

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 9, 2020

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 9, 2020, Intercept Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2020. 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 November 9, 2020
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/ Sandip Kapadia

Name: Sandip Kapadia

Title: Chief Financial Officer and Treasurer

Date: November 9, 2020



Intercept Pharmaceuticals Reports Third Quarter 2020 Financial Results, Announces Updates to Financial Guidance and Provides Business Update

Worldwide Ocaliva net sales of \$79.5 million in the third quarter 2020, representing 29% growth over the prior year quarter

Intercept updates 2020 Ocaliva Net Sales Guidance to narrow the range to \$310 million to \$320 million

Intercept updates 2020 non-GAAP Adjusted Operating Expenses Guidance to narrow the range to \$460 million to \$480 million

Productive Type A Meeting held with FDA on NASH Fibrosis Program

Conference call scheduled for 8:30 a.m. ET today

NEW YORK, November 9, 2020 – 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, 2020.

“We were pleased to reengage with FDA at our recent Type A end-of-review meeting to discuss the Agency’s benefit-risk assessment in the CRL based on its review of the available data, as well as our proposed way forward to resubmitting our NDA for OCA in NASH fibrosis,” said Mark Pruzanski, M.D., President and Chief Executive Officer of Intercept. “The meeting was constructive and FDA has provided us with helpful guidance regarding supplemental data we can provide to further characterize OCA’s efficacy and safety profile that could support resubmission based on our Phase 3 REGENERATE 18-month biopsy data, together with a safety update from our ongoing studies. We are advancing accordingly and plan to hold additional meetings with the Agency with the goal of achieving sufficient alignment to proceed on this basis and potentially resubmit our NDA next year. Of note, the REGENERATE outcomes phase is ongoing and our Phase 3 REVERSE study in NASH patients with compensated cirrhosis is expected to read out by the end of next year. We continue to lead the NASH field and believe that, if approved, OCA has the potential to become an important treatment for patients with advanced fibrosis due to NASH. Meanwhile, our PBC business continued its strong performance in the third quarter and we have updated our 2020 financial guidance with anticipated Ocaliva net sales of \$310 to \$320 million and non-GAAP adjusted operating expenses of \$460 to \$480 million, providing us with a strong financial footing for the future.”

Ocaliva® (obeticholic acid) Commercial Highlights

We recognized \$79.5 million of Ocaliva net sales in the third quarter of 2020, as compared to \$61.5 million in the prior year quarter. Ocaliva net sales in the third quarter of 2020 were comprised of U.S. net sales of \$58.6 million and ex-U.S. net sales of \$20.9 million, as compared to U.S. net sales of \$45.2 million and ex-U.S. net sales of \$16.3 million in the prior year quarter.

Selected Third Quarter 2020 Financial Results

Revenues

We recognized \$79.5 million in total revenue in the third quarter of 2020, as compared to \$61.9 million in total revenue in the prior year quarter. Total revenue in the third quarter of 2019 included approximately \$0.4 million of licensing revenue.

Operating Expenses

Our cost of sales was \$1.8 million in the third quarter of 2020, as compared to \$0.5 million in the prior year quarter. Our cost of sales for the quarters ended September 30, 2020 and 2019 consisted primarily of packaging, labeling, materials and related expenses.

Our selling, general and administrative expenses decreased to \$70.6 million in the third quarter of 2020, from \$76.8 million in the prior year quarter. The decrease was primarily driven by reductions in spend resulting from the delay of the potential approval and commercialization of obeticholic acid (OCA) for liver fibrosis due to nonalcoholic steatohepatitis (NASH).

Our research and development expenses decreased to \$48.9 million in the third quarter of 2020, from \$60.2 million in the prior year quarter. The decrease was primarily driven by lower NASH development costs, including the conclusion of enrollment activities for the REGENERATE and REVERSE studies and reduced costs related to our preparations for regulatory interactions.

Restructuring expenses were \$13.4 million and \$0 for the three months ended September 30, 2020 and 2019, respectively. The increase between periods was driven primarily by severance costs and other related termination benefits incurred in conjunction with the previously announced plan to reduce workforce in response to the receipt of the complete response letter.

In the quarters ended September 30, 2020 and 2019, we recorded \$134.7 million and \$137.5 million, respectively, in total operating expenses and \$118.1 million and \$123.4 million, respectively, in non-GAAP adjusted operating expenses, which excludes non-cash stock-based compensation expense of \$15.8 million and \$13.1 million, respectively, and depreciation expense of \$0.7 million and \$0.9 million, respectively.

References in this press release to “non-GAAP adjusted operating expenses” mean our total operating expenses, as calculated and presented in accordance with U.S. Generally Accepted Accounting Principles (“GAAP”), adjusted for the effects of two non-cash items: stock-based compensation and depreciation. See “Non-GAAP Financial Measures” below. A reconciliation of non-GAAP adjusted operating expenses to total operating expenses for all historical periods presented is included below under the heading “Reconciliation of Non-GAAP Adjusted Operating Expenses to Total Operating Expenses.”

Interest Expense

Interest expense in the quarters ended September 30, 2020 and 2019 was \$12.1 million and \$11.8 million, respectively. For the quarter ended September 30, 2020, interest expense related to the \$460.0 million aggregate principal amount of 3.25% Convertible Senior Notes due 2023 that we issued in July 2016 and 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.

Net Loss

In the third quarter of 2020 we reported a net loss of \$66.5 million, a decrease compared to a net loss of \$84.8 million in the third quarter 2019.

Cash Position

As of September 30, 2020, we had cash, cash equivalents, restricted cash, and investment debt securities available for sale of approximately \$496.8 million. As of December 31, 2019, we had cash, cash equivalents, restricted cash, and investment debt securities available for sale of approximately \$657.3 million.

2020 Financial Guidance

We are updating our 2020 Ocaliva net sales guidance to narrow the range at the upper end of our previously announced guidance, and now anticipate Ocaliva net sales of \$310 million to \$320 million. We are also updating our non-GAAP adjusted operating expenses guidance to narrow the range at the lower end of the previously announced guidance, and now anticipate non-GAAP adjusted operating expenses of \$460 million to \$480 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 9, 2020 at 8:30 a.m. ET

We are hosting our third quarter 2020 financial results conference call and webcast on November 9, 2020 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 3798851. 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; 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; 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 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 and short-term investments; our ability to acquire, license and invest in businesses, technologies, product candidates and products; our ability to attract and retain key personnel to manage our business effectively; our ability to manage the growth of our operations, infrastructure, personnel, systems and controls; our ability to obtain and maintain adequate insurance coverage; the impact of COVID-19, including any impact on our results of operations or financial position, related quarantines and 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, facility closures or other restrictions, and the extent and duration thereof; the impact of general U.S. and foreign economic, industry, market, regulatory or political conditions, including the potential 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, 2019 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020.

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,	
	2020	2019	2020	2019
Revenue:				
Product revenue, net	\$ 79,521	\$ 61,545	\$ 229,422	\$ 179,286
Licensing revenue	-	405	-	1,216
Total revenue	79,521	61,950	229,422	180,502
Operating expenses:				
Cost of sales	1,826	487	4,555	1,738
Selling, general and administrative	70,619	76,828	262,537	223,738
Research and development	48,858	60,168	139,587	178,163
Restructuring	13,381	-	13,381	-
Total operating expenses	134,684	137,483	420,060	403,639
Operating loss	(55,163)	(75,533)	(190,638)	(223,137)
Other income (expense):				
Interest expense	(12,091)	(11,795)	(35,801)	(29,518)
Other income, net	785	2,495	3,706	6,132
	(11,306)	(9,300)	(32,095)	(23,386)
Net loss	\$ (66,469)	\$ (84,833)	\$ (222,733)	\$ (246,523)
Net loss per common and potential common share:				
Basic and diluted	\$ (2.01)	\$ (2.59)	\$ (6.76)	\$ (7.88)
Weighted average common and potential common shares outstanding:				
Basic and diluted	32,989	32,717	32,957	31,275

Condensed Consolidated Balance Sheet Information
(In thousands)

	September 30, 2020	December 31, 2019 (1)
	(Unaudited)	
Cash, cash equivalents, restricted cash and investment debt securities, available for sale	\$ 496,760	\$ 657,347
Total assets	\$ 591,352	\$ 754,886
Total liabilities (2)	\$ 721,639	\$ 703,330
Stockholders' (deficit) equity	\$ (130,287)	\$ 51,556

- (1) Derived from the audited financial statements included in Intercept's Annual Report on Form 10-K for the year ended December 31, 2019
- (2) Includes \$553.2 million and \$532.1 million related to the 2023 Convertible Notes and the 2026 Convertible Notes (together, the "Convertible Notes") as of September 30, 2020 and December 31, 2019, 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 September 30, 2020, and December 31, 2019.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Total operating expenses	\$ 134,684	\$ 137,483	\$ 420,060	\$ 403,639
Adjustments:				
Stock-based compensation	15,825	13,130	44,381	42,809
Depreciation	710	914	2,282	2,839
Non-GAAP adjusted operating expenses	<u>\$ 118,149</u>	<u>\$ 123,439</u>	<u>\$ 373,397</u>	<u>\$ 357,991</u>
