

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): August 2, 2023

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

Delaware	001-35668	22-3868459
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

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 August 2, 2023, Intercept Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2023.

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.*

<u>Exhibit Number</u>	<u>Description</u>
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: August 2, 2023



Intercept Pharmaceuticals Reports Second Quarter 2023 Financial Results and Provides Business Updates

- *Ocaliva® (obeticholic acid or OCA) net sales of \$83.7 million, representing 17% growth over the prior year quarter*
- *Company updates full-year 2023 Ocaliva net sales guidance to \$320 million to \$340 million; reiterates non-GAAP adjusted operating expense guidance of \$350 million to \$370 million*
- *Restructuring plan is on track to reduce operating expenses by approximately \$140 million*
- *Company expects to achieve meaningful profitability in 2024*
- *OCA-bezafibrate combination making considerable progress; enrollment of both Phase 2 studies completed; Company expects to have necessary data to submit request in 2023 for End-of-Phase 2 meeting with FDA*
- *Company to host conference call today at 8:30 a.m. ET*

MORRISTOWN, NJ, August 2, 2023 – Intercept Pharmaceuticals, Inc. (Nasdaq: ICPT), a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat rare and serious liver diseases, today announced its financial results for the quarter ended on June 30, 2023.

“Intercept delivered strong double-digit growth of Ocaliva for the fourth consecutive quarter and made considerable progress with the OCA-bezafibrate combination program, including presenting positive new data that suggest best-in-class potential,” said Jerry Durso, President and Chief Executive Officer of Intercept. “Our exceptional execution in PBC, coupled with the implementation of our restructuring plan to significantly reduce costs, has Intercept well on the way toward quickly achieving profitability while advancing our leadership position in rare and serious liver diseases.”

Selected Second Quarter 2023 Highlights

Revenue

- Intercept recognized \$83.7 million in net sales in the second quarter 2023, representing 17% growth compared to \$71.8 million in net sales in the prior year quarter.

Operating Expenses

- In the quarter ended June 30, 2023, Intercept recorded \$90.8 million in total operating expenses and \$84.5 million in non-GAAP adjusted operating expenses, which excludes non-cash stock-based compensation expense of \$6.2 million and depreciation expense of \$0.1 million. This compares to the quarter ended on June 30, 2022, where Intercept recorded \$85.1 million in total operating expenses and \$79.6 million in non-GAAP adjusted operating expenses, which excluded non-cash stock-based compensation expense of \$5.4 million and depreciation expense of \$0.1 million.
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- Selling, general and administrative expenses increased to \$53.3 million in the second quarter of 2023, from \$40.0 million in the prior year quarter. The increase was primarily driven by investment in NASH launch preparation costs.
- Research and development expenses decreased to \$37.3 million in the second quarter of 2023, from \$44.8 million in the prior year quarter. The decrease was primarily driven by the completion of the REVERSE study and R&D cost-sharing reimbursements.
- References in this press release to “non-GAAP adjusted operating expenses” mean our total operating expenses, as calculated and presented in accordance with U.S. Generally Accepted Accounting Principles (“GAAP”), adjusted for the effects of two non-cash items: stock-based compensation and depreciation. See “Non-GAAP Financial Measures” below. A reconciliation of non-GAAP adjusted operating expenses to total operating expenses for all historical periods presented is included below under the heading “Reconciliation of Non-GAAP Adjusted Operating Expenses to Total Operating Expenses.”

Interest Expense

- Interest expense in the quarters ended June 30, 2023, and 2022 was \$2.8 million and \$6.7 million, respectively. For the quarters ended June 30, 2023 and 2022, interest expense was related to our Convertible Notes.

Net Loss

- In the second quarter 2023, Intercept reported a net loss from continuing operations of \$5.8 million, a decrease compared to a net loss from continuing operations of \$20.3 million in the second quarter 2022.

Cash Position

- As of June 30, 2023, Intercept had cash, cash equivalents, restricted cash, and investment debt securities available for sale of \$415.0 million. As of December 31, 2022, Intercept had cash, cash equivalents, restricted cash, and investment debt securities available for sale of approximately \$490.9 million.
 - The 2023 Convertible Notes matured on July 1, 2023, upon which the Company made a cash repayment for the total principal amount due of \$109.8 million.
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2023 Financial Guidance

- Intercept has updated its full-year 2023 Ocaliva® net sales guidance to \$320-\$340 million from \$310-\$340 million.
- In June 2023, the Company lowered 2023 non-GAAP adjusted operating expense guidance to \$350-\$370 million, inclusive of restructuring costs.
- The Company remains on track to achieve an expected net reduction in annual non-GAAP adjusted operating expenses of approximately \$140 million – relative to updated 2023 non-GAAP adjusted operating expense guidance.

Corporate Restructuring

- In June 2023, Intercept announced an organizational restructuring to significantly reduce operating expenses, including discontinuing all nonalcoholic steatohepatitis (NASH)-related investment.
- The Company has initiated its workforce reduction, which affects most areas of the company, and anticipates completing the majority of measures by the end of this year. The Company has completed the first wave of notifications, which impacts commercial and general & administrative functions. Intercept plans to maintain the scale of its current field sales organization to support the growth potential of Ocaliva.
- The Company continues to make progress in closing out the REGENERATE study. The closeout process is being actively implemented. REGENERATE trial sites have been notified and the process is expected to be substantially completed by the end of this year.

Primary Biliary Cholangitis (PBC)

- Intercept's combination program for OCA, a farnesoid X receptor (FXR) agonist, and bezafibrate, a pan-peroxisome proliferator-activated receptor (pan-PPAR) agonist, has made considerable progress. The Company has now completed enrollment of both Phase 2 studies (747-213 / NCT04594694, 747-214 / NCT05239468) that are exploring a range of therapeutic doses for the combination of OCA and bezafibrate.
 - On June 23rd, Intercept shared new data at the 2023 European Association for the Study of the Liver (EASL) Congress from a planned interim analysis of Phase 2 study 747-213 assessing improvements in serum biomarkers of cholestasis in patients with PBC after treatment with OCA and bezafibrate. Results showed that the combination of OCA 5-10 mg and bezafibrate 400 mg was effective in normalizing key biochemical markers associated with PBC-induced liver damage.
 - The Company expects to have the necessary data from the OCA-bezafibrate combination program to submit a request in 2023 for an End-of-Phase 2 meeting with the FDA. These data include analyses from both Phase 2 studies, in addition to Phase 1 and preclinical data.
 - Intercept remains on track for its sNDA submission to the FDA this year in support of fulfilling post-marketing requirements for Ocaliva in PBC. This submission will include data from the Company's post-marketing study, COBALT, and supplementary real-world evidence from large datasets in the U.S. and Europe.
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Pipeline

- The Company continues to progress its FRESH (FXR Effect on Severe Alcohol-Associated Hepatitis) study, a Phase 2a trial evaluating the safety, tolerability, efficacy and pharmacokinetics of INT-787 in patients with severe alcohol-associated hepatitis (sAH).

Conference Call on August 2, 2023, at 8:30 a.m. ET

The conference call and webcast discussing the Company's second quarter 2023 financial results will take place on August 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 rare and serious liver diseases, including primary biliary cholangitis (PBC) and severe alcohol-associated hepatitis (sAH). For more information, please visit www.interceptpharma.com or connect with the Company on [Twitter](#) and [LinkedIn](#).

Non-GAAP Financial Measures

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

About the Investigational OCA-bezafibrate Fixed-Dose Combination

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

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

About 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.**
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- **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.
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- **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;
- the safety and efficacy of our approved product, Ocaliva (obeticholic acid or “OCA”) for primary biliary cholangitis (“PBC”), and our product candidates;
- the timing, acceptance, review, feedback, and potential approval for our regulatory filings with the U.S. Food and Drug Administration (the “FDA”) or other regulators;
- the commercial prospects of our products or product candidates;
- our planned corporate restructuring; 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 our products and product candidates;
 - 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;
 - any advisory committee recommendation or dispute resolution determination that any of our products or product candidates should not be approved, or should be approved only under certain conditions;
 - any future determination that the regulatory applications and subsequent information that we submit for our products and product candidates 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, 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 labels of any of our products or product candidates;
 - any potential side effects associated with Ocaliva for PBC or our other products or 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;
 - 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 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 our clinical trial activities;
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- our ability to identify, develop, and successfully commercialize our products and product candidates;
 - 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 or our other products or 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 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 our operations, infrastructure, personnel, systems, and controls, including our planned corporate restructuring;
 - our ability to obtain and maintain adequate insurance coverage;
 - the impact of general economic, industry, market, regulatory, or political conditions;
 - how we use our cash on hand, as well as cash equivalents and investment securities;
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- disagreements or legal, operational, or other business problems arising from our ongoing relationship with Advanz Pharma and its affiliates (collectively, “Advanz”), the purchaser of our ex-U.S. business, including the licensing of the ex-U.S. rights to Ocaliva for PBC, our operational separation from our former ex-U.S. commercial operations, and our agreement to supply Advanz with OCA;
- unexpected tax, regulatory, litigation, or other liabilities;
- whether we receive any future earn-outs under the transaction documents with Advanz; and
- the other risks and uncertainties identified in our periodic filings filed with the U.S. Securities and Exchange Commission (the “SEC”), including our latest Annual Report on Form 10-K and/or Quarterly Report on Form 10-Q.

Contact

For more information about Intercept, please contact:

For investors:

Nareg Sagherian, Executive Director, Global Investor Relations

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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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue:				
Product revenue, net	\$ 83,718	\$ 71,757	\$ 151,676	\$ 130,903
Total revenue	<u>83,718</u>	<u>71,757</u>	<u>151,676</u>	<u>130,903</u>
Operating expenses:				
Cost of sales	185	309	407	532
Selling, general and administrative	53,346	39,985	111,003	77,739
Research and development	37,306	44,826	79,017	92,719
Total operating expenses	<u>90,837</u>	<u>85,120</u>	<u>190,427</u>	<u>170,990</u>
Operating loss	<u>(7,119)</u>	<u>(13,363)</u>	<u>(38,751)</u>	<u>(40,087)</u>
Other income (expense):				
Interest expense	(2,812)	(6,669)	(5,621)	(13,342)
Other income (expense), net	4,105	(289)	6,665	(342)
Loss from continuing operations	<u>\$ (5,826)</u>	<u>\$ (20,321)</u>	<u>\$ (37,707)</u>	<u>\$ (53,771)</u>
(Loss)/Income from discontinued operations	<u>\$ (36)</u>	<u>\$ 12,793</u>	<u>\$ (290)</u>	<u>\$ 28,959</u>
Net loss	<u>\$ (5,862)</u>	<u>\$ (7,528)</u>	<u>\$ (37,997)</u>	<u>\$ (24,812)</u>
Net income/(loss) per common and potential common share:				
Net loss from continuing operations	\$ (0.14)	\$ (0.68)	\$ (0.90)	\$ (1.81)
Net (loss)/income from discontinued operations	\$ -	\$ 0.43	\$ (0.01)	\$ 0.97
Net loss	\$ (0.14)	\$ (0.25)	\$ (0.91)	\$ (0.83)
Weighted average common and potential common shares outstanding:				
Basic and diluted	41,731	29,747	41,700	29,721

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

	June 30, 2023	December 31, 2022 (1)
Cash, cash equivalents, restricted cash and investment debt securities, available for sale	\$ 414,991	\$ 490,909
Total assets	\$ 484,635	\$ 553,711
Total liabilities (2)	\$ 417,089	\$ 460,634
Stockholders' equity (deficit)	\$ 67,546	\$ 93,077

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

(2) Includes \$333.4 million and \$332.7 million related to the 2023 Convertible Notes, 2026 Convertible Notes and the 2026 Secured Convertible Notes (together, the "Convertible Notes") as of June 30, 2023 and December 31, 2022, respectively. The aggregate outstanding principal amount of the Convertible Notes was \$336.3 million as of June 30, 2023 and December 31, 2022, respectively.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Total operating expenses	\$ 90,837	\$ 85,120	\$ 190,427	\$ 170,990
Adjustments:				
Stock-based compensation	6,262	5,489	12,126	10,870
Depreciation	90	70	179	411
Non-GAAP adjusted operating expenses	<u>\$ 84,485</u>	<u>\$ 79,561</u>	<u>\$ 178,122</u>	<u>\$ 181,583</u>