

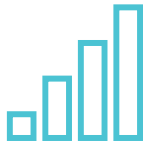
# Q2 2022 Earnings Call Presentation

Disclosed August 3, 2022

# Key Business Updates



**Recognized \$100.4 million in non-GAAP adjusted net sales; U.S. net sales of \$71.8 million representing 5% growth over the prior year quarter**



**Reissued 2022 financial guidance to reflect impact of sale of international business: Ocaliva non-GAAP adjusted net sales guidance of \$325 million to \$345 million and non-GAAP adjusted operating expense guidance of \$335 million to \$365 million**



**Following pre-submission meeting with FDA, Company to resubmit new drug application in liver fibrosis due to NASH by the end of 2022**



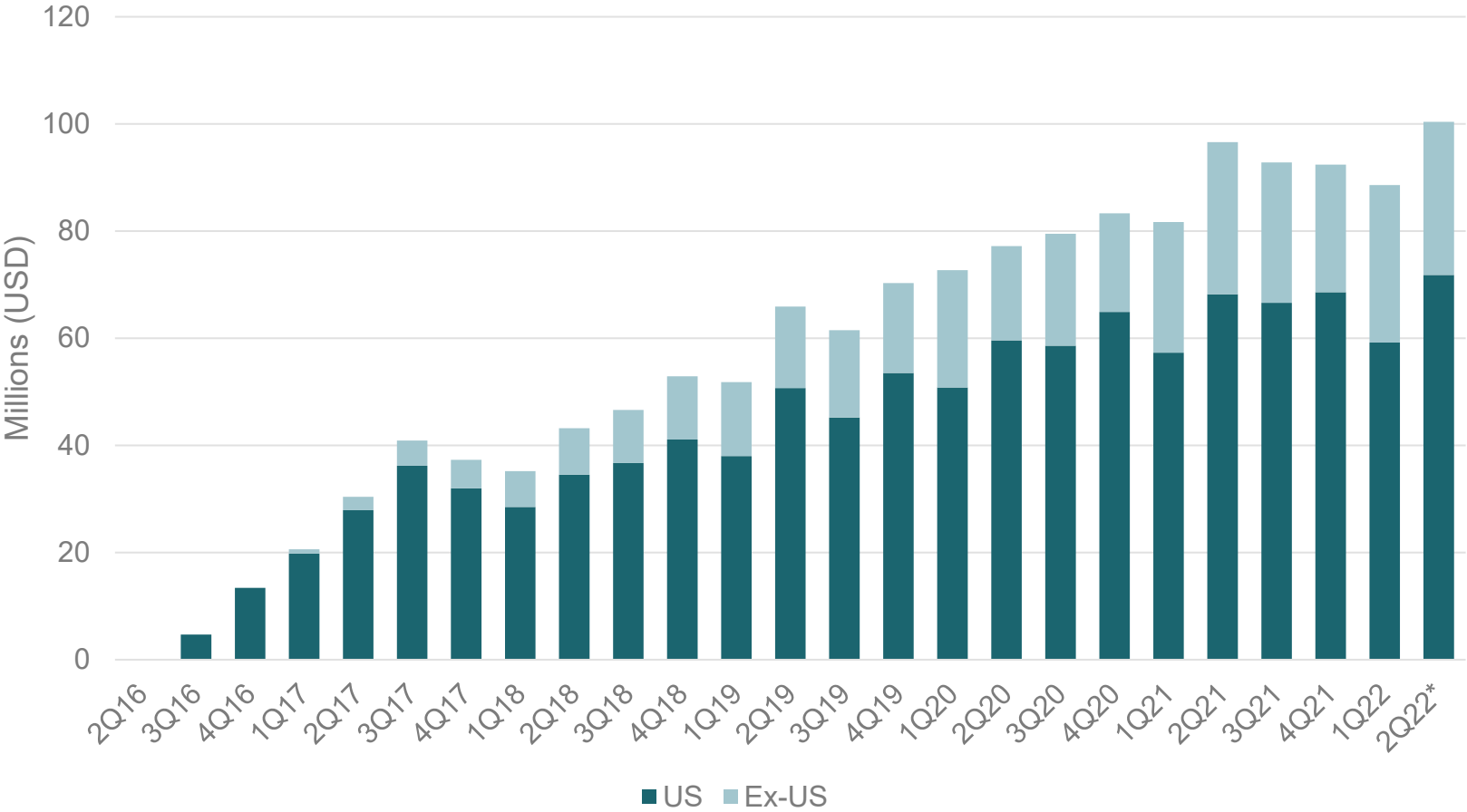
**Topline Phase 3 REVERSE readout anticipated in late Q3; Phase 2 OCA-bezafibrate combination studies in the U.S. and Europe are progressing and Phase 1 combination study is fully enrolled; Phase 1 study of INT-787 has progressed to final cohorts**



**Data from Phase 4 COBALT study and supplemental real-world evidence will be included in a regulatory submission to FDA later this year in support of fulfilling post-marketing requirements**

# Growing Revenue for Ocaliva in U.S. with 5 Percent Increase in Net Sales in 2Q22 vs. 2Q21

Ocaliva Net Sales



\*Intercept completed the sale of its international business for \$405M in upfront consideration on July 1, 2022

## Ocaliva Worldwide non-GAAP Adjusted Net Sales Overview

Worldwide Ocaliva non-GAAP adjusted net sales in PBC of **\$100.4M** with **U.S. sales of \$71.8M**; **INTL sales of \$28.6M** in 2Q22

# Continued to Expand Foundational PBC Business and Generate Long-Term Ocaliva Data

## Ocaliva Continues to Deliver

Recognized \$100.4 million in non-GAAP adjusted net sales; U.S. net sales of \$71.8 million representing 5% growth over the prior year quarter

Recent market research indicates that belief in Ocaliva and intent-to-prescribe have both increased following the label change in the U.S. in 2021

## Generating Long-Term Data to Educate Physicians and Support Post-Marketing Requirements

Initiated multiple real-world evidence studies, including the HEROES studies, which are providing consistent evidence of transplant-free survival in patients receiving Ocaliva for PBC

Data from COBALT and supplemental real-world evidence from the HEROES studies and Phase 3 POISE open-label extension will be included in a regulatory submission to FDA later this year in support of fulfilling post-marketing requirements

# Regulatory Process Ongoing in Liver Fibrosis due to NASH

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**Pursuing an accelerated approval pathway for OCA in the U.S. as the first compound to treat fibrosis due to NASH**

**Announced positive topline results from a new interim analysis of the Phase 3 REGENERATE trial of OCA in patients with liver fibrosis due to NASH**

- This is the second analysis in which OCA has met the primary endpoint for the intent-to-treat (ITT) population in REGENERATE
- Compared to the original analysis, the safety population in this new interim analysis had 3.4 times more exposure to study drug and nearly 1,000 subjects had been on study drug for four years

**In addition to reinforcing the efficacy of OCA as an antifibrotic, this second analysis provides the benefit of a deeper understanding of safety over a longer period of time**

**Had a constructive pre-submission meeting with FDA in July, and look forward to resubmitting our NDA by the end of 2022**

# Continued Pipeline Progress

## INT-787

- Progressed to the final cohorts
- Look forward to sharing data, as well as intended indication and development plans, later this year

## OCA+ Bezafibrate Combination

- Continue to add clinical sites and screen patients in U.S.-based Phase 2 OCA/bezafibrate fixed-dose combination trial in PBC and continue to enroll patients in Phase 2 OCA/bezafibrate fixed-dose combination trial in Europe
- Phase 1 study of this combination in the U.S. has completed enrollment

## REVERSE

- Expect a topline readout in late Q3 for Phase 3 REVERSE study in patients with compensated cirrhosis due to NASH

# Q2 2022 Financial Highlights

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Total revenue	\$ 71.8M	\$ 68.2M	\$ 130.9M	\$ 125.5M
ex-U.S. revenue (discontinued operations)	28.6M	28.4M	58.1M	52.7M
Total non-GAAP net sales	100.4M	96.6M	189.0M	178.2M
GAAP operating expenses	85.1M	81.6M	171.0M	177.5M
Non-GAAP adjusted operating expenses (1)	89.8M	86.5M	181.6M	188.2M
Cost of sales	0.3M	0.3M	0.5M	0.5M
SG&A Expenses	40.0M	43.9M	77.7M	89.0M
R&D Expenses	44.8M	37.7M	92.7M	88.3M

(1) Refer to slide 9 for a reconciliation of non-GAAP adjusted operating expenses to total operating expenses

	6/30/22	12/31/21
Cash, cash equivalents, restricted cash & investment debt securities available for sale	\$ 412.3M	\$ 427.8 M

# Note Regarding Non-GAAP Financial Measures

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This presentation refers to non-GAAP adjusted net sales and non-GAAP adjusted operating expenses on a historical and projected basis.

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 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 and one item for discontinued operations.

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

For reconciliation tables, please refer to the prior slide and 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 Net Sales Financial Guidance to Total Revenue Financial Guidance, and Non-GAAP Adjusted Operating Expenses to Total Operating Expenses

## Reconciliation of Non-GAAP Adjusted Net Sales to Total Revenue

(Unaudited)

(In thousands)

	<u>2022 Financial Guidance</u>	
	<u>Low</u>	<u>High</u>
Total revenue	\$ 266,935	\$ 286,935
Adjustment:		
ex-U.S. revenue (discontinued operations)	58,065	58,065
Non-GAAP adjusted net sales	<u>\$ 325,000</u>	<u>\$ 345,000</u>

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

(Unaudited)

(In thousands)

	<u>Three Months Ended</u>		<u>Six Months Ended</u>	
	<u>June 30,</u>		<u>June 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Total operating expenses	\$ 85,120	\$ 81,644	\$ 170,990	\$ 177,526
Adjustments:				
Add: ex-U.S. operating expenses (discontinued operations)	15,739	14,172	28,723	29,298
Less: Stock-based compensation	8,543	8,448	15,264	16,867
Depreciation	2,491	879	2,866	1,749
Non-GAAP adjusted operating expenses	<u>\$ 89,825</u>	<u>\$ 86,489</u>	<u>\$ 181,583</u>	<u>\$ 188,208</u>

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

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This document contains FLS, including regarding: financial guidance and sales and expense expectations, trends in prescriber and patient behavior and adoption of Ocaliva, 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 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 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 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; competition from new or existing drugs; 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 estimates of future financial needs and results; 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.