

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): November 3, 2021

Intercept Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-35668
(Commission
File Number)

22-3868459
(IRS Employer
Identification No.)

10 Hudson Yards, 37th Floor
New York, NY 10001
(Address of Principal Executive Offices and 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 November 3, 2021, Intercept Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2021.

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 issued November 3, 2021
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: November 3, 2021



Intercept Pharmaceuticals Reports Third Quarter 2021 Financial Results and Provides Business Update

Worldwide Ocaliva® net sales of \$92.8 million, representing 17% growth over the prior year quarter

Company increases 2021 guidance of Ocaliva net sales to \$355 million to \$370 million and narrows Non-GAAP adjusted operating expense guidance to \$380 to \$395 million

NASH data generation remains on track

New PBC POISE long-term data accepted in a late-breaking presentation at The Liver Meeting® next month

Completed successful debt exchange and share buy back

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

NEW YORK, November 3, 2021 – Intercept Pharmaceuticals, Inc. (Nasdaq: ICPT), a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases, today announced its financial results for the quarter ended September 30, 2021.

“Our results in Q3 2021 demonstrate the underlying strength of our PBC business and we are raising sales guidance for Ocaliva,” said Jerry Durso, President and Chief Executive Officer of Intercept. “We are also lowering the top end of our operating expense guidance as we focus on maintaining a strong cash position. Additionally, we remain committed to generating important PBC data, and look forward to sharing a late-breaking podium presentation at The Liver Meeting® this month titled, ‘Patients with primary biliary cholangitis treated with long-term obeticholic acid in a trial-setting demonstrate better transplant-free survival than external controls from the GLOBAL PBC and UK-PBC study groups.’”

“As we approach 2022, we are also entering a pivotal phase for our NASH clinical development program,” Durso continued. “We expect topline results from the Phase 3 REVERSE study in compensated cirrhosis due to NASH to be available near the end of the year. We are also on track with compiling a new data package from the Phase 3 REGENERATE study in fibrosis due to NASH to support a potential resubmission meeting with FDA in the first half of 2022. I’m pleased with the progress our R&D team is making under the leadership of Dr. Michelle Berrey and expect we will have the necessary data to drive our strategic decisions and regulatory dialogue. As we continue to advance our pipeline and explore opportunities to leverage our strong commercial foundation, Intercept is well positioned for success in 2022 and beyond.”

Financial Results

Revenue

- We recognized \$92.8 million in total revenue in the third quarter of 2021, as compared to \$79.5 million in total revenue in the prior year quarter. Ocaliva net sales in the third quarter of 2021 were comprised of U.S. net sales of \$66.6 million and ex-U.S. net sales of \$26.2 million, as compared to U.S. net sales of \$58.6 million and ex-U.S. net sales of \$20.9 million in the prior year quarter.

Operating Expenses

- In the quarters ended September 30, 2021 and 2020, we recorded \$99.0 million and \$134.7 million, respectively, in total operating expenses and \$89.6 million and \$118.1 million, respectively, in non-GAAP adjusted operating expenses, which excludes non-cash stock-based compensation expense of \$8.6 million and \$15.8 million, respectively, and depreciation expense of \$0.8 million and \$0.7 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.”

Cost of Sales

- Our cost of sales was \$0.7 million in the third quarter of 2021, as compared to \$1.8 million in the prior year quarter. Our cost of sales for the quarters ended September 30, 2021 and 2020 consisted primarily of packaging, labeling, materials and related expenses.

Sales, General & Administrative Expenses

- Our selling, general and administrative expenses were \$53.3 million in the third quarter of 2021, down from \$70.6 million in the prior year quarter. The decrease was primarily driven by actions taken to decrease expenses relating to launch preparation activities associated with the potential approval and commercialization of OCA for liver fibrosis due to NASH.

Research & Development Expenses

- Our research and development expenses decreased to \$45.0 million in the third quarter of 2021, down from \$48.9 million in the prior year quarter. The decrease was primarily driven by lower personnel and development costs.

Interest Expense

- Interest expense for the quarters ended September 30, 2021 and 2020 was \$14.1 million and \$12.1 million, respectively. For the three months ended September 30, 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 ended September 30, 2020, interest expense related to the 2026 Convertible Notes and the 2023 Convertible Notes.
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Net Loss

- In the third quarter of 2021 we reported a net loss of \$3.6 million, a decrease compared to a net loss of \$66.5 million in the third quarter 2020.

Cash Position

- As of September 30, 2021, we had cash, cash equivalents, restricted cash, and investment debt securities available for sale of approximately \$428.8 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.

Capital Structure

Convertible Notes Exchange, New Issuance, and Stock Repurchase

In August 2021, we exchanged \$306.5 million of 2023 Convertible Notes and \$114.7 million of 2026 Convertible Notes for \$382.4 million of 2026 Convertible Secured Notes and sold \$117.6 million of new 2026 Convertible Secured Notes for cash. We issued \$500.0 million principal amount of new notes to participating noteholders.

We also completed a buyback of approximately 4.5 million shares of common stock for \$75.8 million in cash.

Convertible Notes Repurchase

In September 2021, we repurchased \$39.9 million of 2023 Convertible Notes for \$38.1 million in cash. As a result of this repurchase and the convertible notes exchange, the principal balance of the 2023 Convertible Notes was reduced by approximately 75% to \$113.7 million.

2021 Financial Guidance

We are increasing our full year 2021 worldwide Ocaliva net sales guidance to \$355 million to \$370 million from \$325 million to \$340 million.

We are narrowing our full year 2021 non-GAAP adjusted operating expense guidance to \$380 million to \$395 million from \$380 million to \$410 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 November 3, 2021 at 8:30 a.m. ET

We are hosting our third quarter 2021 financial results conference call and webcast on November 3, 2021 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 domestic) or (315) 625-6894 (international) passcode 6266006. 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 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 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 Ocaliva® (obeticholic acid)

Ocaliva is indicated in the United States for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.

This indication is approved under the accelerated approval pathway based on a reduction in alkaline phosphatase (ALP) as a surrogate endpoint which is reasonably likely to predict clinical benefit, including an improvement in liver transplant free-survival. 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. We are conducting a Phase 4 clinical outcomes trial, which we refer to as our COBALT trial, of OCA in patients with PBC with the goal of confirming clinical benefit on a post-marketing basis.

In December 2016, Ocaliva received conditional marketing authorization in Europe for the treatment of PBC in combination with UDCA in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA, conditioned upon us providing further data post-approval to confirm benefit. For detailed safety information for Ocaliva 5 mg and 10 mg tablets including posology and method of administration, special warnings, drug interactions and adverse drug reactions, please see the European Summary of Product Characteristics that can be found on www.ema.europa.eu.

U.S. IMPORTANT SAFETY INFORMATION FOR OCALIVA IN PBC

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
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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 postmarketing 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 Annual Report on Form 10-K for the year ended December 31, 2020.

Contact

For more information about Intercept, please contact:

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Product revenue, net	\$ 92,827	\$ 79,521	\$ 271,064	\$ 229,422
Total revenue	92,827	79,521	271,064	229,422
Operating expenses:				
Cost of sales	658	1,826	2,086	4,555
Selling, general and administrative	53,339	70,619	170,265	262,537
Research and development	45,048	48,858	133,606	139,587
Restructuring	2	13,381	(86)	13,381
Total operating expenses	99,047	134,684	305,871	420,060
Operating loss	(6,220)	(55,163)	(34,807)	(190,638)
Other income (expense):				
Interest expense	(14,095)	(12,091)	(39,103)	(35,801)
Gain on extinguishment of debt	16,511	-	16,511	-
Other income, net	172	785	2,253	3,706
	2,588	(11,306)	(20,339)	(32,095)
Net loss	\$ (3,632)	\$ (66,469)	\$ (55,146)	\$ (222,733)
Net loss per common and potential common share:				
Basic and diluted	\$ (0.11)	\$ (2.01)	\$ (1.69)	\$ (6.76)
Weighted average common and potential common shares outstanding:				
Basic and diluted	31,736	32,989	32,679	32,957

Condensed Consolidated Balance Sheet Information
(In thousands)

	September 30, 2021	December 31, 2020 (1)
	(Unaudited)	
Cash, cash equivalents, restricted cash and investment debt securities, available for sale	\$ 428,766	\$ 477,170
Total assets	\$ 523,074	\$ 580,489
Total liabilities (2)	\$ 679,104	\$ 747,342
Stockholders' deficit	\$ (156,030)	\$ (166,853)

(1) Derived from the audited financial statements included in Intercept's Annual Report on Form 10-K for the year ended December 31, 2020.

(2) Includes \$530.4 million related to the 2023 Convertible Notes, 2026 Convertible Notes and the 2026 Secured Convertible Notes (together, the "Convertible Notes") as of September 30, 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 September 30, 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Total operating expenses	\$ 99,047	\$ 134,684	\$ 305,871	\$ 420,060
Adjustments:				
Stock-based compensation	8,616	15,825	25,483	44,381
Depreciation	808	710	2,557	2,282
Non-GAAP adjusted operating expenses	<u>\$ 89,623</u>	<u>\$ 118,149</u>	<u>\$ 277,831</u>	<u>\$ 373,397</u>
