

Q3 2022 Earnings Call Presentation

Disclosed November 1, 2022

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

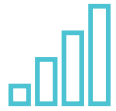
This document contains FLS, including regarding: financial guidance and sales and expense expectations, trends in prescriber and patient behavior and adoption of Ocaliva, and timing and results of our R&D, clinical trials, regulatory submissions, and new product initiatives.

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.

Key Business Updates



U.S. Ocaliva net sales of \$77.6 million; 16.4% growth over the prior year quarter



Increased 2022 Ocaliva non-GAAP adjusted net sales guidance to \$340 million – \$350 million and narrowed non-GAAP adjusted operating expense guidance to \$350 million – \$365 million



Repurchased \$389M of 2026 secured convertible notes, debt reduced by 54% and reduced cash interest expense by 58%, or \$13.6 million annually



On track to resubmit new drug application for OCA in liver fibrosis due to NASH by the end of 2022 based on the positive Phase 3 REGENERATE study



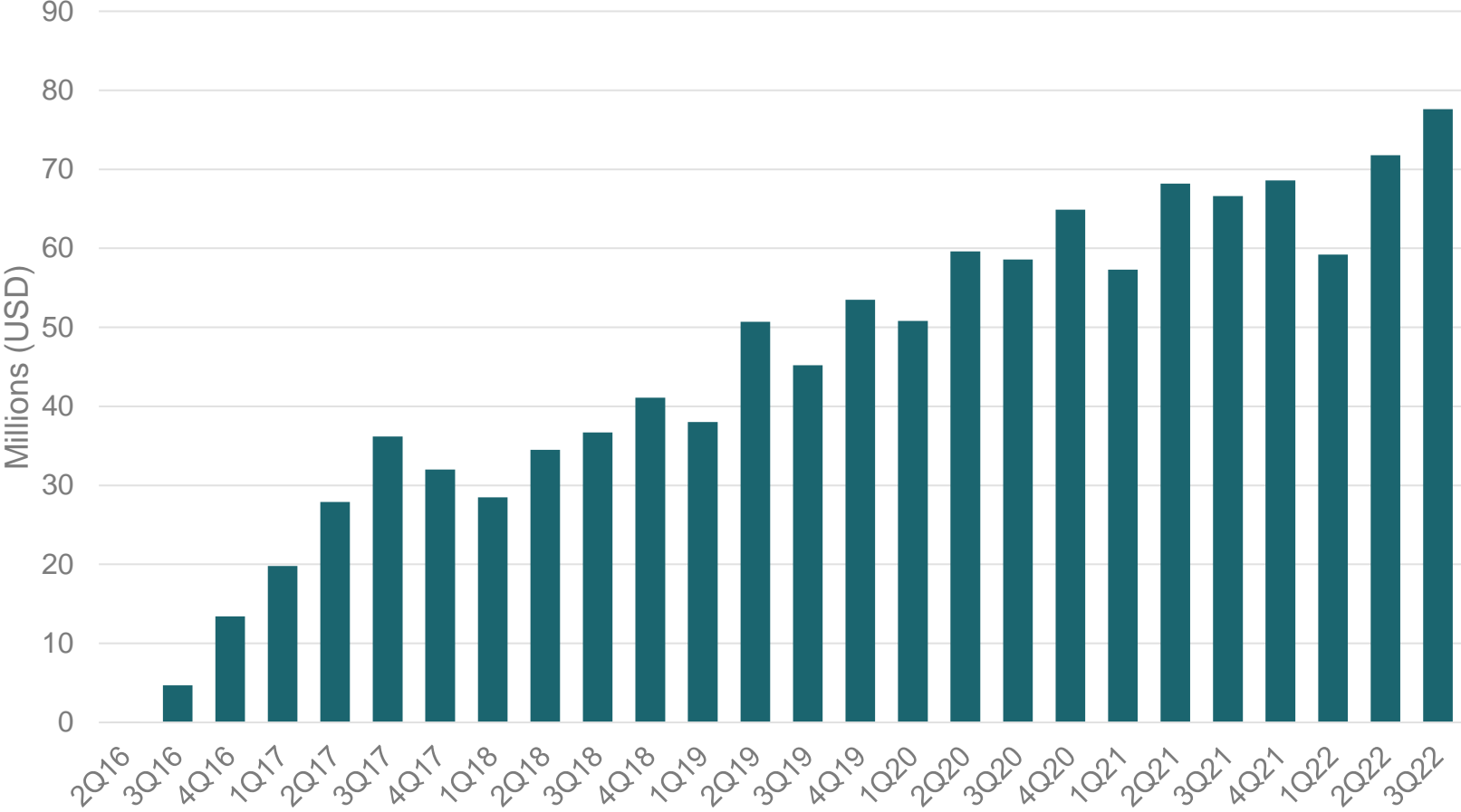
Data from Phase 4 COBALT study and supplemental real-world evidence will be included in a regulatory submission to FDA in 2023 in support of fulfilling post-marketing requirements



OCA/bezafibrate fixed-dose combination development program is ongoing; comprehensive Phase 1 study for next-generation FXR agonist, INT-787, has progressed to its final cohort and Phase 1 data, lead indication and development plans will be shared at The Liver Meeting®

Accelerated, Double-Digit Growth in Ocaliva with 16.4 Percent Increase in U.S. Net Sales in 3Q22 vs. 3Q21

U.S. Ocaliva Net Sales



U.S. Ocaliva net sales of \$77.6 million in 3Q22

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

Ocaliva Continues to Deliver

IQVIA reported NRx volume was up 37% over the same period last year, representing the highest NRx volume in a single quarter since the start of the COVID-19 pandemic

Demand units increased 10% in 3Q22 vs. the same period last year; patient retention and high refill rates at approximately 90% are key contributors

Recognized \$77.6 million in net sales representing 16.4% growth over the prior year quarter

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

Gastroenterology published data showing that patients receiving OCA for PBC in a clinical trial setting had greater transplant-free survival compared to patients with PBC from real-world patient registries who did not receive OCA

Presenting post-marketing data from COBALT and real-world evidence from HEROES-U.S. at The Liver Meeting®

Compiling data from COBALT and supplementary real-world evidence from large datasets in the U.S., UK and Europe to include in a regulatory submission to FDA in 2023 in support of fulfilling post-marketing requirements

Presenting New Data Supporting NDA Re-Submission in Fibrosis due to NASH

Additional efficacy and safety data from new interim analysis of Phase 3 REGENERATE study to be presented at The Liver Meeting® in late-breaker oral presentation

Second analysis in which OCA has met the primary endpoint for the intent-to-treat (ITT) population in REGENERATE (n=931)

REGENERATE baseline, month 18 biopsies and month 48 biopsies were read using new consensus methodology

REGENERATE safety database now includes:

- An additional year of patient data – data cut-off is December 31, 2021
- Almost 1,000 patients who have reached month 48
- 3.5x the drug exposure of the prior analysis

On track for NDA resubmission in fibrosis due to NASH by the end of 2022

Advancing Additional Value-Driving Pipeline Programs

INT-787

- Next-generation farnesoid X receptor (FXR) agonist
- Phase 1 study has progressed to its final cohort
- Phase 1 data, lead indication and development plans to be shared at The Liver Meeting®

OCA+ Bezafibrate Combination

- Continue to screen patients and add clinical sites in our two Phase 2 studies for the planned fixed-dose combination
- Large Phase 1 study in the U.S. to better characterize exposure data and any potential drug-drug interactions of the fixed-dose combination has completed enrollment

Q3 2022 Financial Highlights

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Total revenue	\$77.6M	\$66.6M	\$208.5M	\$192.1M
ex-U.S. revenue (discontinued operations)	-	-	58.1M	52.8M
Total non-GAAP net sales	\$77.6M	\$66.6M	\$266.6M	\$244.9M
GAAP operating expenses	87.7M	86.2M	258.7M	263.7M
Non-GAAP adjusted operating expenses (1)	82.7M	89.6M	264.3M	277.8M
Cost of sales	0.4M	0.2M	1.0M	0.8M
SG&A Expenses	43.3M	41.3M	121.0M	130.3M
R&D Expenses	44.0M	44.7M	136.8M	133.0M

(1) Refer to slide 10 for a reconciliation of non-GAAP adjusted operating expenses to total operating expenses

	9/30/22	12/31/21
Cash, cash equivalents, restricted cash & investment debt securities available for sale	\$497.8M	\$427.8M

Note Regarding Non-GAAP Financial Measures

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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Total revenue	\$ 77,588	\$ 66,640	\$ 208,491	\$ 192,117
Adjustment:				
ex-U.S. revenue (discontinued operations)	-	-	58,065	52,760
Non-GAAP adjusted net sales	<u>\$ 77,588</u>	<u>\$ 66,640</u>	<u>\$ 266,556</u>	<u>\$ 244,877</u>
			2022 Financial Guidance	
			Low	High
Total revenue			\$ 281,935	\$ 291,935
Adjustment:				
ex-U.S. revenue (discontinued operations)			58,065	58,065
Non-GAAP adjusted net sales			<u>\$ 340,000</u>	<u>\$ 350,000</u>

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

(Unaudited)
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Total operating expenses	\$ 87,732	\$ 86,207	\$ 258,722	\$ 263,733
Adjustments:				
Add: ex-U.S. operating expenses (discontinued operations)	822	12,840	29,545	42,138
Less: Stock-based compensation	5,788	8,616	21,052	25,483
Depreciation	80	808	2,946	2,557
Non-GAAP adjusted operating expenses	<u>\$ 82,686</u>	<u>\$ 89,623</u>	<u>\$ 264,269</u>	<u>\$ 277,831</u>