# Q2 2023 Earnings Call Presentation

Disclosed August 2, 2023



### **Cautionary Note Regarding Forward-Looking Statements ("FLS")**

This document contains FLS, including regarding: our finances, financial guidance, and financial results, including expectations regarding sales, expenses, cash position, and balance sheet position; corporate strategy and priorities; corporate financial performance and profitability; timing of profitability; growth in product sales; our operational performance; timing and results of our R&D, clinical trials, and new product initiatives; drug efficacy, safety, and tolerability; trends in prescriber and patient behavior and adoption of our products; our plans regarding product development and launch; timing, substance, and results of interactions with regulators, including meetings and regulatory submissions and the review and prospects for approval thereof; and our intellectual property rights and patent portfolio.

Important factors could cause actual results to differ materially from the FLS, including: we may be less effective than expected in executing on our strategic priorities and implementing strategic changes; restructuring and clinical trial wind-down may be slower and have greater costs than expected; we may fail to achieve profitability due to lower revenues or higher expenses than expected; our future financial needs and results may be different from our current estimates; we may not be able to increase sales as expected; regulatory interactions could take longer than expected; our regulatory submissions could not receive FDA approval in a timely manner or at all; the FDA could require us to provide additional information that is not timely or economical to provide; there could be efficacy, safety, or tolerability concerns about our products or product candidates; our products and product candidates could have less commercial potential than anticipated or could be superseded by competing products; if approved, we could be less effective than anticipated in launching sales of new products; we may not be able to obtain or maintain regulatory approvals; we may not be able to satisfy post-marketing requirements, including using realworld evidence; the initiation, timing, cost, conduct, progress, and results of our R&D activities, preclinical studies, and clinical trials, including regarding safety and efficacy; adverse medical, clinical, efficacy, quality, safety, or pharmacovigilance events or results from clinical trials; the safety and efficacy of, or potential side effects associated with, our products and product candidates; the timing and outcomes of interactions with regulators regarding clinical trials, safety, and efficacy, products and product candidates, and regulatory approvals; marketing conditions, limitations, or warnings required by regulators; the degree of market acceptance of our products among physicians, patients, and healthcare payors; our ability to execute on the drivers of product sales growth (including estimated market size, market penetration, patient satisfaction, refill rates, and sales prices); the success of our competitors and our failure to outperform or outcompete them; competition from new or existing drugs; our ability to manage expenses; our ability to manage successfully our commercial and operational performance and legal, operational, and other risks; our ability to attract and retain key personnel; our estimates of future financial needs and results; 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; and other factors discussed in the FLS and Risk Factors sections of our Form 10-Q and Form 10-K filings, and in our Form 8-K reporting our guarterly earnings.

### **Strengthening Our Focus in Rare and Serious Liver Diseases**

Maximize performance of Ocaliva in PBC	Realize best-in- class potential of OCA-bezafibrate combination	Progress next- generation FXR agonist INT-787	Build on strong financial position to achieve profitability
FY 2023 net sales guidance of \$320M to \$340M Real-world evidence demonstrates improvements in death or liver transplant On track for 2023 regulatory submission to support post- marketing requirements	Potential to redefine efficacy in treatment of PBC Completed enrollment of both ongoing Phase 2 studies Necessary data expected in 2023 to request End-of-Phase 2 meeting with FDA	Ph1 study demonstrated favorable safety and tolerability Ph2a study ongoing in severe alcohol-associated hepatitis MOA holds potential in other areas of high unmet need	Strengthen focus and reduce OpEx by ~\$140M** Focus on cash generation to meet strategic objectives Maintain expense discipline as we transition toward profitability

Abbreviations: FDC, fixed dose combination, FXR, farnesoid X receptor \*\* Relative to updated 2023 non-GAAP adjusted operating expense guidance of \$350M to \$370M



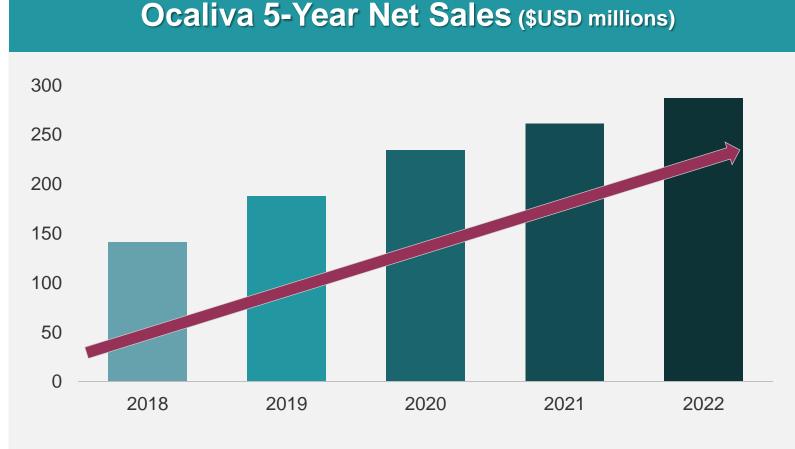
### **Key Business Updates**

	U.S. Ocaliva® net sales of \$83.7 million for the second quarter 2023; 17% growth over the prior year quarter
	Updated full-year 2023 Ocaliva net sales guidance of \$320-\$340 million, 12-19% projected growth vs. 2022; 2023 non-GAAP adjusted operating expense guidance of \$350-\$370 million
	Restructuring plan on track to reduce operating expenses by approximately \$140 million; Company expects to achieve meaningful profitability in 2024
	OCA-bezafibrate combination program completed enrollment of both ongoing Phase 2 studies; expected to have necessary data in 2023 to request End-of-Phase 2 meeting with FDA
<b>&gt;&gt;&gt;</b> <	Phase 2a FRESH study progressing to evaluate INT-787 in patients with severe alcohol- associated hepatitis (sAH)
	Cash, cash equivalents, restricted cash, and investment debt securities available for sale of \$415 million as of June 30, 2023

### Intercept 🚺

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### **Ocaliva Continues to Show Double-Digit Year-over-Year Growth**



Ocaliva has been sold commercially since 2016

Reported Ocaliva net sales of **\$83.7 million in Q2 2023** 

**17% growth** vs. prior year quarter

4<sup>th</sup> consecutive quarter of double-digit sales growth

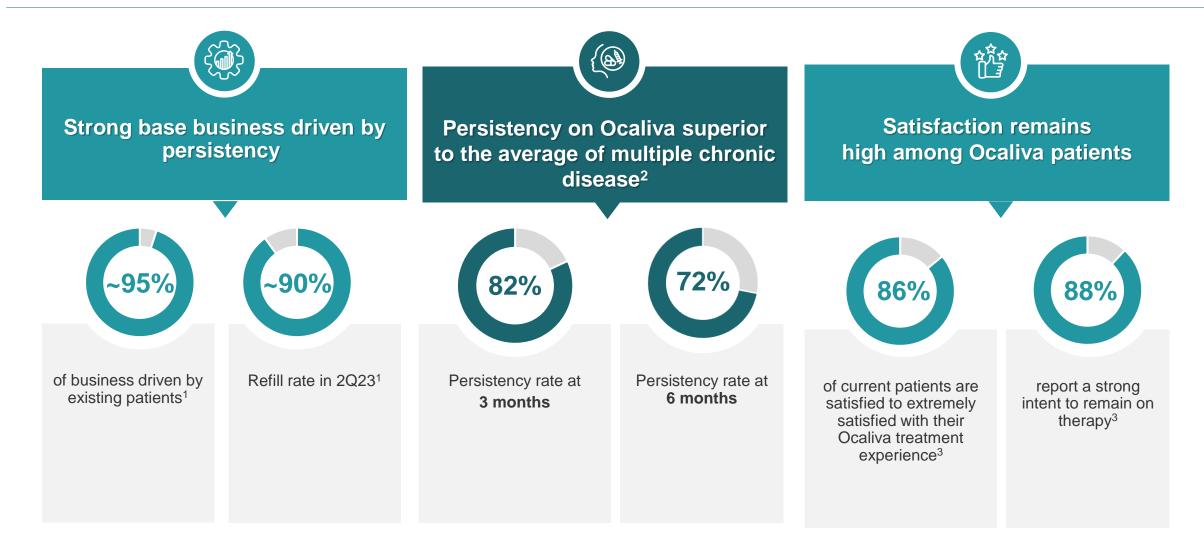
Full-year 2023 Ocaliva net sales guidance of \$320M to \$340M

12-19% projected growth vs. 2022

### Intercept 🚺

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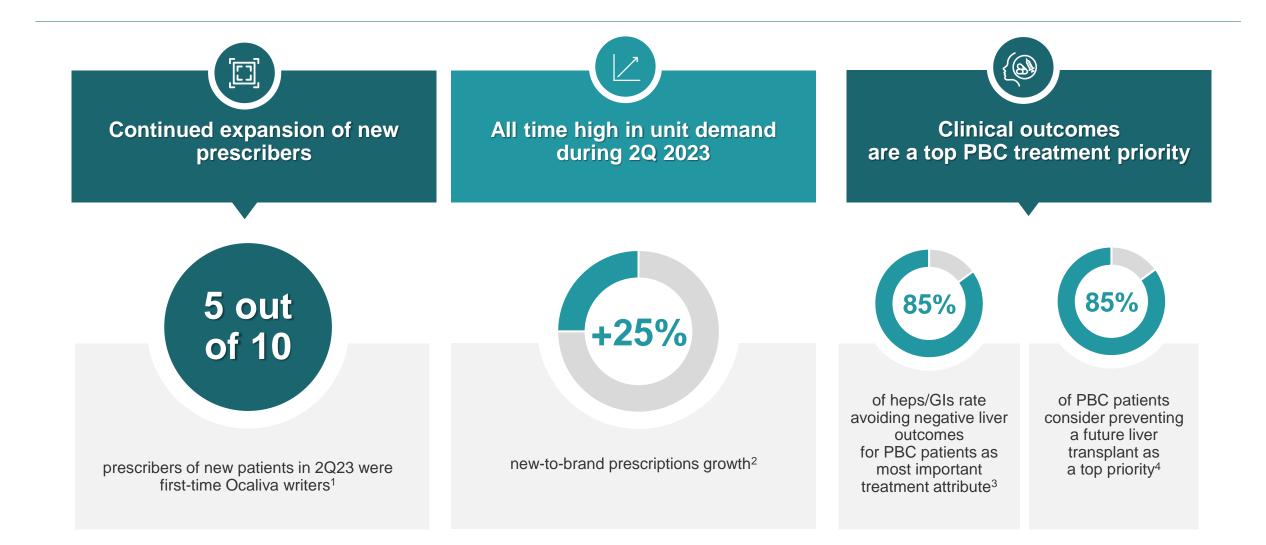
# Ocaliva Business Driven by Strong Persistency and High Patient Satisfaction



1. Data on file, April 2023. 2. Data on file, April 2023. 3. Data on file: Hawk Partners, May 2023 Patient ATU Study.



### **Ocaliva Continues to Expand as Second-Line Therapy for PBC**



1. Data on file, April 2023. 2. IQVIA National Prescription Audit, accessed July 2023. 3. Data on file: Hawk Partners, May 2023 HCP ATU Study. 4. Data on file, Hawk Partners, May 2023 Patient ATU Study.

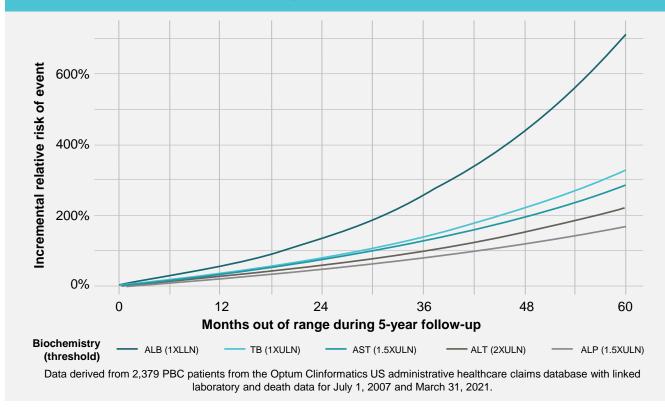
## Range of Biochemical Markers Beyond ALP are Associated with Disease Progression and Negative Clinical Outcomes in PBC

ALP and bilirubin have long been recognized as surrogates for clinical outcomes<sup>1</sup>

Further studies have shown that GGT, in addition to ALP and bilirubin is also associated with negative clinical outcomes<sup>2, 3</sup>

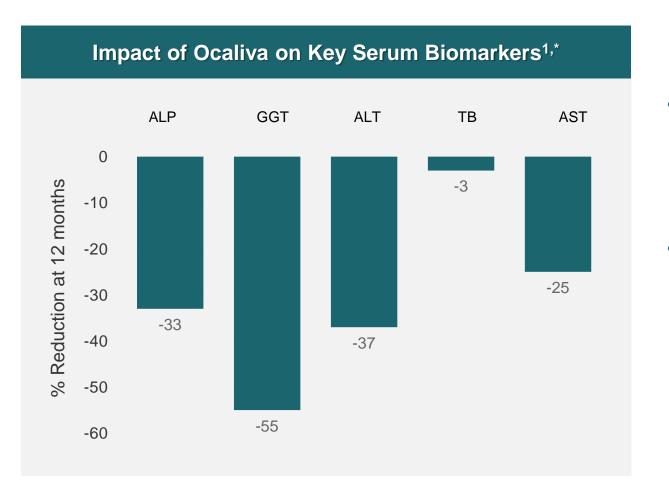
Elevations in AST and ALT are associated with increased risk of hepatic decompensation, liver transplant or death in PBC<sup>4</sup>

Incremental relative risk of hepatic decompensation, liver transplant, or death as a function of proportion of time over liver biochemistry thresholds, 5-year follow-up example<sup>4</sup>



1. Lammers et al. "Levels of ALP and bilirubin are surrogate endpoints of outcomes of patients with PBC" *Gastroenterology* 2014; 147 (6) 1338-49. 2. Murillo Perez et al. Goals of treatment for improved survival in PBC. *Am J Gastroenterol* 2020 115(7) 1066-1074. 3. Gerussi et al. "Measurement of GGT to determine the risk of liver transplantation or death in patients with PBC". *Clin Gastroenterol* 2021 19(8): 1688-1697. 4. Ritter et al, Proportion of time and degree to which liver biochemistries are out-of-range predicts time to first occurrence of negative hepatic outcomes in people with primary biliary cholangitis. Poster, EASL Congress 2022.

### Ocaliva Has Been Shown to Reduce a Range of Biochemical Markers Associated with Clinical Outcomes in PBC<sup>1</sup> (e.g., Risk of Death or Liver Transplant)



- Multiple real-world studies have shown that patients with PBC had greater transplantfree survival when treated with OCA<sup>2,3</sup>
- Ocaliva's demonstrated reduction of multiple biomarkers and real-world evidence data on transplant-free survival reinforces scientific evidence that several markers—beyond ALP—must be evaluated in patients with PBC

\*% reductions based on the mean baseline and mean 12 month data for each biochemical marker, based on data published in the POISE manuscript **1.** Nevens et al 2016. "A Placebo-Controlled Trial of Obeticholic Acid in Primary Biliary Cholangitis" *N Engl J Med.*; 375(7):631-43. **2.** Murillo Perez et al "Greater Transplant-Free Survival in Patients Receiving Obeticholic Acid for Primary Biliary Cholangitis" *N Engl J Med.*; 375(7):631-43. **2.** Murillo Perez et al "Greater Transplant-Free Survival in Patients Receiving Obeticholic Acid for Primary Biliary Cholangitis in a Clinical Trial Setting Compared to Real-World External Controls" *Gastroenterology* 2022 163 (6) 1630-1642. **3.** Brookhart AASLD 2022. Results of the HEROES study: Treatment efficacy of Obeticholic Acid on Hepatic Real-World Outcomes in Patients with Primary Biliary Cholangitis"

## OCA-Bezafibrate Investigational Combination Offers Potential to Establish Best-in-Class Clinical Benefits

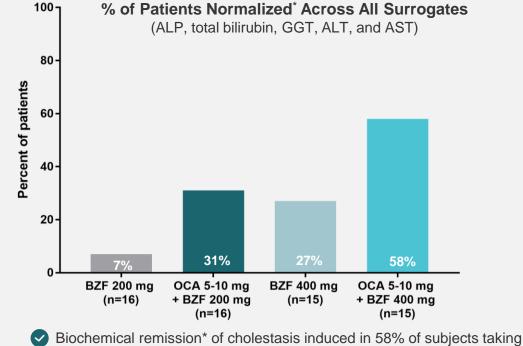
Distinct FXR and PPAR pathways may offer synergistic MOAs to normalize range of biomarkers associated with PBC outcomes (e.g., transplant-free survival)<sup>1</sup>

Two ongoing Ph2 studies exploring range of doses, with planned interim analyses (IA) from both studies expected by end of 2023

Expected to have necessary data in 2023 to request End-of-Phase 2 meeting with FDA

IP runway through 2036, with potential extension based on clinical and regulatory timelines

#### First Ph2 IA presented at EASL Congress 2023<sup>2</sup>



- Biochemical remission\* of cholestasis induced in 58% of subjects taking OCA 5-10 mg + BZF 400 mg
- Significant reductions across range of biomarkers
- Well tolerated with low rates of adverse events

\*Defined as ALP, GTT, ALT and AST all ≤ULN and total bilirubin ≤0.6 xULN

Abbreviations: FXR, farnesoid X receptor; PPAR, pan-peroxisome proliferator-activated receptor; MOA, mechanism of action; PBC, primary biliary cholangitis; Ph, phase; OCA, obeticholic acid; BZF, bezafibrate; IA, interim analysis; ALP, alkaline phosphatase; GGT, gamma-glutamyl transferase; ALT, alanine transaminase; AST, aspartate aminotransferase; ULN, upper limit of normal

1. Soret, et al. Ailment Pharmacology & Therapeutics. 2021;00:1-9. 2. Nevens et al. Results from a Planned Interim Analysis of a Randomized, Double-Blind, Active-Controlled Trial Evaluating the Effects of Obeticholic Acid and Bezafibrate on Serum Biomarkers in Primary Biliary Cholangitis. EASL Congress 2023. Abstract #2495 published 7 June 2023.



### **Advancing INT-787 in Severe Alcohol-Associated Hepatitis**

Alcohol-related liver disease as a cause of chronic liver disease is currently the leading indication for liver transplant (U.S.)<sup>1</sup>

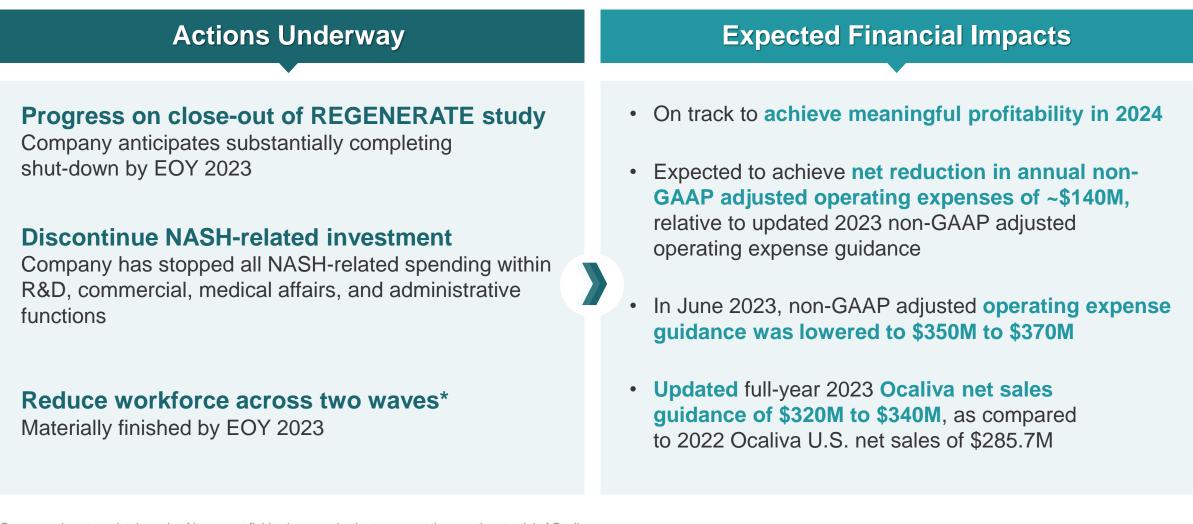
### INT-787 is a next-generation farnesoid X receptor (FXR) agonist

- 16-fold more water soluble than OCA<sup>2</sup>
- Modulates greater number of genes relative to OCA within the liver and intestine in preclinical liver disease models
- Characteristics provide opportunity to explore potential in diseases involving gut as well as liver



**1.** Wong RJ, Singal AK. Trends in liver disease etiology among adults awaiting liver transplantation in the United States, 2014-2019. JAMA Network Open. 2020;3(2): e1920294. **2.** Pellicciari R, et all. "Discovery of 3α,7α,11β-Trihydroxy-6α-ethyl-5β-cholan-24-oic Acid (TC-100), a Novel Bile Acid as Potent and Highly Selective FXR Agonist for Enterohepatic Disorders". *Journal of Medicinal Chemistry*, vol. 59, issue 19, 2016. pp. 9201-9214.

### Taking Decisive Action to Strengthen Focus on Rare and Serious Liver Diseases and Significantly Reduce Operating Expenses



\* Company plans to maintain scale of its current field sales organization to support the growth potential of Ocaliva.

### **Q2 2023 Financial Highlights**

	Three Months Ended June 30,		Six Months Ended June 30,			
	2023	2022	2023	2022		
Total revenue	\$83.7M	\$71.8M	\$151.7M	\$130.9M		
GAAP operating expenses	\$90.8M	\$85.1M	\$190.4M	\$171.0M		
Non-GAAP adjusted operating expenses (1)	\$84.5M	\$79.6M	\$178.1M	\$181.6M		
Cost of sales	\$0.2M	\$0.3M	\$0.4M	\$0.5M		
SG&A Expenses	\$53.3M	\$40.0M	\$111.0M	\$77.7M		
R&D Expenses	\$37.3M	\$44.8M	\$79.0M	\$92.7M		
(1) Refer to the following slides for a reconciliation of non-GAAP adjusted operating expenses to total operating expenses						
		6/30/23		12/31/22		
Cash, cash equivalents, restricted cash & investment debt see	curities available for sale		\$415.0M	\$490.9M		
Total current and long-term debt (2)			\$333.4M	\$332.7M		

(2) Total outstanding principal debt is \$336.3M; \$109.8M of notes paid July 3, 2023; Remainder of notes due 2026

## Intercept Leading Specialty Biopharma in Rare and Serious Liver Diseases



\* As of June 30, 2023, Intercept had cash, cash equivalents, restricted cash, and investment debt securities available for sale of \$415.0 million.



This presentation refers to 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.

This is a non-GAAP financial measure and is not necessarily consistently defined across companies. Investors should consider it in addition to, but not instead of, the GAAP measure. Our management uses this measure for budgeting, operational goals, and managerial purposes. We believe that presentation of this non-GAAP measure is helpful supplemental information for investors and management regarding operating performance and trends.

For a reconciliation table, please refer to the next slide. For non-GAAP adjusted operating expenses, regarding future, projected periods, a quantitative reconciliation would not be available without unreasonable effort, due to the difficulty of predicting with reasonable certainty future amounts of stock-based compensation expense.

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