

Intercept Pharmaceuticals

J.P. Morgan Healthcare Conference

Jerry Durso, President and CEO

January 12, 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; our strategic priorities; growth in Ocaliva sales; trends in prescriber and patient behavior and adoption of Ocaliva; our operational performance; and timing and results of our R&D, clinical trials, regulatory submissions, and new product initiatives.

Important factors could cause actual results to differ materially from the FLS, including: our ability to increase sales as expected; our ability to estimate future financial needs and results; our ability to execute on our strategic priorities and to operate effectively; our ability to obtain and maintain regulatory approvals; our ability to satisfy post-marketing requirements, including using real-world evidence; the initiation, timing, cost, conduct, progress, and results of our R&D activities, preclinical studies, and clinical trials; the safety and efficacy of our products and product candidates; the progress, timing, and results of our clinical trials, including regarding safety and efficacy; adverse medical, clinical, efficacy, quality, safety, or pharmacovigilance events or results from clinical trials; potential side effects associated with our product or product candidates; the timing and outcomes of interactions with regulators including the FDA 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 Ocaliva sales growth (including estimated market size, market penetration, patient satisfaction, refill rates, and sales prices); competition from new or existing drugs; the success of our competitors and our failure to outperform or outcompete them; the impact of the sale of our international business; our ability to manage successfully our commercial and operational performance; our ability to attract and retain key personnel; our ability to manage expenses; our ability to manage legal, operational, and other risks; 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 quarterly earnings.

This document contains FLS regarding our financial results, including net sales and cash position, for Q4 and full year 2022, which remain under internal review and audit as we close our books and prepare our 10-K. Our financial results are subject to the risks and uncertainties described above, and our audited financial results as finalized and reported may differ from the statements in this document due to factors including continued review and reconciliation of our accounting records and consideration of accounting rules.

Our mission

is to build a healthier tomorrow
for people with progressive
non-viral liver diseases



Intercept Today: Established Expertise in Liver Disease

Sustainable and growing PBC business with Ocaliva

Strong revenue of ~\$343M non-GAAP adjusted net sales (~\$285M U.S. net sales), representing ~10% growth in FY 2022*

OCA+bezafibrate fixed-dose combination Phase 2 development program ongoing

Progressing OCA for pre-cirrhotic liver fibrosis due to NASH

NDA re-submitted in December 2022

NDA supported by robust NASH development program, including two positive interim analyses from the Phase 3 REGENERATE study

Advancing internal pipeline in liver diseases with high unmet need

Initiated Phase 2a FRESH study with INT-787 in severe alcohol-associated hepatitis (sAH)

Evaluating and prioritizing short- and long-term internal and external opportunities aligned with our core strengths

Fully integrated organization with ~350 employees focused exclusively in liver disease

Strengthened financial position and an overall improved capital structure

*These totals are unaudited

Strong Financial Foundation for Future Growth and Success

2022 Actions and Select Financial Results

- \$450M sale of rights to Ocaliva in PBC outside the U.S.
- \$389M 2026 convertible notes retired, decreasing debt by 54% and reducing future cash interest expense by 58%
- U.S. Ocaliva net sales (unaudited) of ~\$77M in 4Q22 and ~\$285M for FY22*
- Net cash positive with total cash position of approximately \$490M*

Impact in 2023

- Strong balance sheet with sustainable cash-level above debt
- Financial flexibility to both invest in our core business priorities and sustainably grow
- Efficient launch in NASH leveraging existing infrastructure

*These totals are unaudited



Jennie,
Living with PBC

**Sustainable and Growing PBC
Business with Ocaliva**

**Progressing OCA for Pre-Cirrhotic
Liver Fibrosis due to NASH**

**Advancing Internal Pipeline,
2023 Priorities**

Ocaliva in PBC – A Strong Foundational Business



Ocaliva is approved for the treatment of PBC* in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA

More than 30,000 patient years** of post-marketing experience; 6 years of market data

Strong existing and growing prescriber base of hepatologists and gastroenterologists

Strong patents on Ocaliva with expiration dates into 2036; composition of matter patent into 2027

Only approved second-line therapy in PBC with competition not expected until 2024

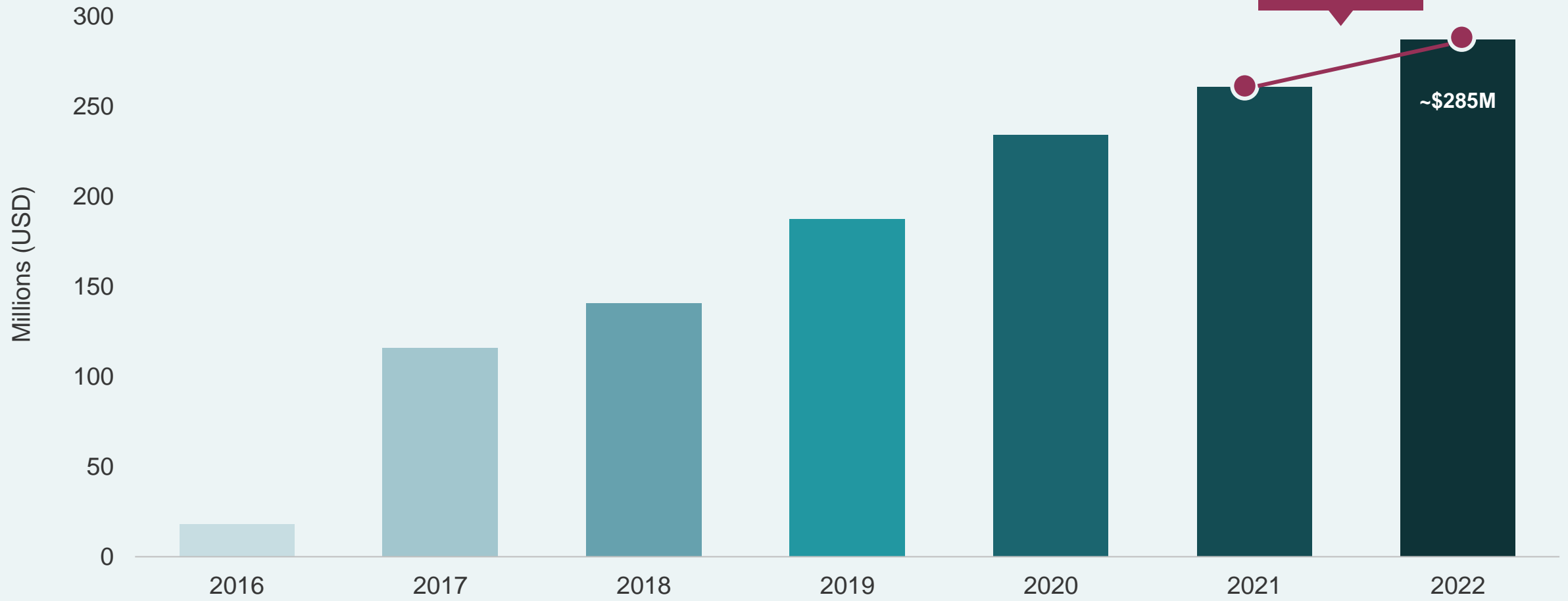
sNDA submission in support of fulfilling post-marketing requirements anticipated in 2023

*In the U.S.: in patients without cirrhosis or with compensated cirrhosis who do not have evidence of portal hypertension

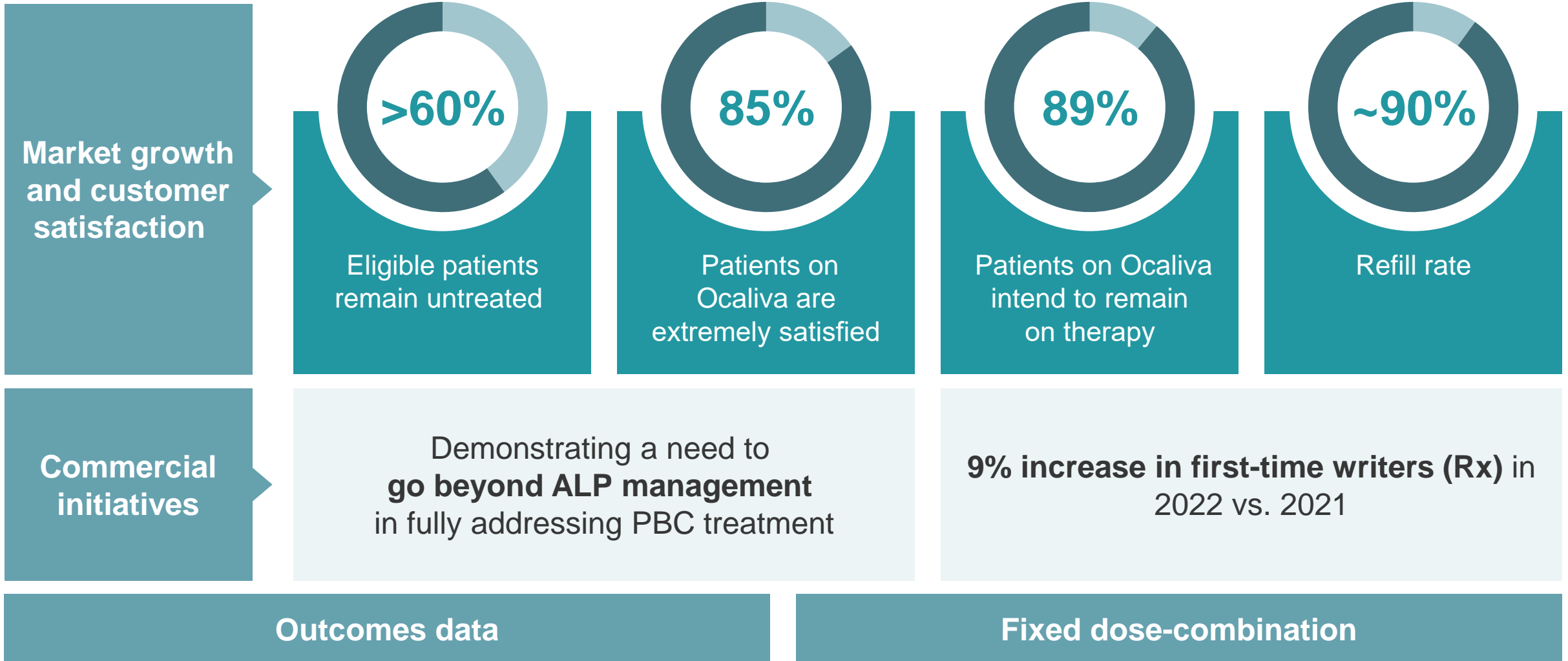
**As of September 2022

Our Ocaliva Business Shows Strong Growth in 2022 (Unaudited)

U.S. Ocaliva Net Sales



Pathway for Long-Term Ocaliva Growth



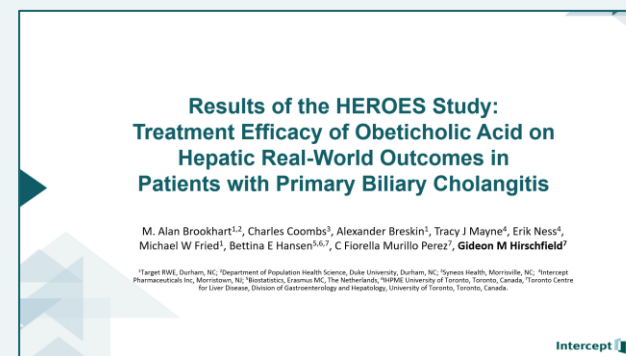
Data Demonstrates Long-Term Improved Clinical Outcomes in Patients Taking OCA for PBC

Publishing and presenting multiple real-world analyses demonstrating long-term clinical benefits of OCA in PBC, including transplant-free survival: the most important goal for patients and clinicians

A **70% lower risk of death or liver transplant compared to control patients** was demonstrated in a key publication in *Gastroenterology*¹



HEROES-US study showed statistically significant and clinically meaningful reduction in all-cause death, liver transplant, or hospitalization for hepatic decompensation among OCA-treated patients compared to a control group who were not treated with OCA



Reference: 1. C. Fiorella 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*, vol. 163, issue 6, 2022. pp. 1630-1642.

Fixed-Dose Combination of OCA+Bezafibrate May Establish New Best-in-Class Clinical Benefits

Exploring the potential for improved efficacy and tolerability with a fixed-dose combination of OCA and bezafibrate for the treatment of PBC

OCA + Bezafibrate FDC Overview

Synergistic mechanisms of action

Potential to lower key biochemical measures that predict long-term outcomes in PBC¹

Strong additive effect on cholestasis and improved pruritus¹

Phase 2 Studies

Ongoing global Phase 2 study evaluating the safety, efficacy and tolerability of OCA+bezafibrate and different dosing regimens of the combination

Ongoing Phase 2 study in Europe evaluating different dosing regimens of OCA+bezafibrate

Phase 2 clinical program will inform dose selection and study design for a Phase 3 development program

Reference: 1. L. Smets, et al. "Bezafibrate improves the effect of obeticholic acid on cholestasis in patients with primary biliary cholangitis." *Hepatology*, vol. 70, supplement n°1S, 2019. F. Nevens, et al. "A Placebo-Controlled Trial of Obeticholic Acid in Primary Biliary Cholangitis." *New England Journal of Medicine*, vol. 375, issue 7, 2016.



Terri,

*Living with Advanced
Fibrosis due to NASH*

Sustainable and Growing PBC
Business with Ocaliva

Progressing OCA for Pre-Cirrhotic
Liver Fibrosis due to NASH

Advancing Internal Pipeline,
2023 Priorities

OCA: Unique Opportunity To Help Patients With Pre-Cirrhotic Fibrosis due to NASH

Fibrosis is the strongest predictor of outcomes in patients with NASH:

- Patients with advanced fibrosis have significant risk of increased liver-related morbidity and mortality¹⁻²

No NASH medications are currently approved

OCA is an **antifibrotic that has twice demonstrated statistically significant antifibrotic efficacy in a Phase 3 study**

NDA re-submitted in December 2022; anticipating a PDUFA target review time of six months

References: 1. Dulai PS, et al. "Increased Risk of Mortality by Fibrosis Stage in Nonalcoholic Fatty Liver Disease: Systematic Review and Meta-Analysis." *Hepatology*, vol. 75, issue 5, 2017. pp. 1557-1565. 2. Hagström H, et al. "Fibrosis stage but not NASH predicts mortality and time to development of severe liver disease in biopsy-proven NAFLD." *Hepatology*, vol. 67, 2017. pp. 1265-1273.

Reaching Patients with OCA at a Pivotal Point in NASH Disease Progression

Early Fibrosis (F0-F1)

- Predominantly managed in primary care
- Focus on screening for fibrosis in at-risk populations
- Treatment goals are managing long-term risk factors and lifestyle change

Pre-Cirrhotic Fibrosis (F2-F3)

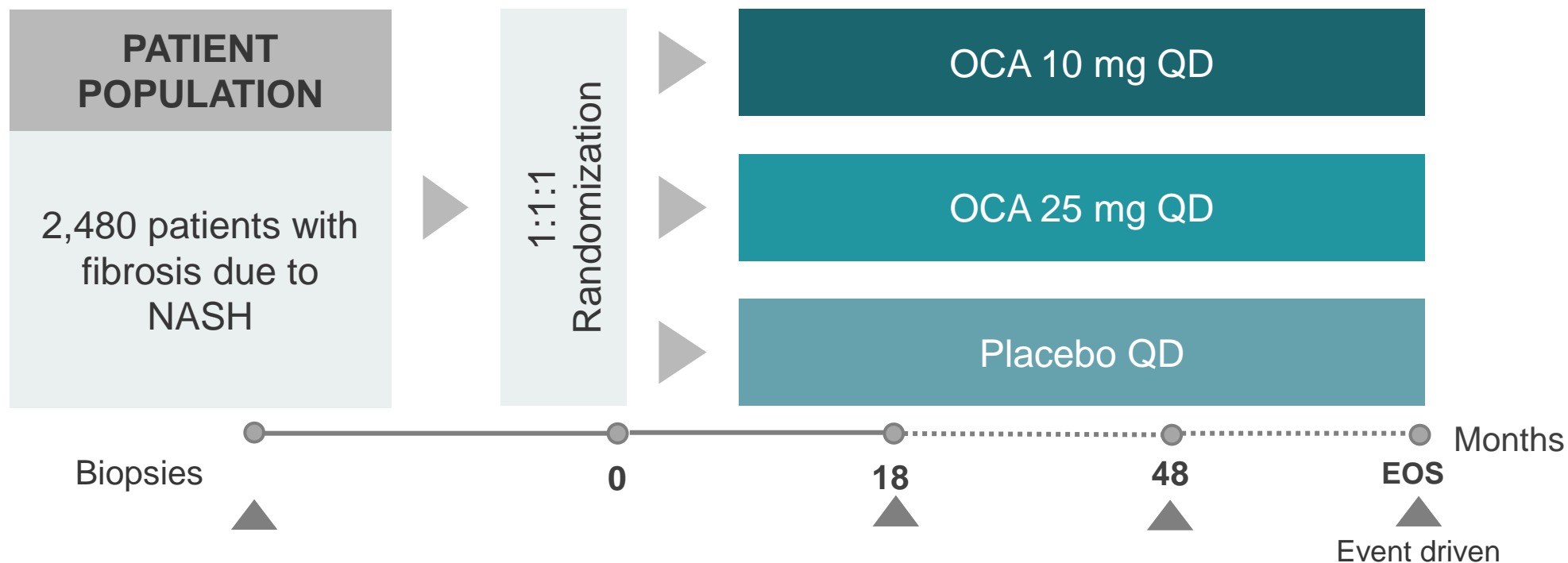
- 1 in 5 patients with pre-cirrhotic fibrosis progresses to cirrhosis after approx. 2.5 years¹
- Reversing fibrosis and preventing progression to cirrhosis are central goals for providers and payers

Cirrhosis (F4)

- Patients who progress from F3 to F4 have a more than 2x increase in risk of liver-related death²
- Accounts for a disproportionate amount of NASH-related healthcare costs – >80% of predicted annual direct medical costs³⁻⁴

References: 1. Hagström H, et al. "Fibrosis stage but not NASH predicts mortality and time to development of severe liver disease in biopsy-proven NAFLD." *Hepatology*, vol. 67, 2017. pp. 1265-1273. 2. Sanyal AJ, et al. "The Natural History of Advanced Fibrosis Due to Nonalcoholic Steatohepatitis: Data From the Simtuzumab Trials." *Hepatology*, vol. 70, issue 6, 2019. pp. 1913-1927. 3. Estes C, et al. "Modeling the epidemic of nonalcoholic fatty liver disease demonstrates an exponential increase in burden of disease." *Hepatology*, vol. 67, issue 1, 2018. pp. 123-133. 4. Younossi ZM, et al. "Global epidemiology of nonalcoholic fatty liver disease-Meta-analytic assessment of prevalence, incidence, and outcomes." *Hepatology*, vol. 64, issue 5, 2016. pp. 577-1586.

REGENERATE: The First, Largest and Longest-Running Pivotal Phase 3 Study in Patients With Fibrosis Due to NASH Achieved its Primary Endpoint in Two Analyses



18-month interim cohort of 931 patients
Original interim analysis readout in February 2019;
second interim analysis readout in July 2022

OCA achieved the primary endpoint by demonstrating fibrosis improvement ≥ 1 stage without worsening of NASH in both analyses

The analyses were conducted after 931 randomized patients with fibrosis stage 2 or 3 had or would have reached their actual/planned Month 18 visit (ITT population). The REGENERATE study will continue through clinical outcomes for verification and description of clinical benefit.

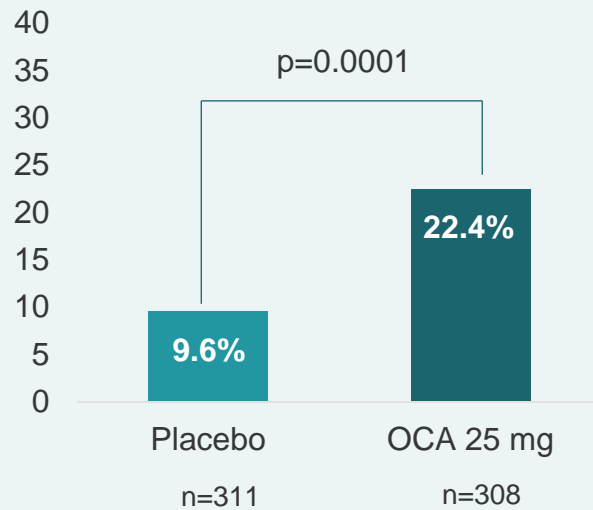
EOS analysis of clinical outcomes to confirm clinical benefit.

EOS, end of study; ITT, intent to treat; QD, once a day.

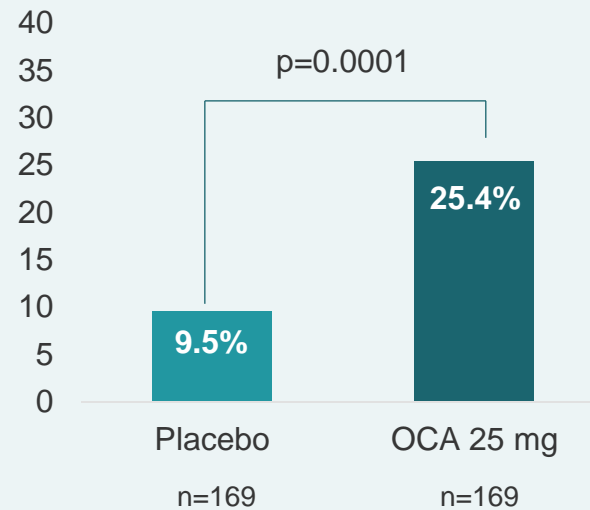
Reference: <https://clinicaltrials.gov/ct2/show/NCT03439254>.

OCA Demonstrated Strong Antifibrotic Effect and Monitorable and Manageable Safety Profile

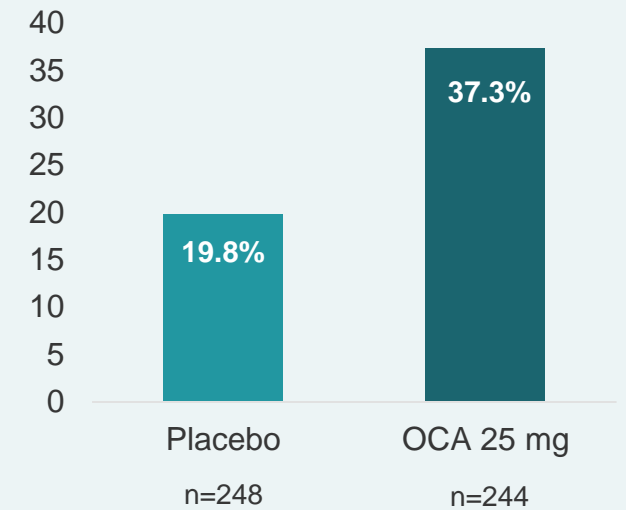
OCA 25 mg demonstrated double the response rate of placebo in reduction of liver fibrosis without worsening of NASH (regulatory endpoint)¹



Antifibrotic effect was more pronounced in individuals with advanced fibrosis without cirrhosis (F3) at baseline¹



Improvement of liver fibrosis was observed in 37% of subjects with available baseline and month 18 liver biopsies¹

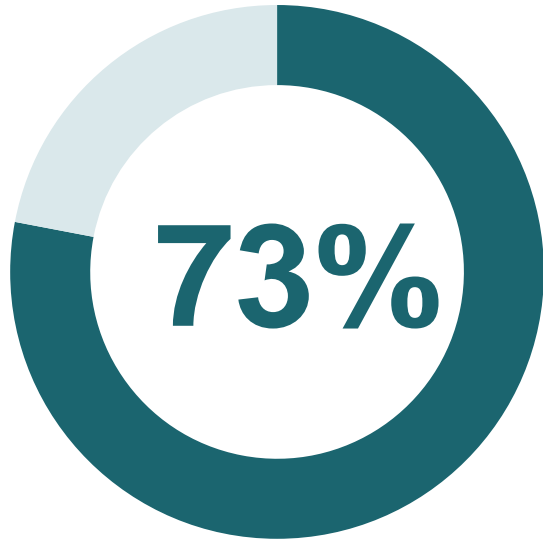


Dose-dependent reductions in alanine transaminase (ALT) and liver stiffness observed with OCA via non-invasive tests in subjects out to 4 years¹

Robust safety assessment of 2,477 patients, including 1,000 on study drug for four years demonstrated a monitorable and manageable safety profile that supports chronic administration of OCA

Reference: 1. A. Sanyal, et al., "Topline Results From a New Analysis of the REGENERATE Trial of Obeticholic Acid for the Treatment of Nonalcoholic Steatohepatitis." NASH-TAG, Jan 5-7, 2023.

Intercept Is Poised To Deliver OCA in NASH Upon Approval



**of highest potential
Heps/GIs are within
our existing PBC
customer base**

Established U.S. field presence with broad geographic footprint

- 55 Territory Business Managers in 7 regions with all states covered
 - Key account coverage and relationships
-

Deep disease state knowledge

- Robust patient and HCP disease education campaigns
 - Existing medical affairs team that targets top specialists and payers
-

Recognized industry leadership

- Ongoing engagement with patients and key advocacy organizations
- Significant presence at major liver and gastroenterology congresses



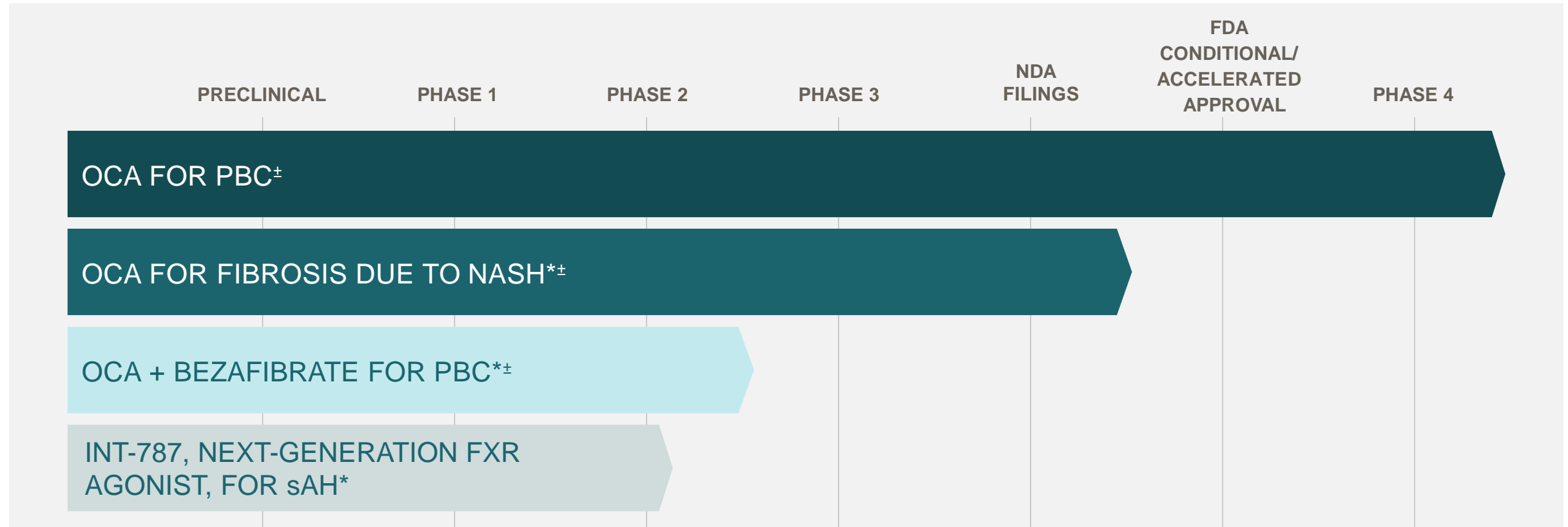
**Sustainable and Growing PBC
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**Advancing Internal Pipeline,
2023 Priorities**

Clinical Development Programs

Our scientific platform is based on validated and novel scientific targets with the potential for therapeutic application across multiple liver diseases.



*Currently used for investigational purposes only. Has not been approved by the FDA or any other worldwide regulatory agency. Safety and efficacy have not been established.

±Intercept owns or licenses U.S. rights and has the right to commercialize in the U.S. only.

Advancing INT-787 in Lead Indication: Severe Alcohol-Associated Hepatitis

Alcohol-related liver disease is currently the leading indication for liver transplant listing in the U.S., with a marked increase in patients with sAH needing liver transplant

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

- 16-fold more water-soluble than OCA¹
- In pre-clinical liver disease models, modulates a significantly greater number of genes relative to OCA within the liver and intestine

Phase 1 and proof-of-concept Phase 2a study underway

- Initiated the FRESH study, a Phase 2a trial evaluating the safety, tolerability, efficacy and pharmacokinetics of INT-787 in patients with sAH
 - Randomized, double-blind, dose-escalation study
 - Expected to enroll approximately 50 patients with sAH across multiple clinical sites in the U.S., UK and France
- Phase 1 trial of INT-787 demonstrated a favorable safety and tolerability profile based on adverse events
 - Expected to complete in Q1 2023

Reference: 1. Pellicciari R, et al. "Discovery of 3 α ,7 α ,11 β -Trihydroxy-6 α -ethyl-5 β -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.

2023 Strategic Priorities: Building on Our Strong Foundation in Liver Disease

Ensure long-term growth and leadership with Ocaliva in PBC

Maintain IP protection of the lifecycle of Ocaliva into the 2030s

Progress OCA+bezafibrate combination

Gain FDA approval for OCA in NASH

Successfully launch first-to-market therapy for NASH

Continue to progress REGENERATE trial to outcomes

Advance internal pipeline in liver diseases with high unmet need

Progress proof-of-concept FRESH study of INT-787 in sAH

Prioritize internal and external opportunities aligned with core strengths

Continue to maintain our strong financial position

Sufficient cash to meet strategic objectives

Maintain expense discipline to ensure a net cash positive balance sheet

Appendix

Q4 and FY 2022 Financial Highlights / Reconciliation of Non-GAAP Adjusted Net Sales To Total Revenue (Unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
Total Revenue	~\$77M	\$68.6M	~\$285M	\$260.7M
Ex-U.S. revenue (discontinued operations)	-	-	~\$58M	\$52.8M
Total non-GAAP adjusted net sales	~\$77M	\$68.6M	~\$343M	\$313.5M

	12/31/22	12/31/21
Cash, cash equivalents, restricted cash & investment debt securities available for sale	~\$490M	\$427.8M

2022 Financial Guidance	Low	High
Total revenue	~\$282M	~\$292M
Adjustment: Ex-U.S. revenue (discontinued operations)	~\$58M	~\$58M
Non-GAAP adjusted net sales	~\$340M	~\$350M

Notes Regarding Non-GAAP Financial Measures

- This presentation refers to non-GAAP adjusted net sales.
- For the periods presented, non-GAAP adjusted net sales include in total revenue, as calculated and presented in GAAP, the effect of one item: total revenue from discontinued operations, for the first half of the year.
- 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 reconciliation tables, please see above.