

Intercept Pharmaceuticals

March 2022



Debbie,
Living with PBC

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 presentation, 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 the newly identified safety signal relating to Ocaliva identified by the FDA in May 2020; 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 ongoing discussion with the FDA and the European Medicines Agency regarding the feasibility of the COBALT and 401 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 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; 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 and short-term investments; our ability to acquire, license and invest in businesses, technologies, product candidates and products; our ability to attract and retain key personnel to manage our business effectively; our ability to manage the growth of our operations, infrastructure, personnel, systems and controls; our ability to obtain and maintain adequate insurance coverage; the impact of COVID-19, including any impact on our results of operations or financial position, related quarantines and 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, facility closures or other restrictions, and the extent and duration thereof; the impact of general U.S. and foreign economic, industry, market, regulatory or political conditions, including the potential 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. Investors should refer to the table reconciling non-GAAP adjusted operating expenses to total operating expenses included in our earnings release for the quarter and year ended December 31, 2020 under the heading “Reconciliation of Non-GAAP Adjusted Operating Expenses to Total Operating Expenses”, available on our website and on our Current Report on Form 8-K dated February 25, 2021. 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.

Our mission

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



Experienced Team with Proven Global Commercial and Development Success

Average 20+ years of diverse industry leadership experience

JERRY DURSO
President, Chief Executive
Officer and Director



ANDREW SAIK
Chief Financial Officer



DAVID FORD
Chief Human
Resources Officer



GAIL CAWKWELL, M.D., PH.D.
Senior Vice President, Medical
Affairs, Safety & Pharmacovigilance



MICHELLE BERREY, M.D., M.P.H.
President of Research & Development;
Chief Medical Officer



LINDA RICHARDSON
Chief Commercial Officer



BRYAN BALL
Chief Quality Officer



ROCCO VENEZIA
Chief Accounting Officer

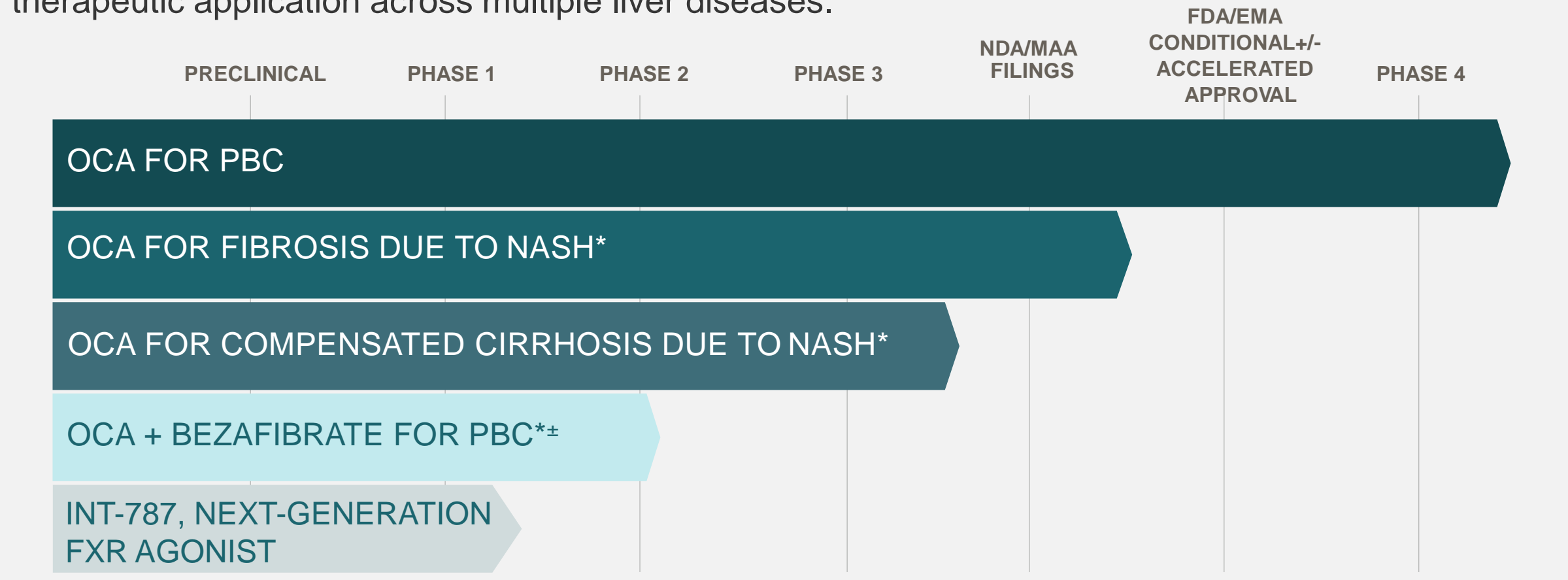


JARED M. FREEDBERG, J.D.
General Counsel



Our Clinical Development Program

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



*Investigational uses and have not been approved by the FDA or any other worldwide regulatory agency. Safety and efficacy have not been established.

±Intercept has a license to develop and commercialize in the U.S. only.

Our Business Today: Established Expertise in Liver Disease

Sustainable and Growing PBC Business with Ocaliva

Strong worldwide
revenue growth
+16% FY 2021

Nearly 30% of FY 2021 sales from
international region with strong
potential for continued growth
and penetration

Two Pivotal Phase 3 Trials in NASH

REGENERATE
First-and-only positive Phase 3
study in liver fibrosis due to NASH;
additional data analyses
anticipated in 2022

REVERSE
Only antifibrotic in Phase 3 for
subjects with compensated
cirrhosis due to NASH

Advancing Pipeline

Two OCA-bezafibrate
Phase 2 studies in PBC
in the U.S. and Europe

INT-787
Phase 1 study ongoing

Core focus areas supported by strong, established expertise
in liver diseases with high unmet needs

Committed to Partnering with the Liver Disease Community

We are proud to engage with stakeholders that further education and research for the liver disease community.





Jennie,
Living with PBC

Sustainable Growth in PBC: An Overview of Ocaliva

Two Pivotal Phase 3 Trials in NASH

Additional Opportunities for Growth and Expansion, 2022 Priorities

We Have a Strong Foundational Rare Disease Franchise in PBC



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

First new medicine for PBC in nearly 20 years at time of approval

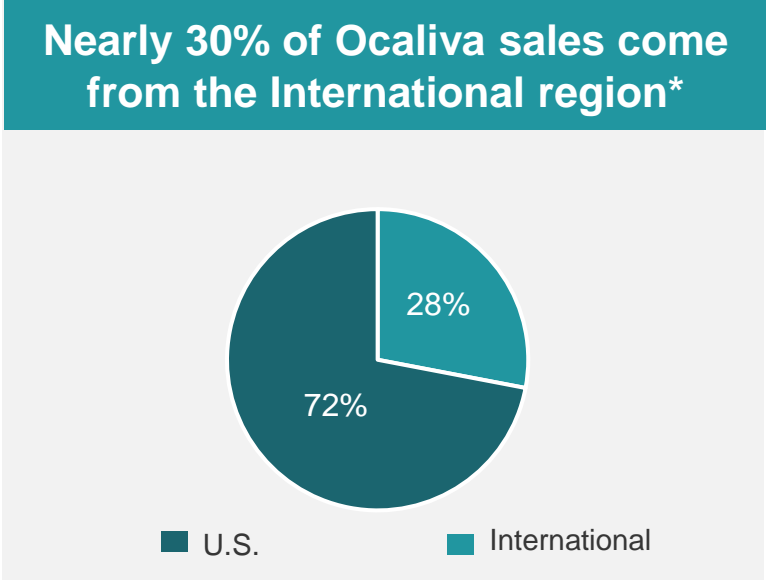
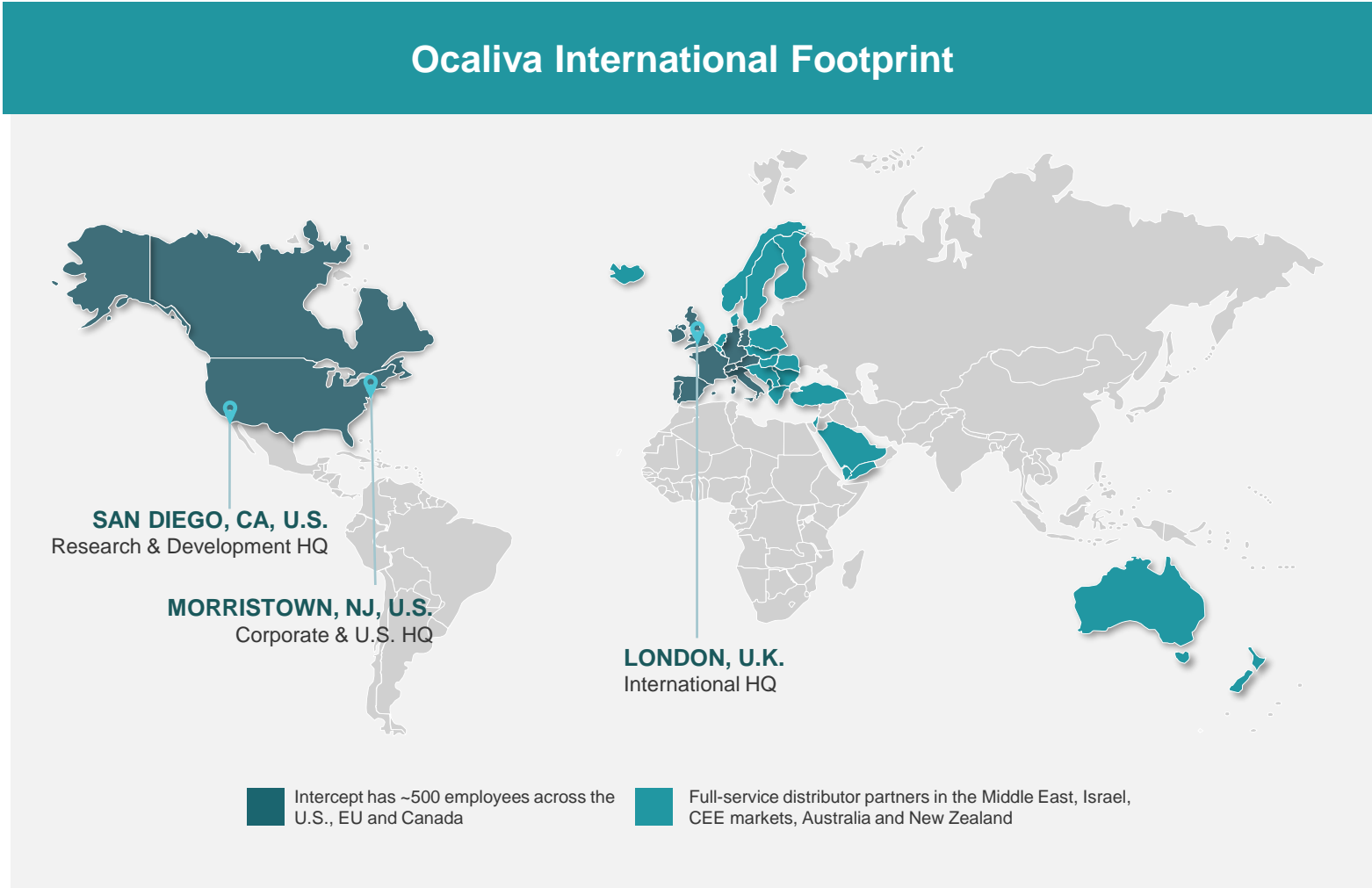
First FXR agonist approved for liver disease

More than 20,000 patient years of post-marketing experience

Supported by strong IP and patent term extension granted

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

We Are Leveraging Our International Commercial Infrastructure to Deliver Ocaliva to Patients with PBC



**Based on FY2021 sales*



Our Fully Integrated U.S. Commercial and Medical Organization Is a Foundational Strength



Exceptional Liver Specialty Sales Force

~55 reps calling on GIs and hepatologists

Quality rating from customers exceeds industry average¹



Broad Payer Coverage

Access for > 95% of covered lives²



Industry-Leading Patient Support Services Hub

Conversion and persistency rates are high and consistently above those for specialty pharmacies³



Established Scientific Leadership

>50 congress presentations and journal articles in 2021

Innovative real world and clinical trial hybrid approach to assessing disease outcomes

Strong relationships with the liver patient community, medical thought leaders and clinicians
Deep experience in rare disease

1. IQVIA benchmarks in gastroenterology. 2. Based on ICPT internal data. 3. Data Source: ICPT Data Warehouse; 12/7/2020.

Continually Evolving Our U.S.-Based Approach to Reach More Physicians Who Manage People Living with PBC

Launch

Today



**HCP
Coverage**

4,300

**Focus on hepatologists
at launch**

5,500

**Expanded reach
within GIs**

7,500

**Extended reach via
digital channels**



**Customer
Team
Buildout**

**Territory Business
Managers**

**+ Regional access
management team**

**+ GI group
practice/IDN focus**



**Data and
Message
Evolution**

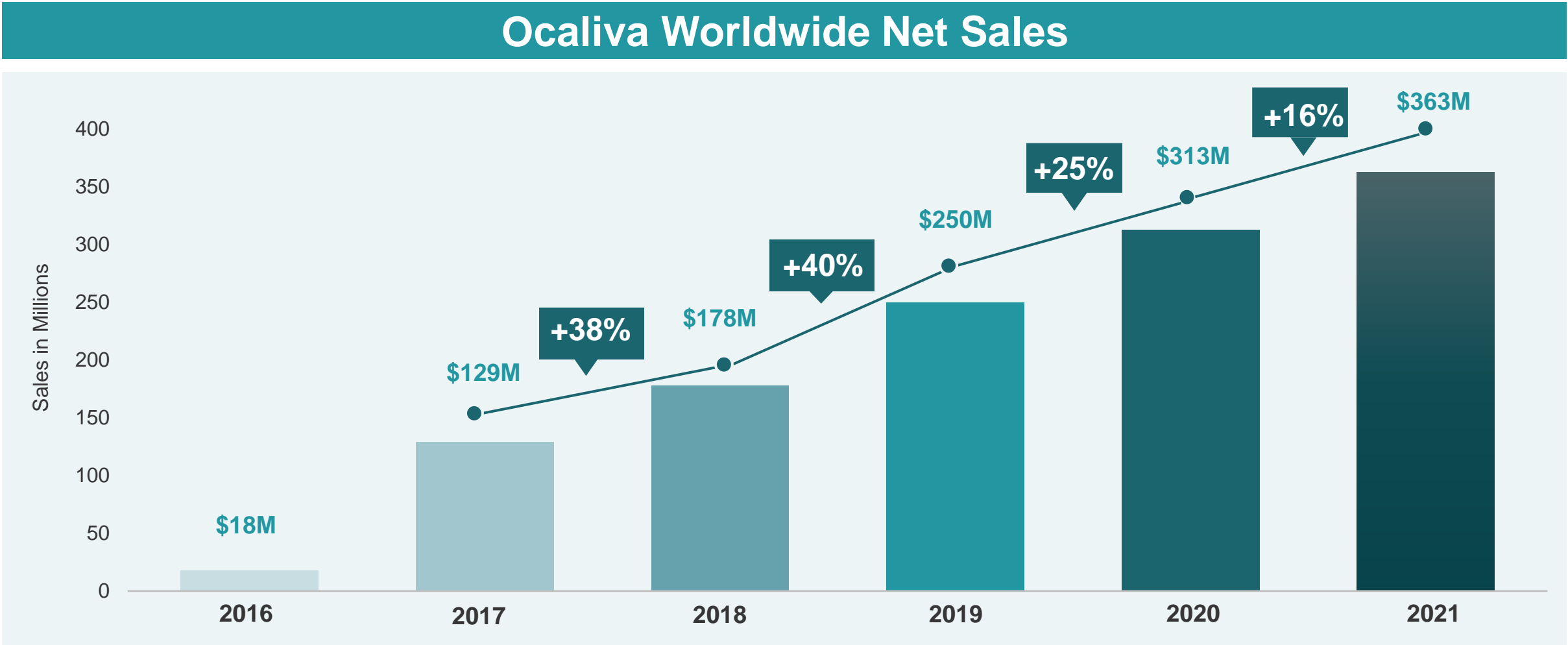
**POISE
ALP reduction**

**Bilirubin
reduction**

**POISE
5-year data and
liver outcomes**

IDN: Integrated Delivery Network; ALP: Alkaline Phosphatase

More Than Six Years Into Launch, Our PBC Business Continues to Grow





Terri,





*Living with Advanced
Fibrosis due to NASH*

Sustainable Growth in PBC: An
Overview of Ocaliva

Two Pivotal Phase 3 Trials in NASH

Additional Opportunities for
Growth and Expansion, 2022
Priorities

As the Field Evolves, the NASH Landscape Is Bifurcating

EARLY		ADVANCED	
NAFLD	Early Fibrosis	Advanced Fibrosis without Cirrhosis	Advanced Fibrosis with Cirrhosis
Up to 3X elevated risk with early fibrosis ¹		 Up to 11X elevated risk with cirrhosis ²	
Predominantly managed in primary care		 Treated by liver specialists	
Focus on screening for fibrosis in at-risk populations		 Focus on urgently identifying patients with advanced fibrosis	
Treatment goals: NASH Resolution, lifestyle change		 Treatment goals: Halt or reverse fibrosis	

References: 1. Dulai PS, et al. Increased Risk of Mortality by Fibrosis Stage in Nonalcoholic Fatty Liver Disease: Systematic Review and Meta-Analysis. *Hepatology*. 2017; 65(5):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. *Journal of Hepatology*. 2017; 67:1265-1273.

We Are Pursuing the First Therapy for Patients With Advanced Fibrosis Due to NASH

No medications approved to treat Advanced Fibrosis due to NASH

Few late-stage trials evaluating medications to treat compensated cirrhosis due to NASH

Reversing fibrosis is a central goal for providers and payers in Advanced Fibrosis due to NASH

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

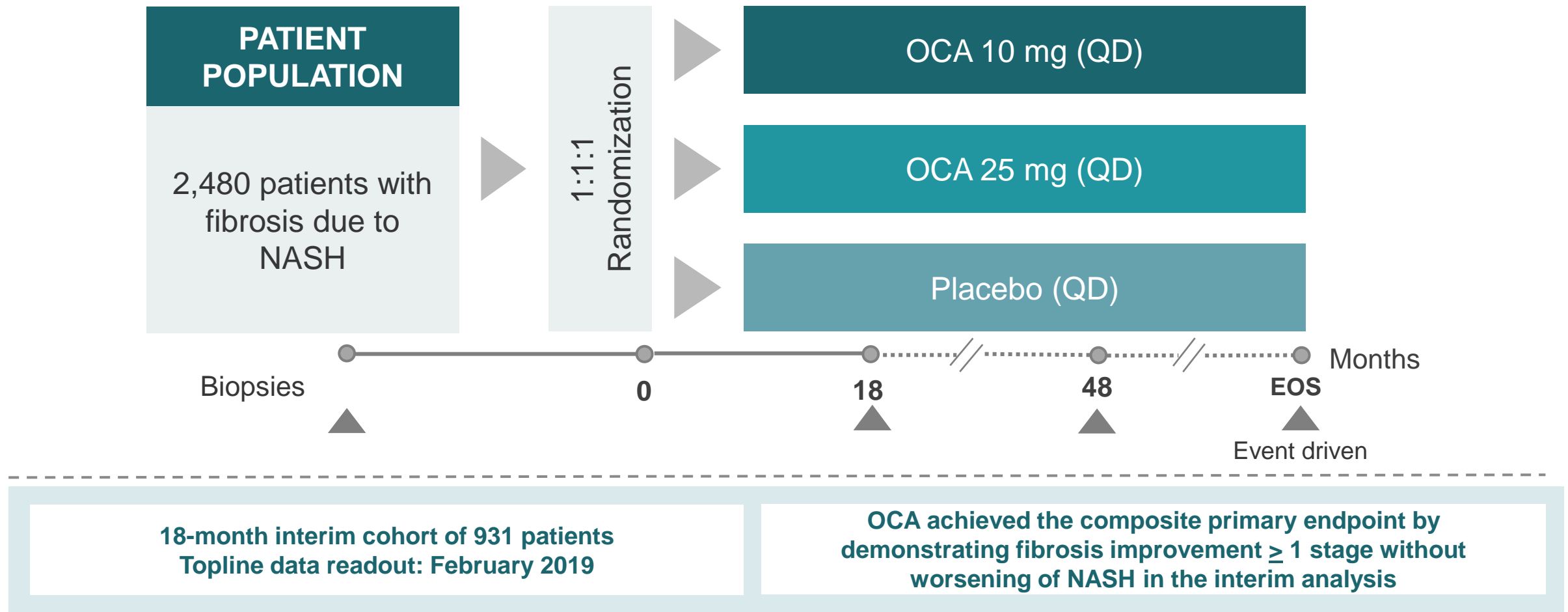


OCA has a **unique opportunity** to help patients with the highest unmet need for treatment

OCA is an **antifibrotic**.
Only OCA has demonstrated antifibrotic efficacy in a Phase 3 study¹

Reference: 1. Younossi ZM, et al. Obeticholic acid for the treatment of non-alcoholic steatohepatitis: interim analysis from a multicentre, randomised, placebo-controlled phase 3 trial. Lancet. 2019; 394(10215):2184-2196.

REGENERATE: The First and Largest Pivotal Phase 3 Study in Patients With Fibrosis Due to NASH Remains Ongoing



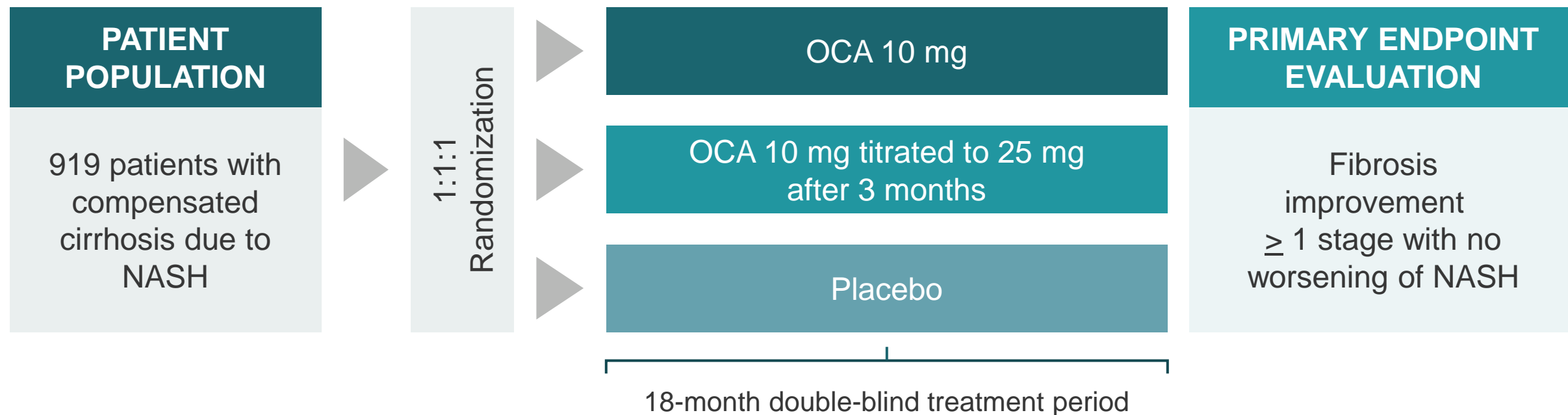
The interim analysis was conducted after 931 randomized patients with fibrosis stage 2 or 3 had or would have reached their actual/planned Month 18 visit (ITT population). The REGENERATE study will continue through clinical outcomes for verification and description of clinical benefit.

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>.

Important Phase 3 REVERSE Trial Remains Ongoing



**Trial fully enrolled
as of January 2020**

**Topline data readout anticipated
by Q3**

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

Data Generation and Regulatory Processes Ongoing in NASH

Comprehensive safety update and biopsy reading ongoing; company to ultimately accumulate the largest dataset in the NASH field

- All REGENERATE baseline, month 18 biopsies and month 48 biopsies, as well as REVERSE baseline and end-of-study (month 18) biopsies being read with new consensus reading methodology
- REGENERATE safety database will now include:
 - An additional year of patient data – data cut-off at 31DEC2021
 - Almost 1,000 patients who have reached month 48
 - 3.5x the drug exposure of the prior analysis

If REGENERATE data support accelerated approval, targeting a potential pre-submission meeting with FDA in the first half of 2022

REVERSE topline data readout now anticipated in 3Q22 due to the magnitude of data and complexities associated with reading biopsies in the cirrhotic population with a new consensus reading methodology

Data generation in pursuit of an accelerated approval pathway for OCA in the U.S. as the first compound to treat fibrosis due to NASH on track



Sustainable Growth in PBC: An Overview of Ocaliva

Two Pivotal Phase 3 Trials in NASH

Additional Opportunities for Growth and Expansion, 2022 Priorities

Continued Pipeline Progress

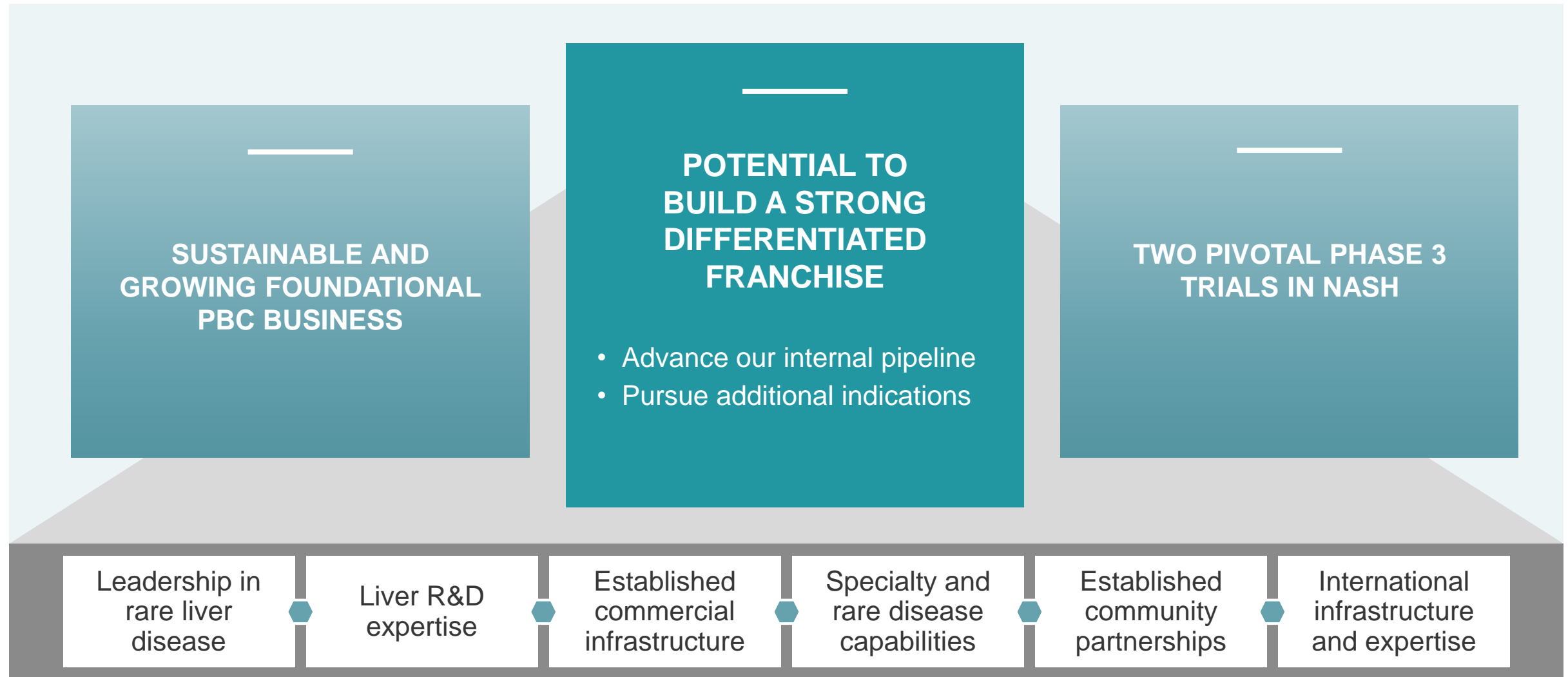
INT-787

- Phase 1 study is ongoing
- Expect to submit an IND in the first half of 2022
- In the process of determining a target indication

OCA+ Bezafibrate Combination

- Ex-U.S. Phase 2 trial continuing to enroll
- Sites now open and screening for a Phase 2 study in the U.S.

Committed to Building on Our Strong Foundation in Liver Disease



Our Strategic Priorities for 2022

Expand

*and grow our
commercial
PBC business*

Deliver

*data from our
Phase 3 NASH
development
program*

Progress

*pipeline
opportunities*

Maintain operational excellence, including lower non-GAAP adjusted operating expenses, and strong balance sheet

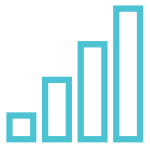
Q2 2022 Earnings Call Presentation

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

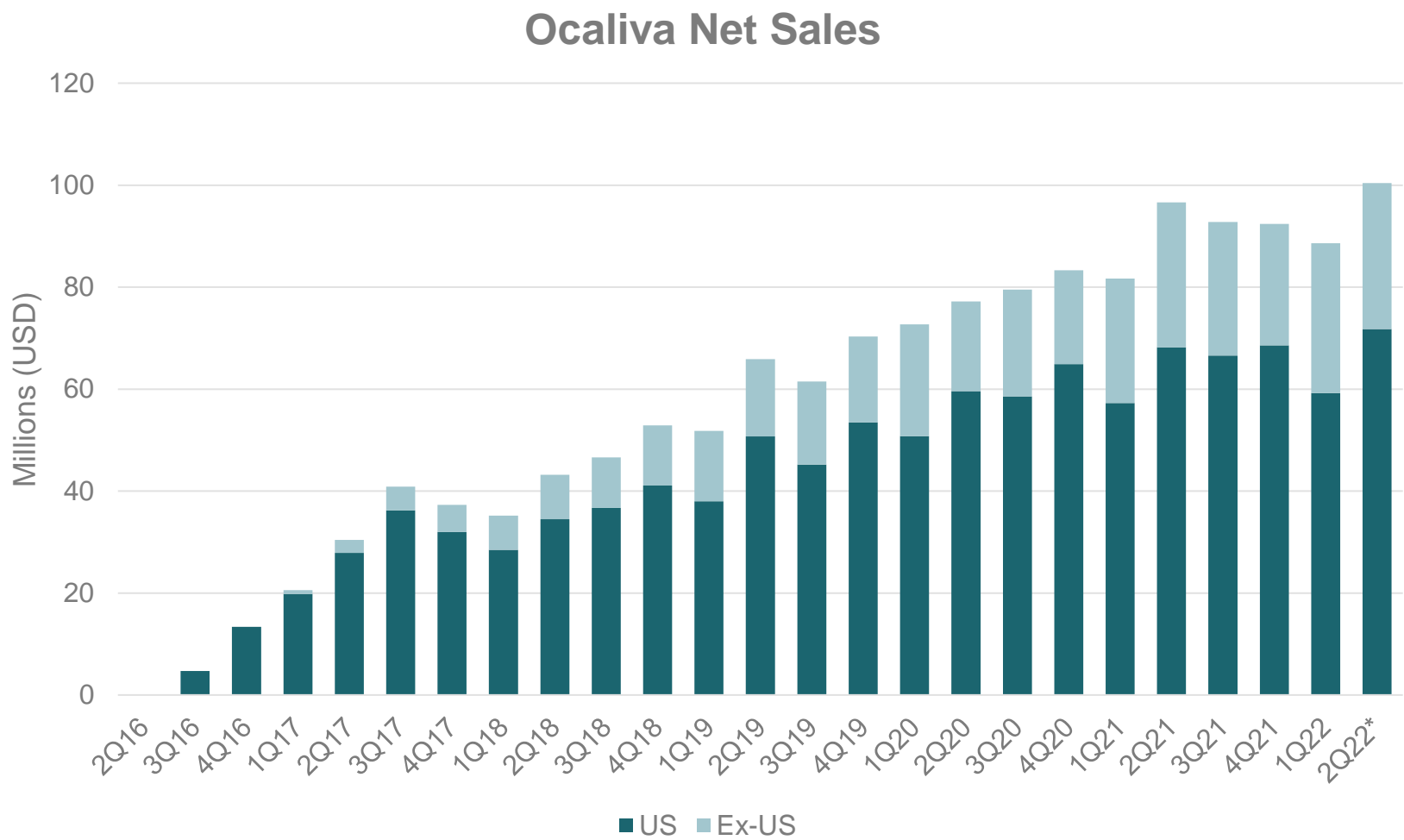


Topline Phase 3 REVERSE readout anticipated in late Q3; Phase 2 OCA-bezafibrate combination studies in the U.S. and Europe are progressing and Phase 1 combination study is fully enrolled; Phase 1 study of INT-787 has progressed to final cohorts



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



*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

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

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)

	2022 Financial Guidance	
	Low	High
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)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
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")

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.