



Intercept Pharmaceuticals Reports Fourth Quarter and Full Year 2021 Financial Results, Issues 2022 Financial Guidance and Provides Business Update

March 2, 2022

Worldwide Ocaliva® net sales of \$92.4 million and \$363.5 million for the fourth quarter and full year 2021, representing 11% and 16% growth over the prior year

Company provides 2022 Ocaliva net sales guidance of \$375 million to \$405 million and non-GAAP adjusted operating expense guidance of \$360 million to \$390 million

Data package from REGENERATE Phase 3 study in fibrosis due to NASH being generated; targeting potential pre-submission meeting with FDA in 1H 2022

Topline results from REVERSE Phase 3 study in compensated cirrhosis due to NASH now expected in Q3

Company to host conference call today at 8:30 a.m. ET

NEW YORK, March 02, 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 fourth quarter and full year ended on December 31, 2021.

"In 2021, our team was focused on continuing to grow our foundational PBC business; executing on our clinical and regulatory goals in PBC and NASH; and advancing our pipeline while also taking important steps to significantly strengthen our financial position," said Jerry Durso, President and Chief Executive Officer of Intercept. "Our team delivered strong double-digit revenue growth for Ocaliva, despite the challenges associated with the pandemic and the U.S. label update. Looking ahead, we continue to see long-term potential for Ocaliva given the number of patients with PBC who are eligible for second-line therapy."

"We also made important progress in generating what will ultimately be the largest data set in the NASH field," Durso continued. "We remain focused on delivering the new data package from our Phase 3 REGENERATE study, and if we believe these data support accelerated approval, we will continue to target a potential pre-submission meeting with FDA in the first half of this year. We also look forward to communicating topline results from the Phase 3 REVERSE study, the only active late-stage study in compensated cirrhosis due to NASH, a disease with no approved therapies. Given the magnitude and complexity of these analyses, we now expect to deliver these data in the third quarter of this year. Taken together, REGENERATE and REVERSE continue to represent the most robust, active clinical development program to date in NASH and include more than 3,300 patients across both studies."

Ocaliva (obeticholic acid) Commercial Highlights

Full year 2021 Ocaliva net sales were \$363.5 million, which represented growth of 16% as compared to the prior year. Ocaliva net sales in 2021 were comprised of U.S. net sales of \$260.8 million and ex-U.S. net sales of \$102.7 million, as compared to U.S. net sales of \$234.0 million and ex-U.S. net sales of \$78.7 million in 2020.

We recognized \$92.4 million of Ocaliva net sales in the fourth quarter of 2021, as compared to \$83.3 million in the prior year quarter. Ocaliva net sales in the fourth quarter of 2021 were comprised of U.S. net sales of \$68.7 million and ex-U.S. net sales of \$23.7 million, as compared to U.S. net sales of \$64.9 million and ex-U.S. net sales of \$18.4 million in the prior year quarter.

Selected Fourth Quarter and Full Year 2021 Financial Results

Revenues

We recognized \$92.4 million in total revenue in the fourth quarter of 2021, as compared to \$83.3 million in total revenue in the prior year quarter.

We recognized \$363.5 million in total revenue in 2021, as compared to \$312.7 million in 2020.

Operating Expenses

Our cost of sales was \$1.0 million in the fourth quarter of 2021, as compared to \$0.8 million in the prior year quarter. Cost of sales was \$3.1 million in 2021, as compared to \$5.3 million in 2020. Our cost of sales for the quarters and years ended December 31, 2021 and 2020 consisted primarily of packaging, labeling, materials and related expenses.

Our selling, general and administrative expenses decreased to \$60.6 million in the fourth quarter of 2021, from \$70.0 million in the prior year quarter. The fourth quarter period-over-period decrease was primarily driven by reductions from the September 2020 restructuring activities, including reduction of activities associated with the potential approval and commercialization of OCA for liver fibrosis due to NASH. Selling, general and administrative expenses decreased to \$230.9 million in 2021, from \$332.5 million in 2020. The full year period-over-period decrease was primarily driven by decreases in expenses relating to our activities associated with the potential approval and commercialization of OCA for liver fibrosis due to NASH.

Our research and development expenses decreased to \$51.7 million in the fourth quarter of 2021, from \$51.9 million in the prior year quarter. The fourth quarter period-over-period results were primarily driven by a reduction in costs associated with NASH development activities, offset by increased development activities for cholestasis and pipeline programs. Research and development expenses decreased to \$185.3 million in 2021,

down from \$191.5 million in 2020. The full year period-over-period decrease was primarily driven by lower personnel costs, including stock compensation expense and lower costs for NASH-related R&D activities, offset by the recognition of lower R&D tax credits and higher costs for cholestasis related R&D activities.

In the quarters ended December 31, 2021 and 2020, we recorded \$113.3 million and \$123.9 million, respectively, in total operating expenses and \$104.4 million and \$106.6 million, respectively, in non-GAAP adjusted operating expenses, which excludes non-cash stock-based compensation expense of \$8.4 million and \$16.5 million, respectively, and depreciation expense of \$0.5 million and \$0.8 million, respectively.

In the years ended December 31, 2021 and 2020, we recorded \$419.1 million and \$543.9 million, respectively, in total operating expenses and \$382.3 million and \$480.0 million, respectively, in non-GAAP adjusted operating expenses, which excludes non-cash stock-based compensation expense of \$33.8 million and \$60.8 million, respectively, and depreciation expense of \$3.0 million and \$3.1 million, respectively.

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 December 31, 2021 and 2020 was \$15.3 million and \$12.3 million, respectively. Interest expense in the years ended December 31, 2021 and 2020 was \$54.4 million and \$48.1 million, respectively. For the three months and year ended December 31, 2021, interest expense related to the Convertible Senior Secured Notes due 2026 (the “2026 Convertible Secured Notes”) that we issued in August 2021, the Convertible Senior Notes due 2026 (the “2026 Convertible Notes”) that we issued in May 2019 and the Convertible Senior Notes due 2023 (the “2023 Convertible Notes”) that we issued in July 2016. For the three months and year ended December 31, 2020, interest expense related to the 2026 Convertible Notes and the 2023 Convertible Notes.

Net Loss

In the fourth quarter and full year of 2021 we reported a net loss of \$36.3 million and \$91.4 million, respectively, a decrease compared to a net loss of \$52.1 million and \$274.9 million in the fourth quarter and full year 2020.

Cash Position

As of December 31, 2021, we had cash, cash equivalents, restricted cash, and investment debt securities available for sale of approximately \$429.4 million. As of December 31, 2020, we had cash, cash equivalents, restricted cash, and investment debt securities available for sale of approximately \$477.2 million.

2022 Financial Guidance

We are announcing 2022 Ocaliva net sales guidance of \$375 million to \$405 million. In addition, we are announcing 2022 non-GAAP adjusted operating expense guidance of \$360 million to \$390 million. See “Non-GAAP Financial Measures” below. 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 March 2, 2022 at 8:30 a.m. ET

We are hosting our fourth quarter and full year 2021 financial results conference call and webcast on March 2, 2022 at 8:30 a.m. ET. The conference call will be available on the investor page of our website at <http://ir.interceptpharma.com> or by calling (855) 232-3919 (toll-free) with passcode 3258502. A replay of the call will be available on our website shortly following the completion of the call and will be available for two weeks.

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). Founded in 2002 in New York, Intercept has operations in the United States, Europe and Canada. 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 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 is a Phase 3, randomized, double-blind, placebo-controlled, multicenter 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 analysis was conducted to assess the effect of OCA on liver histology comparing month 18 biopsies with baseline. REGENERATE has completed target enrollment for the clinical outcomes cohort, with 2,480 adult NASH patients randomized at over 300 qualified centers worldwide, 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 complete the double-blind phase of REVERSE will be eligible to enroll in an open-label extension phase 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 ($\geq 5\%$) 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 for OCA for the treatment of liver fibrosis due to NASH by the U.S. Food and Drug Administration (FDA), our intent to work with the FDA to address the issues raised in the 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 the date of this release, 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: our ability to successfully commercialize Ocaliva for PBC; our ability to maintain our regulatory approval of Ocaliva for PBC in the United States, Europe, Canada, Israel, Australia and other jurisdictions in which we have or may receive marketing authorization; 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 following the issuance of the CRL by the FDA; 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; 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 REMS, 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 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 in the jurisdictions in which we intend to seek approval or completing and timely reporting the results of our NASH or PBC clinical trials; the outcomes of interactions with regulators (e.g., the FDA and the European Medicines Agency) 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 impact of the foregoing on our results of operations and financial position; the impact of general U.S. and foreign economic, industry, market, regulatory or political conditions, including the impact of Brexit; and the other risks and uncertainties identified in our periodic filings filed with the U.S. Securities and Exchange Commission, 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 December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Revenue:				
Product revenue, net	\$ 92,404	\$ 83,268	\$ 363,468	\$ 312,690
Total revenue	92,404	83,268	363,468	312,690

Operating expenses:

Cost of sales	1,014	767	3,100	5,322
Selling, general and administrative	60,590	69,956	230,855	332,493
Research and development	51,666	51,898	185,272	191,485
Restructuring	-	1,249	(86)	14,630
Total operating expenses	113,270	123,870	419,141	543,930
Operating loss	(20,866)	(40,602)	(55,673)	(231,240)
Other income (expense):				
Interest expense	(15,316)	(12,253)	(54,419)	(48,054)
Gain on extinguishment of debt	-	-	16,511	-
Other (loss)/income, net	(98)	708	2,155	4,414
	(15,414)	(11,545)	(35,753)	(43,640)
Net loss	\$ (36,280)	\$ (52,147)	\$ (91,426)	\$ (274,880)
Net loss per common and potential common share:				
Basic and diluted	\$ (1.23)	\$ (1.58)	\$ (2.87)	\$ (8.34)
Weighted average common and potential common shares outstanding:				
Basic and diluted	29,563	33,007	31,894	32,970

Condensed Consolidated Balance Sheet Information

(In thousands)

	December 31, 2021	December 31, 2020
Cash, cash equivalents, restricted cash and investment debt securities, available for sale	\$ 429,389	\$ 477,170
Total assets	\$ 527,023	\$ 580,489
Total liabilities (1)	\$ 710,985	\$ 747,342
Stockholders' deficit	\$ (183,962)	\$ (166,853)

(1) Includes \$539.8 million related to the 2023 Convertible Notes, 2026 Convertible Notes and the 2026 Secured Convertible Notes (together, the "Convertible Notes") as of December 31, 2021 and \$560.6 million related to the 2023 Convertible Notes and 2026 Convertible Notes as of December 31, 2020. Intercept separately accounts for the debt and equity components of the Convertible Notes. The aggregate outstanding principal amount of the Convertible Notes was \$729.0 million as of December 31, 2021, and \$690.0 million as of December 31, 2020.

Reconciliation of Non-GAAP Adjusted Operating Expenses to Total Operating Expenses

(Unaudited)

(In thousands)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Total operating expenses	\$ 113,270	\$ 123,870	\$ 419,141	\$ 543,930
Adjustments:				
Stock-based compensation	8,405	16,469	33,888	60,850
Depreciation	421	836	2,978	3,118
Non-GAAP adjusted operating expenses	\$ 104,444	\$ 106,565	\$ 382,275	\$ 479,962



Source: Intercept Pharmaceuticals, Inc.