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): May 6, 2021

Intercept Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-35668**	**22-3868459**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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:

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 May 6, 2021, Intercept Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2021. A copy of such press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 2.02 and Exhibit 99.1 attached hereto is being furnished to the Securities and Exchange Commission and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit Number	Description
99.1	Press Release issued May 6, 2021
104	Cover Page Interactive Data File (embedded as Inline XBRL document)

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/ Rocco Venezia
Name: Rocco Venezia
Title: Chief Accounting Officer;
Acting Chief Financial Officer and Treasurer

Date: May 6, 2021

Exhibit 99.1

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

Worldwide Ocaliva® net sales of $81.7M, representing 12% growth over the prior year quarter

Company narrows 2021 financial guidance; now expects worldwide Ocaliva net sales guidance of $325 million to $340 million and reiterates Non-GAAP adjusted operating expense guidance of $380 to $410 million

Process between Intercept and FDA remains ongoing regarding updates to the Ocaliva U.S. Prescribing Information

Intercept continues to work toward potential resubmission of OCA in NASH fibrosis in the U.S.

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

NEW YORK, May 6, 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 March 31, 2021.

“Our global commercial strategy and our continued progress in educating specialists including gastroenterologists have produced another quarter of double-digit sales growth for Ocaliva,” said Jerry Durso, President and Chief Executive Officer of Intercept. “As we continue our dialogue with FDA, which is reaching its conclusion regarding updates to the Ocaliva U.S. Prescribing Information, we expect that the final label will restrict Ocaliva in patients with decompensated cirrhosis and in a subset of patients with compensated cirrhosis. Following this label update, Ocaliva will remain an important option for the significant majority of second line PBC patients.

“We are currently preparing for a NASH safety update from the ongoing Phase 3 REGENERATE study that will reflect more than twice the patient exposure to OCA relative to our first submission. We are also planning to generate additional data pursuant to upcoming discussions with the agency. While we are making progress, significant work remains and alignment with FDA on the necessary elements will be a key dependency for a potential resubmission in support of accelerated approval. So at this time we cannot reiterate our potential filing timing for this year and expect to provide an update in the third quarter of this year,” Durso continued. “We have also formally received a 6-month clock stop of the review of OCA for development of NASH fibrosis in the EU in order to allow us to focus on executing on the feedback we have received. Additionally, our Phase 3 REVERSE study in NASH patients with compensated cirrhosis is ongoing and we expect to have top-line data by end-of-year, and we continue to make progress on our pipeline programs including our combination program with bezafibrate.”

Program Highlights

Primary Biliary Cholangitis

- Process with FDA regarding updates to the U.S. Prescribing Information is nearing completion. Final label will restrict Ocaliva in patients with decompensated cirrhosis and in a subset of patients with compensated cirrhosis.
- Discussion remains ongoing with FDA and EMA regarding the COBALT post-marketing trial.

NASH

- Held multiple formal interactions with FDA regarding our NASH fibrosis development program and are preparing for a safety update that will reflect a doubling of patient exposure to OCA relative to our first submission. We are also gathering data that will be the subject of upcoming interactions.
- The REVERSE Phase 3 study in patients with compensated cirrhosis due to NASH remains ongoing and a top-line readout is expected to be available by the end of 2021.
- We have formally received a 6-month clock stop of the review of OCA for development of NASH fibrosis in the EU to allow us to focus on executing on the feedback we have received and the data we are developing for potential U.S. resubmission.

Additional Pipeline

- The Company continues to enroll the OCA/bezafibrate combination trial outside the U.S. and will provide updates when enrollment is complete. Intercept now has an open IND for the combination in the U.S.
- Intercept intends to initiate first-in-human work with INT-787 in 2021.

Financial Results

Revenue

- We recognized $81.7 million in total revenue in the first quarter of 2021, as compared to $72.7 million in total revenue in the prior year quarter. Ocaliva net sales in the first quarter of 2021 were comprised of U.S. net sales of $57.3 million and ex-U.S. net sales of $24.4 million, as compared to U.S. net sales of $50.8 million and ex-U.S. net sales of $21.9 million in the prior year quarter.

Operating Expenses

- In the quarters ended March 31, 2021 and 2020, we recorded $111.0 million and $156.1 million, respectively, in total operating expenses and $101.7 million and $142.9 million, respectively, in non-GAAP adjusted operating expenses, which excludes non-cash stock-based compensation expense of $8.4 million and $12.5 million, respectively, and depreciation expense of $0.9 million and $0.8 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 $0.8 million in the first quarter of 2021, as compared to $0.9 million in the prior year quarter. Our cost of sales for the quarters ended March 31, 2021 and 2020 consisted primarily of packaging, labeling, materials and related expenses.

Sales, General & Administrative Expenses

- Our selling, general and administrative expenses were $59.3 million in the first quarter of 2021, down from $98.6 million in the prior year quarter. The decrease was primarily driven by actions taken to decrease expenses relating to our launch preparation activities associated with the potential approval and commercialization of OCA for liver fibrosis due to NASH following the complete response letter in 2020.

Research & Development Expenses

- Our research and development expenses decreased to $50.8 million in the first quarter of 2021, down from $56.7 million in the prior year quarter. The decrease was primarily driven by lower NASH and Ocaliva API development costs.

Interest Expense

- Interest expense in the quarters ended March 31, 2021 and 2020 was $12.4 million and $11.8 million, respectively. For the three months ended March 31, 2021 and 2020, interest expense related to the $230.0 million aggregate principal amount of 2.00% Convertible Senior Notes due 2026 (the “2026 Convertible Notes”) that we issued in May 2019 and the $460.0 million aggregate principal amount of 3.25% Convertible Senior Notes due 2023 (the “2023 Convertible Notes” and together with the 2026 Convertible Notes, the “Convertible Notes”) that we issued in July 2016.

Net Loss

- In the first quarter of 2021 we reported a net loss of $40.4 million, a decrease compared to a net loss of $93.0 million in the first quarter 2020.

Cash Position

- As of March 31, 2021, we had cash, cash equivalents, restricted cash, and investment debt securities available for sale of approximately $418.6 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.

2021 Financial Guidance

As a result of the latest dialogue with the FDA, which we expect to result in a label update restricting the use of Ocaliva in patients with decompensated cirrhosis and in a subset of patients with compensated cirrhosis, we are narrowing our Ocaliva net sales guidance range.

We now expect full year 2021 worldwide Ocaliva net sales to be between $325 million to $340 million. Once the label is finalized and as we monitor post-label update market dynamics, we will plan to refine this range throughout the year as necessary.

We are reiterating our full year 2021 non-GAAP adjusted operating expenses to be between $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 May 6, 2021 at 8:30 a.m. ET

We are hosting our first quarter 2021 financial results conference call and webcast on May 6, 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 (888) 517-2458 (toll-free domestic) or (847) 413-3538 (international) passcode 9873 994. 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. In the United States, NASH is currently the second leading cause for liver transplantation overall, and in females, the leading cause. NASH is anticipated to become the leading indication for liver transplantation in Europe within the next decade. 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 INCORRECTLY DOSED PBC PATIENTS WITH CHILD-PUGH CLASS B OR C OR DECOMPENSATED CIRRHOSIS

- **In postmarketing reports, hepatic decompensation and failure, in some cases fatal, have been reported in patients with Primary Biliary Cholangitis (PBC) with decompensated cirrhosis or Child-Pugh Class B or C hepatic impairment when OCALIVA was dosed more frequently than recommended.**
- **The recommended starting dosage of OCALIVA is 5 mg once weekly for patients with Child-Pugh Class B or C hepatic impairment or a prior decompensation event.**

Contraindications

OCALIVA is contraindicated in PBC patients with complete biliary obstruction.

Warnings and Precautions

Hepatic Decompensation and Failure in Incorrectly-Dosed PBC Patients with Child-Pugh Class B or C or Decompensated Cirrhosis

In postmarketing reports, hepatic decompensation and failure, in some cases fatal, have been reported in PBC patients with decompensated cirrhosis or Child-Pugh B or C hepatic impairment when OCALIVA was dosed more frequently than the recommended starting dosage of 5 mg once weekly. Reported cases typically occurred within 2 to 5 weeks after starting OCALIVA and were characterized by an acute increase in total bilirubin and/or ALP concentrations in association with clinical signs and symptoms of hepatic decompensation (e.g., ascites, jaundice, gastrointestinal bleeding, worsening of hepatic encephalopathy).

Routinely monitor patients for progression of PBC disease, including liver-related complications, with laboratory and clinical assessments. Dosage adjustment, interruption or discontinuation may be required. Close monitoring is recommended for patients at an increased risk of hepatic decompensation. Severe intercurrent illnesses that may worsen renal function or cause dehydration (e.g., gastroenteritis), may exacerbate the risk of hepatic decompensation. Interrupt treatment with OCALIVA in patients with laboratory or clinical evidence of worsening liver function indicating risk of decompensation, and monitor the patient's liver function. Consider discontinuing OCALIVA in patients who have experienced clinically significant liver-related adverse reactions. Discontinue OCALIVA in patients who develop complete biliary obstruction.

Liver-Related Adverse Reactions

Dose-related, liver-related adverse reactions including jaundice, worsening ascites and primary biliary cholangitis flare have been observed in clinical trials, as early as one month after starting treatment with OCALIVA 10 mg once daily up to 50 mg once daily (up to 5-times the highest recommended dosage). Monitor PBC patients during treatment with OCALIVA for elevations in liver biochemical tests and for the development of liver-related adverse reactions.

Severe Pruritus

Severe pruritus was reported in 23% of PBC patients in the OCALIVA 10 mg arm, 19% of PBC patients in the OCALIVA titration arm, and 7% of PBC patients in the placebo arm in a 12-month double-blind randomized controlled trial of 216 PBC 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 PBC patients with new onset or worsening severe pruritus. Management strategies include the addition of bile acid 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 PBC patients, 20% and 9% in the 10 mg and titration arms, respectively, compared to 2% in the placebo arm. Monitor PBC patients for changes in serum lipid levels during treatment. For PBC 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 from subjects taking OCALIVA for PBC were 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 coadministering OCALIVA and warfarin.

CYP1A2 Substrates with Narrow Therapeutic Index

Obeticholic acid, the active ingredient in OCALIVA, 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 coadministered 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 see **Full Prescribing Information, including Boxed WARNING** and **Medication Guide** for OCALIVA.

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 the newly identified safety signal relating to Ocaliva identified by the FDA in May 2020 and with respect to patients with PBC with decompensated cirrhosis and in a subset of patients with compensated cirrhosis; 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 ongoing discussion with the FDA and the European Medicines Agency regarding the feasibility of the COBALT and 401 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 system failures, data breaches or violations of 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

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

	Three Months Ended March 31,	
	2021	**2020**
Revenue:		
Product revenue, net	$ 81,661	$ 72,652
Total revenue	81,661	72,652
Operating expenses:		
Cost of sales	810	852
Selling, general and administrative	59,271	98,558
Research and development	50,766	56,687
Restructuring	161	-
Total operating expenses	111,008	156,097
Operating loss	(29,347)	(83,445)
Other income (expense):		
Interest expense	(12,419)	(11,777)
Other income, net	1,346	2,239
Total other (expense), net	(11,073)	(9,538)
Net loss	$ (40,420)	$ (92,983)
Net loss per common and potential common share:		
Basic and diluted	$ (1.22)	$ (2.86)
Weighted average common and potential common shares outstanding:		
Basic and diluted	33,139	32,561

Condensed Consolidated Balance Sheet Information
(In thousands)

	March 31, 2021	**December 31, 2020 (1)**
	(Unaudited)	
Cash, cash equivalents, restricted cash and investment debt securities, available for sale	$ 418,616	$ 477,170
Total assets	$ 520,111	$ 580,489
Total liabilities (2)	$ 720,109	$ 747,342
Stockholders' (deficit) equity	$ (199,998)	$ (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 $568.1 million and $560.6 million related to the Convertible Notes as of March 31, 2021 and December 31, 2020, respectively. Intercept separately accounts for the debt and equity components of the Convertible Notes. The aggregate outstanding principal amount of the Convertible Notes was $690.0 million as of March 31, 2021 and December 31, 2020, respectively.

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

	Three Months Ended March 31,	
	2021	**2020**
Total operating expenses	$ 111,008	$ 156,097
Adjustments:		
Stock-based compensation	8,419	12,473
Depreciation	870	764
Non-GAAP adjusted operating expenses	$ 101,719	$ 142,860