for the first three months with titration in

accordance with the study protocol up to OCA 25 mg for the remaining study period, or once-daily placebo. Patients who successfully completed the double-blind phase of REVERSE were eligible to enroll in an open-label extension phase of the study for up to 12 additional months.

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 planned resubmission of an NDA to the FDA for OCA for liver fibrosis due to NASH, and the potential timing, review, acceptance, and approval of the NDA;
- conditions that may be imposed by regulatory authorities on our marketing approvals for our products and product candidates, including OCA for liver fibrosis due to NASH, such as the need for clinical outcomes data (and not just results based on achievement of a surrogate endpoint), any risk mitigation programs such as a Risk Evaluation and Mitigation Strategies ("REMS") program, and any related restrictions, limitations and/or warnings contained in the label of any of our products or product candidates;
- any potential side effects associated with Ocaliva for PBC, OCA for liver fibrosis due to NASH or our other product candidates that could delay or prevent approval, require that an approved product be taken off the market, require the inclusion of safety warnings or precautions, or otherwise limit the sale of such product or product candidate, including in connection with our update to the Ocaliva prescribing information in May 2021 contraindicating Ocaliva for patients with PBC and decompensated cirrhosis, a prior decompensation event, or compensated cirrhosis with evidence of portal hypertension;
- the initiation, timing, cost, conduct, progress and results of our research and development activities, preclinical studies and clinical trials, including any issues, delays or failures in identifying patients, enrolling patients, treating patients, retaining patients, meeting specific endpoints, or completing and timely reporting the results of our NASH or PBC clinical trials;
- the outcomes of interactions with regulators including the FDA regarding our clinical trials;
- our ability to establish and maintain relationships with, and the performance of, third-party manufacturers, contract research organizations and other vendors upon whom we are substantially dependent for, among other things, the manufacture and supply of our products, including Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH, and our clinical trial activities;
- our ability to identify, develop and successfully commercialize our products and product candidates, including our ability to successfully launch OCA for liver fibrosis due to NASH, if approved;
- our ability to obtain and maintain intellectual property protection for our products and product candidates, including our ability to cost-effectively file, prosecute, defend and enforce any patent claims or other intellectual property rights;
- the size and growth of the markets for our products and product candidates and our ability to serve those markets;
- the degree of market acceptance of Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH or our other product candidates among physicians, patients and healthcare payors;
- the availability of adequate coverage and reimbursement from governmental and private healthcare payors for our products, including Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH, and our ability to obtain adequate pricing for such products;
- our ability to establish and maintain effective sales, marketing and distribution capabilities, either directly or through collaborations with third parties;
- competition from existing drugs or new drugs that become available;
- our ability to attract and retain key personnel to manage our business effectively;
- our ability to prevent or defend against system failures or security or data breaches due to cyber-attacks, or cyber intrusions, including ransomware, phishing attacks and other malicious intrusions;
- our ability to comply with data protection laws;
- costs and outcomes relating to any disputes, governmental inquiries or investigations, regulatory proceedings, legal proceedings or litigation, including any securities, intellectual property, employment, product liability or other litigation;
- our collaborators' election to pursue research, development and commercialization activities;
- our ability to establish and maintain relationships with collaborators with development, regulatory and commercialization expertise;
- our need for and ability to generate or obtain additional financing;

- our estimates regarding future expenses, revenues and capital requirements and the accuracy thereof;
- our use of cash, cash equivalents and short-term investments;
- our ability to acquire, license and invest in businesses, technologies, product candidates and products;
- our ability to manage the growth of our operations, infrastructure, personnel, systems and controls;
- our ability to obtain and maintain adequate insurance coverage;
- continuing threats from COVID-19, including additional waves of infections, and their impacts including quarantines and other government actions; delays relating to our regulatory applications; disruptions relating to our ongoing clinical trials or involving our contract research organizations, study sites or other clinical partners; disruptions relating to our supply chain or involving our third-party manufacturers, distributors or other distribution partners; and facility closures or other restrictions; and the impact of the foregoing on our results of operations and financial position;
- the impact of general economic, industry, market, regulatory or political conditions;
- how we use the funds received from the sale of our ex-U.S. business to Advanz Pharma;
- disagreements or legal, operational, or other business problems arising from our ongoing relationship with Advanz Pharma, including the licensing of the ex-U.S. rights to Ocaliva for PBC and, if approved, OCA for NASH, our operational separation from our former ex-U.S. commercial operations, and our agreement to supply Advanz Pharma with OCA;
- unexpected tax, regulatory, litigation, or other liabilities;
- whether we receive any future earn-outs or royalties under the Advanz Pharma transaction documents; and
- the other risks and uncertainties identified 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.

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Intercept Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except per share data)

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

Net income/(loss)	$ 7.80	$ (0.11)	$ 7.76	$ (1.69)
Weighted average common and potential common shares outstanding:				
Basic and diluted	34,293	31,736	31,262	32,679

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

	September 30, 2022	December 31, 2021 (1)
Cash, cash equivalents, restricted cash and investment debt securities, available for sale	$ 497,832	$ 427,808
Total assets, including current assets of discontinued operations	$ 559,404	$ 527,023
Total liabilities, including current liabilities of discontinued operations (2)	$ 451,728	$ 710,985
Stockholders' equity (deficit)	$ 107,676	$ (183,962)

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(1) Derived from the reclassified financial statements included in Intercept's Quarterly Report on Form 10-Q for the period ended September 30, 2022.

(2) Includes $332.3 million and $539.8 million related to the 2023 Convertible Notes, 2026 Convertible Notes and the 2026 Secured Convertible Notes (together, the "Convertible Notes") as of September 30, 2022 and December 31, 2021, respectively. The aggregate outstanding principal amount of the Convertible Notes was $336.3 million as of September 30, 2022 and $729.0 million as of December 31, 2021.

Reconciliation of Non-GAAP Adjusted Net Sales to Total Revenue
(Unaudited)
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Total revenue	$ 77,588	$ 66,640	$ 208,491	$ 192,117
Adjustment:				
ex-U.S. revenue (discontinued operations)	-	-	58,065	52,760
Non-GAAP adjusted net sales	$ 77,588	$ 66,640	$ 266,556	$ 244,877

	2022 Financial Guidance	
	Low	High
Total revenue	$ 281,935	$ 291,935
Adjustment:		
ex-U.S. revenue (discontinued operations)	58,065	58,065
Non-GAAP adjusted net sales	$ 340,000	$ 350,000

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Total operating expenses	$ 87,732	$ 86,207	$ 258,722	$ 263,733
Adjustments:				
Add: ex-U.S. operating expenses (discontinued operations)	822	12,840	29,545	42,138

Less: Stock-based compensation	5,788	8,616	21,052	25,483
Depreciation	80	808	2,946	2,557
Non-GAAP adjusted operating expenses	$ 82,686	$ 89,623	$ 264,269	$ 277,831

Source: Intercept Pharmaceuticals, Inc.