

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): March 2, 2023

Intercept Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

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|---|--|--|
| Delaware (State or other jurisdiction of incorporation) | 001-35668 (Commission File Number) | 22-3868459 (IRS Employer Identification No.) |
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305 Madison Avenue, Morristown, NJ 07960
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (646) 747-1000

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|-------------------|---|
| Common Stock, par value \$0.001 per share | ICPT | Nasdaq Global Select Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

Item 2.02 Results of Operations and Financial Condition.

On March 2, 2023, Intercept Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter and year ended December 31, 2022.

A copy of the press release is attached as Exhibit 99.1 and incorporated by reference.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

| Exhibit Number | Description |
|----------------------|---|
| 99.1 | Press Release |
| 104 | Cover Page Interactive Data File (embedded as Inline XBRL document) |

The information in Item 2.02 and Exhibit 99.1 is being furnished, not filed.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INTERCEPT PHARMACEUTICALS, INC.

By: /s/ Andrew Saik

Name: Andrew Saik

Title: Chief Financial Officer

Date: March 2, 2023



Intercept Pharmaceuticals Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Updates; Issues 2023 Financial Guidance

U.S. Ocaliva[®] net sales of \$77.2 million and \$285.7 million for the fourth quarter and full year 2022, representing 13% and 10% growth over the prior year

Worldwide Ocaliva[®] non-GAAP adjusted net sales of \$343.8 million for the full year 2022

As of December 31, 2022, Company has cash, cash equivalents, restricted cash, and investment debt securities available for sale of \$490.9 million

PDUFA target action date set for June 22, 2023, for OCA for the treatment of pre-cirrhotic liver fibrosis due to NASH

Company has fully resolved the patent infringement litigation that was scheduled for trial on February 27, 2023; settlements protect Ocaliva market exclusivity into the 2030s

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

MORRISTOWN, NJ, March 2, 2023 – 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, 2022.

“2022 was a strong year for Intercept,” said Jerry Durso, President and Chief Executive Officer of Intercept. “We resubmitted our new drug application for OCA in pre-cirrhotic liver fibrosis due to NASH, advanced our pipeline programs in PBC and severe alcohol-associated hepatitis, and successfully delivered double-digit revenue growth for Ocaliva. Moreover, we fully resolved the patent infringement case for Ocaliva that was scheduled for trial this week, reinforcing the long-term opportunity we have in PBC. This progress was complemented by the transformation of our capital structure, positioning us well to manage this exciting period and drive growth.”

“Looking ahead in NASH, we continue to believe that OCA has the potential to become an impactful therapy given the strong and confirmed antifibrotic effect, and manageable safety profile, demonstrated in our landmark Phase 3 REGENERATE study,” Durso continued. “With the acceptance of our NDA and a PDUFA target action date on the horizon, we are focused on advancing through the regulatory review process and preparing for an anticipated commercial launch.”

Company Highlights

Primary Biliary Cholangitis (PBC)

- Intercept continues to compile data from its 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 this year in support of fulfilling post-marking requirements for Ocaliva in PBC.
- The OCA and bezafibrate (PPAR) fixed-dose combination development program is progressing. One of Intercept's two Phase 2 studies is now fully enrolled, and the Company is accelerating recruitment of patients into a second. Intercept anticipates selecting doses for its Phase 3 fixed-dose combination, as well as sharing data from planned analyses of the Phase 1 and Phase 2 studies, later this year.
- The Company has fully resolved the patent infringement case in the United States District Court for the District of Delaware that was scheduled for trial on February 27, 2023, and the case has been terminated by the Court. Similar patent litigation previously disclosed by the Company against another ANDA filer seeking approval to market generic Ocaliva remains pending, with trial scheduled for July 22, 2024.

Nonalcoholic Steatohepatitis (NASH)

- In January 2023, the U.S. FDA accepted the company's NDA for OCA in pre-cirrhotic liver fibrosis due to NASH. FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of June 22, 2023, for the application. Intercept anticipates an advisory committee meeting as part of the FDA review process; however, a date has not yet been confirmed.
- Intercept's NDA for OCA in pre-cirrhotic liver fibrosis due to NASH is supported by a robust body of evidence from the OCA NASH clinical development program, including two positive 18-month interim analyses from the pivotal Phase 3 REGENERATE study and a robust safety assessment of 2,477 patients, with nearly 1,000 on study drug for four years. OCA has demonstrated a strong and confirmed antifibrotic effect across multiple analyses.

Pipeline

- In November 2022, Intercept announced severe alcohol-associated hepatitis (sAH) as the lead indication for the company's next-generation FXR agonist, INT-787. The company also initiated the 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 sAH.
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Selected Fourth Quarter and Full Year 2022 Financial Results

Revenues

- Intercept recognized \$77.2 million in U.S. net sales in the fourth quarter 2022 as compared to \$68.7 million in U.S. net sales in the prior year quarter.
- Intercept recognized \$285.7 million in total U.S. net sales in 2022 as compared to \$260.8 million in total U.S. net sales in 2021.

Operating Expenses

- In the quarters ended December 31, 2022 and 2021, Intercept recorded \$96.1 million and \$97.8 million, respectively, in total operating expenses and \$90.9 million and \$104.4 million, respectively, in non-GAAP adjusted operating expenses, which excludes non-cash stock-based compensation expense of \$5.3 million and \$8.4 million, respectively, and depreciation expense of \$0.1 million and \$0.4 million, respectively, and adds back ex-U.S. operating expense of \$0.2 million and \$15.5 million, respectively.
 - In the years ended December 31, 2022 and 2021, Intercept recorded \$353.9 million and \$361.2 million, respectively, in total operating expenses and \$355.2 million and \$382.3 million, respectively, in non-GAAP adjusted operating expenses, which excludes non-cash stock-based compensation expense of \$26.4 million and \$33.9 million, respectively, and depreciation expense of \$3.0 million and \$3.0 million, respectively, and adds back ex-U.S. operating expense of \$30.7 million and \$58.0 million, respectively.
 - Selling, general and administrative expenses increased to \$55.4 million in the fourth quarter of 2022, from \$46.3 million in the prior year quarter. The fourth quarter period-over-period increase was primarily driven by investment in NASH launch preparation. Selling, general and administrative expenses were \$176.3 million in 2022, compared to \$177.5 million in 2021 with a decrease in personnel-related costs, offset by an increase in NASH launch preparation.
 - Research and development expenses decreased to \$40.7 million in the fourth quarter of 2022, from \$51.1 million in the prior year quarter. The fourth quarter period-over-period decrease was primarily driven by lower NASH costs and cost-sharing reimbursements from Advanz. Research and development expenses decreased to \$176.6 million in 2022, down from \$182.7 million in 2021. The full year period-over-period decrease was primarily driven by lower NASH costs and cost-sharing reimbursements from Advanz, offset by the recognition of lower R&D tax credits.
 - 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.”
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Interest Expense

- Interest expense in the quarters ended December 31, 2022 and 2021 was \$2.8 million and \$15.3 million, respectively. Interest expense in the years ended December 31, 2022 and 2021 was \$21.4 million and \$54.4 million, respectively. For the fourth quarters and years ended December 31, 2022 and 2021, interest expense was related to our Convertible Notes.

Net Income/Loss

- In the fourth quarter and full year of 2022, Intercept reported a net loss of \$20.8 million and net income of \$221.8 million, respectively, a decrease compared to a net loss of \$36.3 million and \$91.4 million in the fourth quarter and full year 2021. The full year 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 December 31, 2022, Intercept had cash, cash equivalents, restricted cash, and investment debt securities available for sale of \$490.9 million. As of December 31, 2021, Intercept 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, Intercept 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, the company decreased annual cash interest expense by 58% or \$13.6 million to \$9.8 million.

2023 Financial Guidance

- Intercept is announcing 2023 Ocaliva net sales guidance of \$310 million to \$340 million, as compared to 2022 Ocaliva U.S. net sales of \$285.7 million.
 - In addition, the company is announcing 2023 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.
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Conference Call on March 2, 2023, at 8:30 a.m. ET

The fourth quarter and full-year 2022 financial results conference call and webcast will take place on March 2, 2023, 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), 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 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 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 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 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 interim analysis was conducted in 931 subjects who had a liver biopsy at Month 18 to assess the effect of OCA on liver histology as compared to baseline biopsies. REGENERATE is fully enrolled with 2,480 randomized participants and is expected to continue while collecting data on the incidence of clinical outcomes for verification and description of clinical benefit. The end-of-study primary endpoint will compare the impact of treatment group (placebo, OCA 10 mg or OCA 25 mg daily) on all-cause mortality and liver-related clinical outcomes, as well as on long-term safety.

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 ($\geq 5\%$) 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 (“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.
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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;
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- 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;
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- 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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Contact

For more information about Intercept, please contact:

For investors:

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For media:

Karen Preble, Executive Director, Global Corporate Communications

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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, | |
|---|------------------------------------|--------------------|----------------------------|---------------------|
| | 2022 | 2021 | 2022 | 2021 |
| Revenue: | | | | |
| Product revenue, net | \$ 77,219 | \$ 68,633 | \$ 285,710 | \$ 260,750 |
| Total revenue | <u>77,219</u> | <u>68,633</u> | <u>285,710</u> | <u>260,750</u> |
| Operating expenses: | | | | |
| Cost of sales | 29 | 404 | 984 | 1,205 |
| Selling, general and administrative | 55,418 | 46,338 | 176,303 | 177,488 |
| Research and development | 40,681 | 51,067 | 176,639 | 182,747 |
| Restructuring | - | - | - | (284) |
| Total operating expenses | <u>96,128</u> | <u>97,809</u> | <u>353,926</u> | <u>361,156</u> |
| Operating loss | <u>(18,909)</u> | <u>(29,176)</u> | <u>(68,216)</u> | <u>(100,406)</u> |
| Other income (expense): | | | | |
| Interest expense | (2,806) | (15,317) | (21,385) | (54,419) |
| (Loss)/gain on extinguishment of debt | - | - | (91,778) | 16,511 |
| Other income, net | 4,172 | (103) | 6,521 | 1,962 |
| Loss from continuing operations | <u>\$ (17,543)</u> | <u>\$ (44,596)</u> | <u>\$ (174,858)</u> | <u>\$ (136,352)</u> |
| (Loss)/Income from discontinued operations, net of tax | <u>\$ (3,281)</u> | <u>\$ 8,315</u> | <u>\$ 396,674</u> | <u>\$ 44,926</u> |
| Net (loss)/income, net of tax | <u>\$ (20,824)</u> | <u>\$ (36,281)</u> | <u>\$ 221,816</u> | <u>\$ (91,426)</u> |
| Net income/(loss) per common and potential common share: | | | | |
| Net loss from continuing operations | \$ (0.42) | \$ (1.51) | \$ (5.17) | \$ (4.28) |
| Net (loss)/income from discontinued operations | \$ (0.08) | \$ 0.28 | \$ 11.72 | \$ 1.41 |
| Net (loss)/income | \$ (0.50) | \$ (1.23) | \$ 6.56 | \$ (2.87) |
| Weighted average common and potential common shares outstanding: | | | | |
| Basic and diluted | 41,479 | 29,563 | 33,837 | 31,894 |

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

| | December 31, 2022 | December 31, 2021 (1) |
|--|------------------------------|----------------------------------|
| Cash, cash equivalents, restricted cash and investment debt securities, available for sale | \$ 490,909 | \$ 427,808 |
| Total assets, including current assets of discontinued operations | \$ 553,711 | \$ 527,023 |
| Total liabilities, including current liabilities of discontinued operations (2) | \$ 460,634 | \$ 710,985 |
| Stockholders' equity (deficit) | \$ 93,077 | \$ (183,962) |

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

(2) Includes \$332.7 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 December 31, 2022 and December 31, 2021, respectively. The aggregate outstanding principal amount of the Convertible Notes was \$336.3 million as of December 31, 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 December 31, | | Twelve Months Ended December 31, | |
|---|------------------------------------|-----------|-------------------------------------|------------|
| | 2022 | 2021 | 2022 | 2021 |
| Total revenue | \$ 77,219 | \$ 68,633 | \$ 285,710 | \$ 260,750 |
| Adjustment: | | | | |
| ex-U.S. revenue (discontinued operations) | - | - | 58,065 | 52,760 |
| Non-GAAP adjusted net sales | \$ 77,219 | \$ 68,633 | \$ 343,775 | \$ 313,510 |

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

| | Three Months Ended December 31, | | Twelve Months Ended December 31, | |
|---|------------------------------------|------------|-------------------------------------|------------|
| | 2022 | 2021 | 2022 | 2021 |
| Total operating expenses | \$ 96,128 | \$ 97,809 | \$ 353,926 | \$ 361,156 |
| Adjustments: | | | | |
| Add: ex-U.S. operating expenses (discontinued operations) | 227 | 15,461 | 30,683 | 57,985 |
| Less: Stock-based compensation | 5,338 | 8,405 | 26,390 | 33,888 |
| Depreciation | 92 | 421 | 3,038 | 2,978 |
| Non-GAAP adjusted operating expenses | \$ 90,925 | \$ 104,444 | \$ 355,181 | \$ 382,275 |
