

Intercept Pharmaceuticals

2021 Second Quarter Financial and Corporate Update

July 29, 2021

Cautionary Note Regarding Forward-Looking Statements and Non-GAAP Financial Measures

This presentation 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 announced 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 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, including joint research based on our current partnership agreements; 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.

This presentation also refers to non-GAAP adjusted operating expenses. 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 in the Appendix hereto 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.

Today's Agenda

Opening Remarks

Jerry Durso, *President and CEO*

PBC Commercial Update

Linda Richardson, *Chief Commercial Officer*

NASH Regulatory and Pipeline Update

Dr. M. Michelle Berrey, *President R&D, Chief Medical Officer*

Q2 2021 Financial Highlights

Andrew Saik, *Chief Financial Officer*

Key Business Updates



Delivered strong Ocaliva net sales in Q2 2021 with 25% worldwide sales growth over the prior year quarter; reported first cash positive quarter in history of the company



Finalized updates to the Ocaliva Prescribing Information in the U.S., and education efforts are well underway



Had several interactions with FDA to gain alignment and feedback on safety, biopsy methodology and efficacy data; now reading baseline and 18-month biopsies, analyzing safety data to make data-driven decisions regarding a potential NASH NDA resubmission



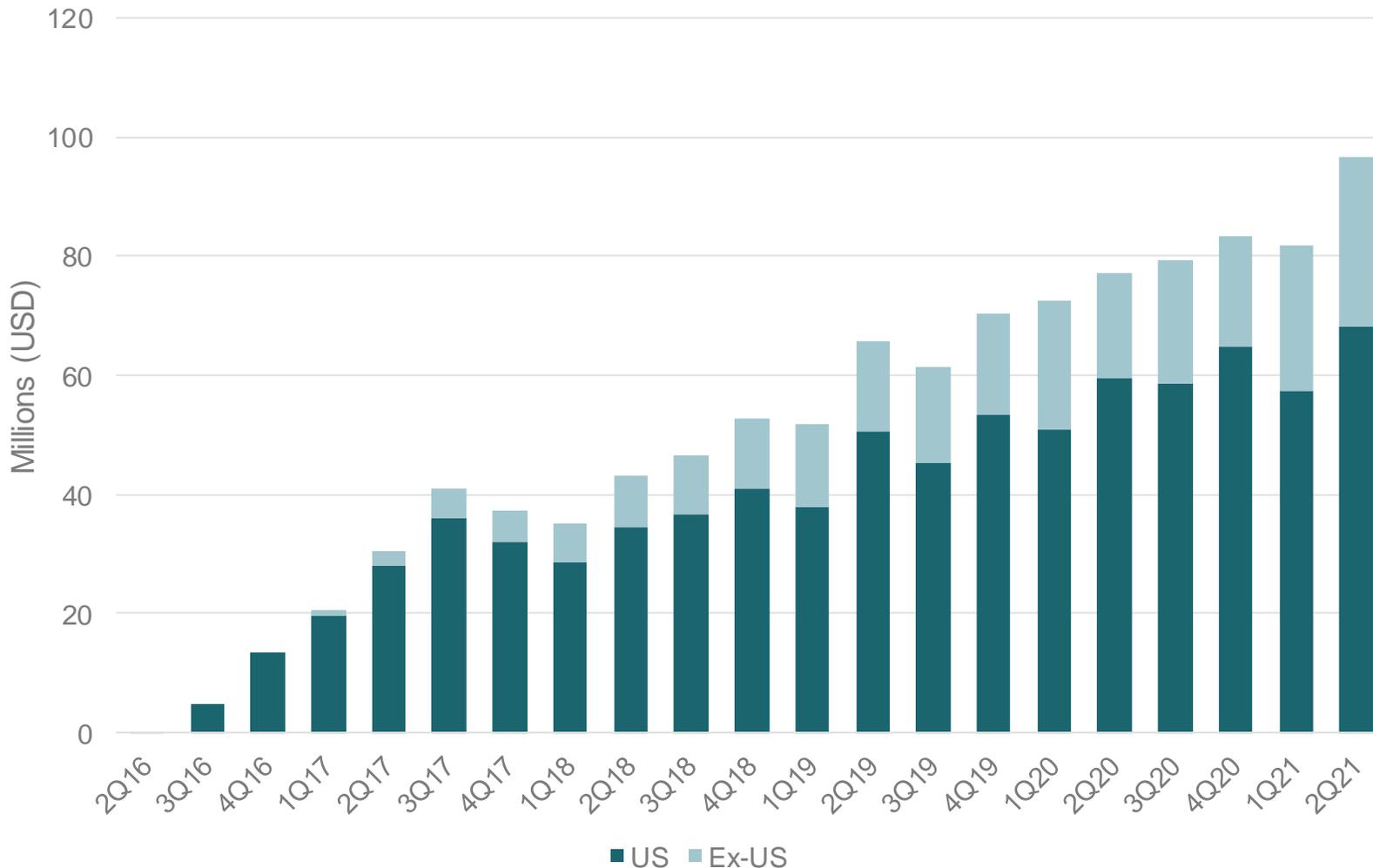
Initiated INT-787 first-in-human clinical trial, continued to advance Phase 2 work for the OCA-bezafibrate combination program and on track to deliver topline data from REVERSE by YE 2021



Reiterated FY2021 sales guidance of \$325-340M and non-GAAP adjusted operating expense guidance of \$380-410M

Delivered Strong Ocaliva Sales of More than \$96.6 Million

Ocaliva Net Sales



Q2 2021 Worldwide Net Sales Overview

US and EU sales of, \$68.2M and \$28.4M, respectively, reflecting strong growth and increased demand

Drove Continued Growth in Foundational PBC Business

Ocaliva Net Sales Continue to Deliver

Achieved our first cash positive quarter as a result of our strong business performance in the U.S. and internationally

Updated Prescribing Information Education Efforts Well Underway

Educated almost two-thirds of our existing prescribers

Plan to return to branded messaging and prior strategy of driving growth in community GI setting once effectively educated

International Sales Up More Than 60% YOY

Strong sales driven, in part, by increased access to institutions as COVID restrictions ease

Outperformance driven by strong new patient starts

Data Generation Underway in NASH Regulatory Process

Process and team in place has made significant progress

- Working to pursue accelerated approval pathway for OCA in advanced fibrosis due to NASH
- Frequent interactions with FDA in 2021 have given us enough insight and feedback to move toward generating data

Comprehensive safety update and biopsy reading underway

- Safety database to include double the exposure of patient data from interim analysis to median of 30 months
- All biopsies including month 18 biopsies, additional 500 month 18 biopsies and REVERSE biopsies being read with new consensus reading methodology
- Company to ultimately accumulate the largest data set in NASH field

Pre-submission meeting with FDA expected during 1H22

- Will continuously evaluate data internally as it becomes available in the fall into early 2022
- If data supports a path forward, plan to meet with FDA in the first half of next year

Significant progress on our evaluation of OCA's safety and tolerability profile in NASH

Continued Pipeline Progress

INT-787

- First-in-human study underway
- Additional animal model data expected in 2H21 expected to deepen understanding of compound's profile

OCA-Beza

- Phase 2 OCA + bezafibrate trial currently enrolling outside the U.S.
- Recently published data support the benefit of bezafibrate in PBC

Q2 2021 Financial Highlights

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Total revenue	\$ 96.6M	\$ 77.2M	\$ 178.2M	\$ 149.9M
Ocaliva net sales – U.S.	68.2M	59.6M	125.5M	110.4M
Ocaliva net sales – ex-U.S.	28.4M	17.6M	52.6M	39.5M
GAAP operating expenses	95.8M	129.3M	206.8M	285.4M
Non-GAAP adjusted operating expenses (1)	86.5M	112.4M	188.2M	255.2M
Cost of sales	0.6M	1.9M	1.4M	2.7M
SG&A Expenses	57.7M	93.4M	116.9M	191.9M
R&D Expenses	37.8M	34.0M	88.6M	90.7M

(1) Refer to slide 11 for a reconciliation of non-GAAP adjusted operating expenses to total operating expenses

	6/30/21	12/31/20
Cash, cash equivalents, restricted cash & investment debt securities available for sale	\$ 422.5 M	\$ 477.2 M

Appendix

Reconciliation of Non-GAAP Adjusted Operating Expenses to Total Operating Expenses

Reconciliation of Non-GAAP Adjusted Operating Expenses to Total Operating Expenses

(Unaudited)

(In thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Total operating expenses	\$ 95,816	\$ 129,279	\$ 206,824	\$ 285,376
Adjustments:				
Stock-based compensation	8,448	16,083	16,867	28,556
Depreciation	879	808	1,749	1,572
Non-GAAP adjusted operating expenses	<u>\$ 86,489</u>	<u>\$ 112,388</u>	<u>\$ 188,208</u>	<u>\$ 255,248</u>

Ocaliva[®] (obeticholic acid) U.S. Important Safety Information

WARNING: HEPATIC DECOMPENSATION AND FAILURE IN PRIMARY BILIARY CHOLANGITIS PATIENTS WITH CIRRHOSIS

- Hepatic decompensation and failure, sometimes fatal or resulting in liver transplant, have been reported with OCALIVA treatment in primary biliary cholangitis (PBC) patients with either compensated or decompensated cirrhosis.
- OCALIVA is contraindicated in PBC patients with decompensated cirrhosis, a prior decompensation event, or with compensated cirrhosis who have evidence of portal hypertension.
- Permanently discontinue OCALIVA in patients who develop laboratory or clinical evidence of hepatic decompensation; have compensated cirrhosis and develop evidence of portal hypertension, or experience clinically significant hepatic adverse reactions while on treatment.

Contraindications

OCALIVA is contraindicated in patients with:

- decompensated cirrhosis (e.g., Child-Pugh Class B or C) or a prior decompensation event
- compensated cirrhosis who have evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia)
- complete biliary obstruction

Warnings and Precautions

Hepatic Decompensation and Failure in PBC Patients with Cirrhosis

Hepatic decompensation and failure, sometimes fatal or resulting in liver transplant, have been reported with OCALIVA treatment in PBC patients with cirrhosis, either compensated or decompensated. Among 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.

Ocaliva[®] (obeticholic acid) U.S. Important Safety Information (Cont.)

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 (≥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.