



# Intercept Second Quarter 2017 Earnings Presentation

July 31<sup>st</sup> 2017

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This presentation contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These "forward-looking statements" are based on management's current expectations of future events and are subject to a number of important risks and uncertainties that cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: the potential benefit and commercial potential of Ocaliva® in PBC, and Intercept's ability to maintain its regulatory approval in jurisdictions in which Ocaliva is approved for use in PBC; the initiation, cost, timing, progress and results of Intercept's development activities, preclinical studies and clinical trials; the timing of and Intercept's ability to obtain and maintain regulatory approval of OCA in PBC in countries outside the ones in which it is approved and in indications other than PBC and any other product candidates it may develop such as INT-767; conditions that may be imposed by regulatory authorities on Intercept's marketing approvals for its products and product candidates such as the need for clinical outcomes data (and not just results based on achievement of a surrogate endpoint), and any related restrictions, limitations, and/or warnings in the label of any approved products and product candidates; Intercept's plans to research, develop and commercialize its product candidates; Intercept's ability to obtain and maintain intellectual property protection for its products and product candidates; Intercept's ability to successfully commercialize OCA in indications other than PBC and its other product candidates; the size and growth of the markets for Intercept's products and product candidates and its ability to serve those markets; the rate and degree of market acceptance of any of Intercept's products, which may be affected by the reimbursement that it may receive for its products from payors; the success of competing drugs that are or become available; the election by Intercept's collaborators to pursue research, development and commercialization activities; Intercept's ability to attract collaborators with development, regulatory and commercialization expertise; regulatory developments in the United States and other countries; the performance of third-party suppliers and manufacturers; Intercept's need for and ability to obtain additional financing; Intercept's estimates regarding expenses, future revenues and capital requirements and the accuracy thereof; Intercept's use of cash, short-term investments and the proceeds from the offering; Intercept's ability to attract and retain key scientific or management personnel; and other factors discussed under the heading "Risk Factors" contained in Intercept's Annual Report, Quarterly Reports and other filings with the Securities and Exchange Commission. All information in this presentation is as of the date hereof, and Intercept undertakes no duty to update this information unless required by law.

This presentation presents adjusted operating expense, which is a non-GAAP measure, both on a historical and projected basis. Adjusted operating expense should be considered in addition to, but not as a substitute for, operating expense that Intercept prepares and announces in accordance with GAAP. Intercept excludes certain items from adjusted operating expense, such stock-based compensation and depreciation, that management does not believe affect Intercept's basic operations and that do not meet the GAAP definition of unusual or nonrecurring items. For the year ended December 31, 2016, adjusted operating expense also excludes a one-time \$45 million net expense for the settlement of a purported class action lawsuit.

# Agenda

- Mark Pruzanski, M.D., Chief Executive Officer
  - Corporate update
- Richard Kim, Senior Vice President, Head of U.S. Commercial
  - U.S. Launch Update
- Lisa Bright, President International
  - International Launch Update
- Sandip Kapadia, Chief Financial Officer
  - Financial Update
- Questions/Answers
  - Rachel McMinn, Ph.D., Chief Business and Strategy Officer

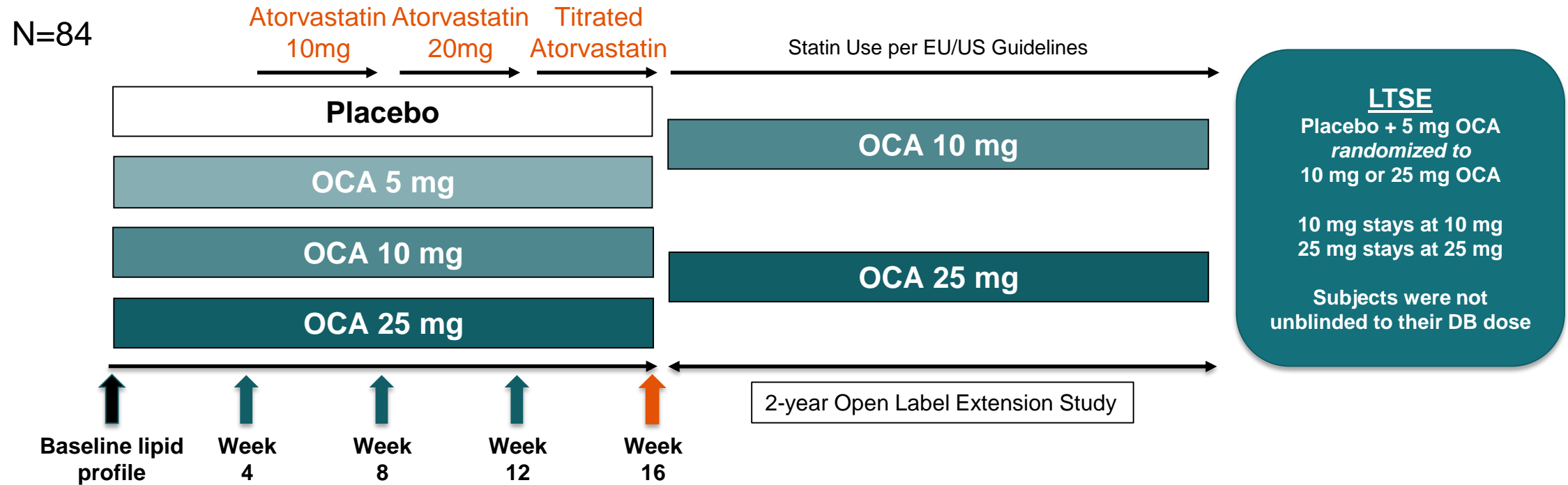
# Corporate Update

Mark Pruzanski, M.D.

# Corporate Overview & Key Milestones

<b>PBC</b>	<b>WW Ocaliva net sales \$30.4M</b>	<b>2Q 2017</b>
	<b>Continue enrollment of Phase 4 COBALT trial</b>	<b>2017</b>
<b>NASH</b>	<b>Complete enrollment of interim analysis cohort in Phase 3 REGENERATE trial</b>	<b>May 2017</b> ✓
	<b>Report Phase 2 CONTROL results</b>	<b>July 2017</b> ✓
	<b>Initiate Phase 3 OCA cirrhosis trial</b>	<b>2H 2017</b>
	<b>Initiate INT-767 Phase 2 trial</b>	<b>2H 2017</b>
<b>PSC</b>	<b>Report Phase 2 AESOP results</b>	<b>July 2017</b> ✓

# Phase 2 CONTROL Trial : Combination of OCA And Statins for Monitoring of Lipids



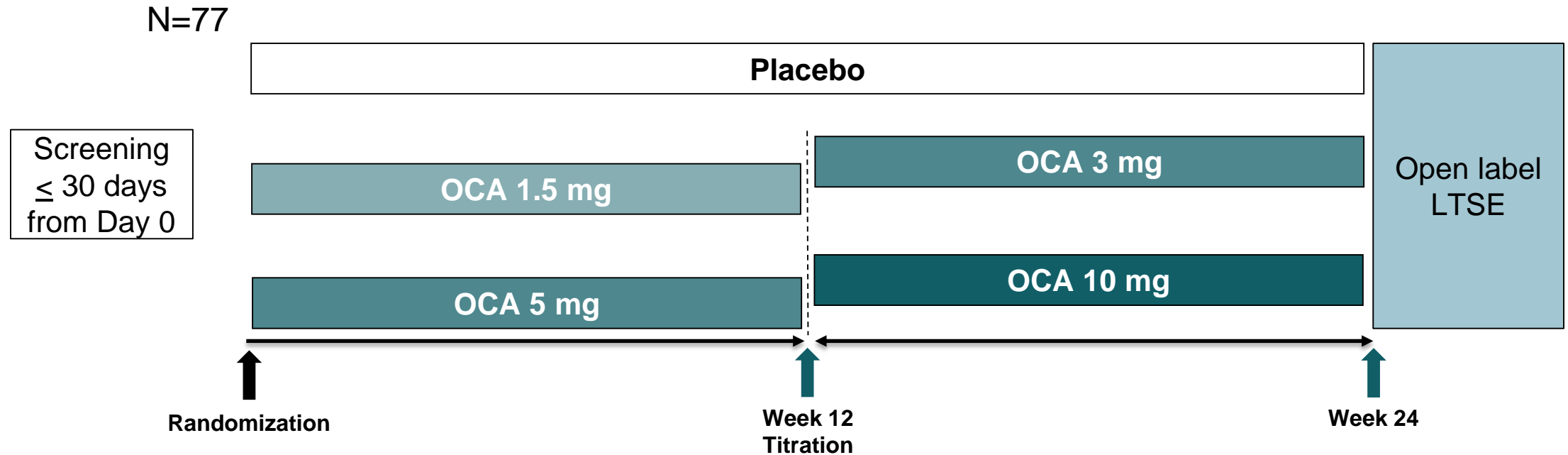
## Primary Objectives:

- Evaluate the impact of varying doses of OCA on LDL and lipid metabolism
- Evaluate the impact of low doses of statin therapy to modulate LDL in combination with OCA treatment

# Phase 2 CONTROL Trial : Combination of OCA And Statins for Monitoring of Lipids

(mg/dL)	Placebo (N=21)	OCA 5 mg (N=20)	OCA 10 mg (N=21)	OCA 25 mg (N=22)
Mean LDL at Baseline	118	135	122	126
Mean LDL at Week 4	113	153	141	158
Mean LDL at Week 8 (+ atorvastatin 10 mg)	75	96	91	93
Mean LDL at Week 16 (+ atorvastatin 10-40 mg)	70	95	82	85
Mean LDL Change from Baseline at Week 16	-48	-40	-40	-45

# Phase 2 AESOP Trial: Assessment of Efficacy and Safety of OCA in PSC



Primary Endpoint:

- Change in ALP relative to placebo at week 24 for the OCA 5 – 10 mg titration group.



# Phase 2 AESOP Trial: Assessment of Efficacy and Safety of OCA in PSC

(U/L)	Placebo (N=25)	OCA 1.5-3 mg (N=25)	OCA 5-10 mg (N=26)
Mean Baseline ALP	<b>563</b>	<b>423</b>	<b>429</b>
LS <sup>1</sup> Mean Change from Baseline in ALP at Week 12	<b>-53</b>	<b>-57</b>	<b>-135*</b>
LS Mean Change from Baseline in ALP at Week 24	<b>-27</b>	<b>-105</b>	<b>-110*†</b>
LS Mean Change from Baseline in ALP at Week 24	<b>+1%</b>	<b>-22%*</b>	<b>-22%*</b>

1: Least Squares

\* p<0.05

† Primary endpoint was ALP change OCA 5-10 mg relative to placebo at week 24

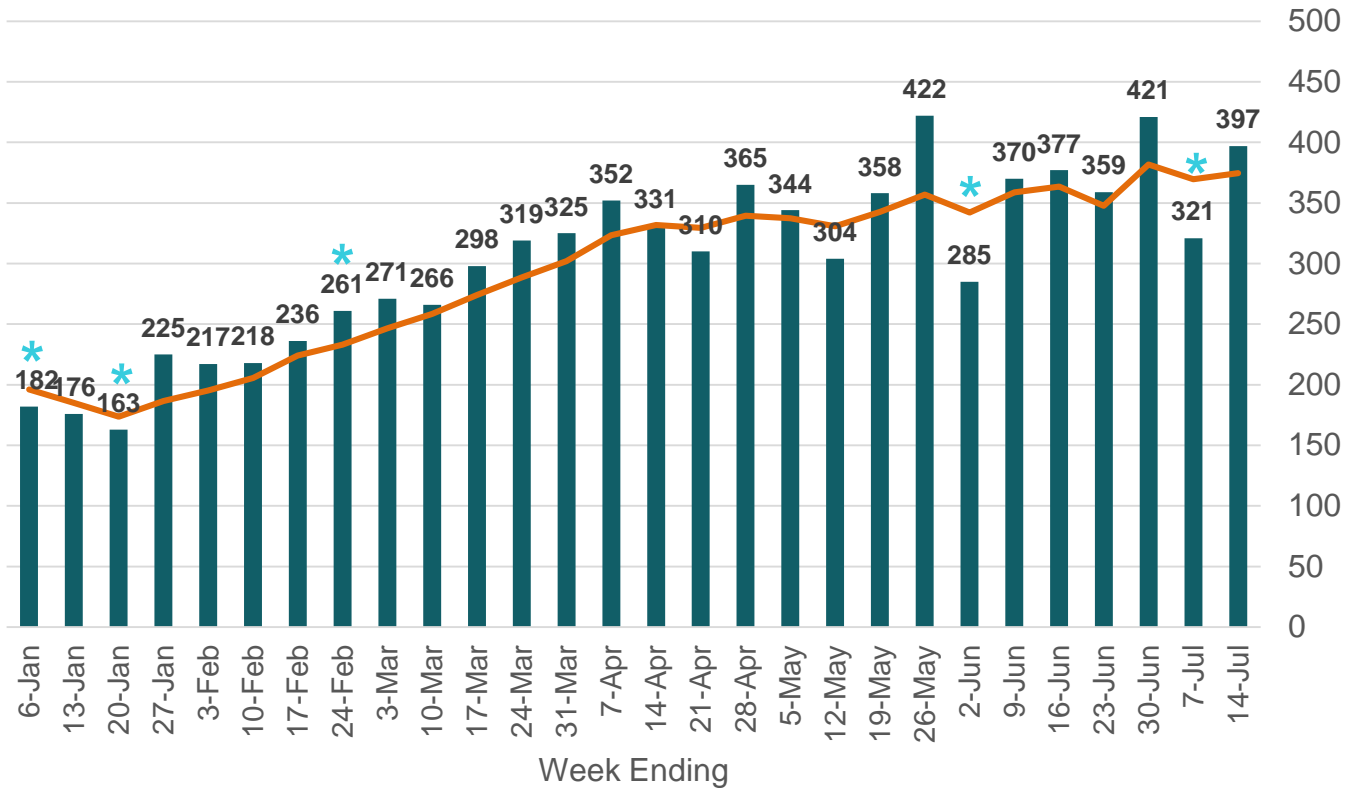
# U.S. Commercial Update

Richard Kim

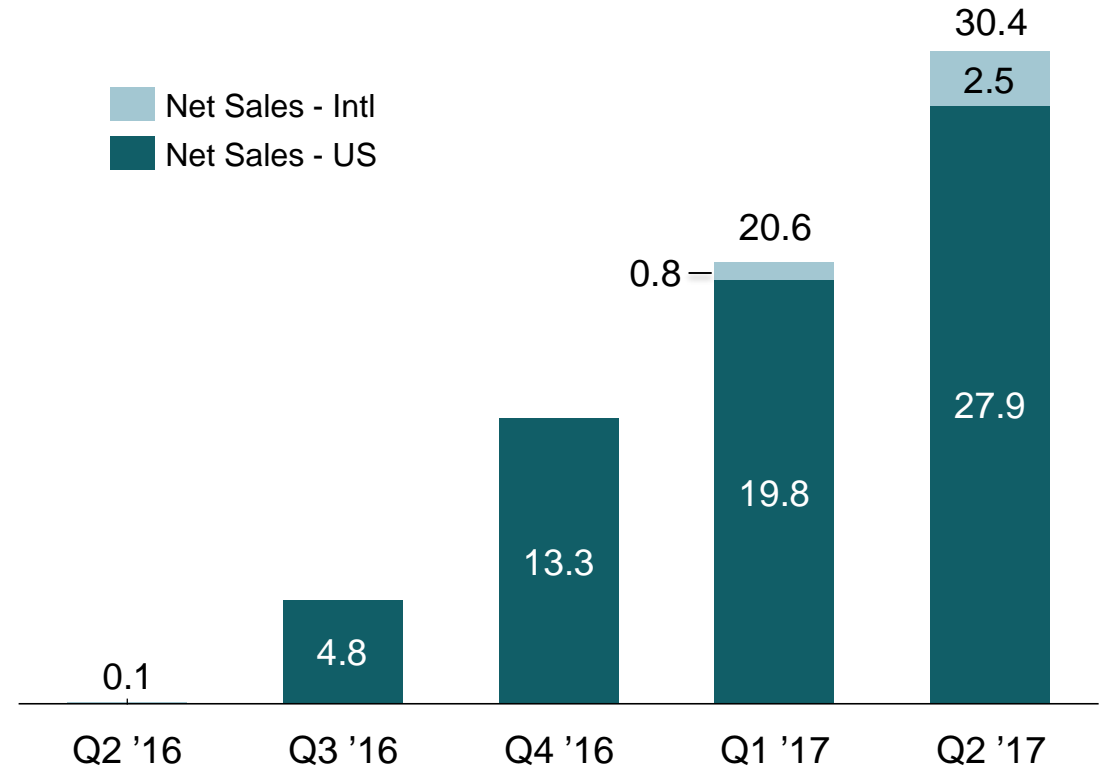
# 2Q Commercial Update

## Weekly U.S. IMS Ocaliva Prescription Data\*

IMS Weekly TRx      IMS TRx - Rolling 4Wk Avg  
 \* Denotes holiday week



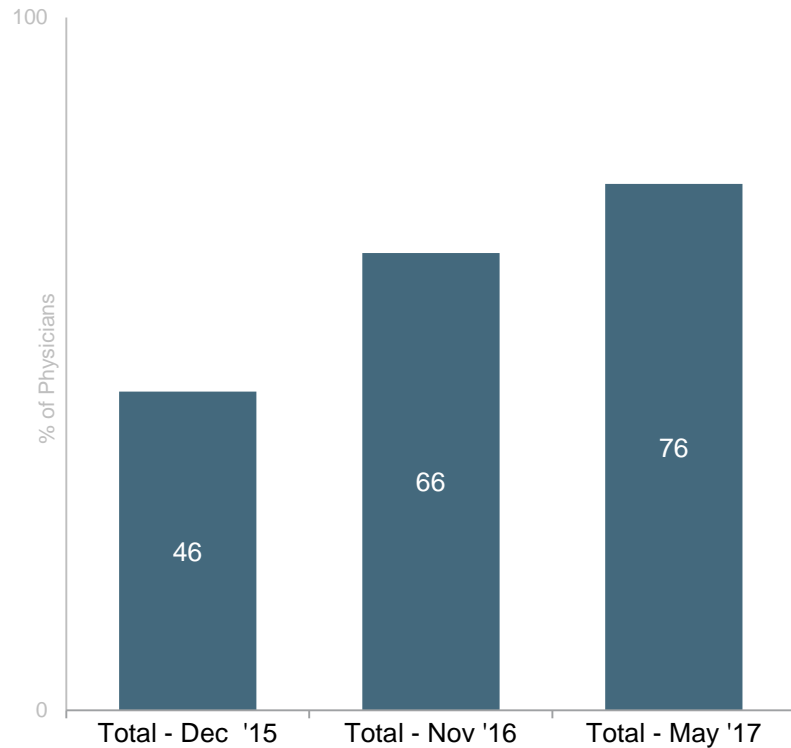
## Worldwide Quarterly OCALIVA Net Sales –(\$M)



\*Source IMS

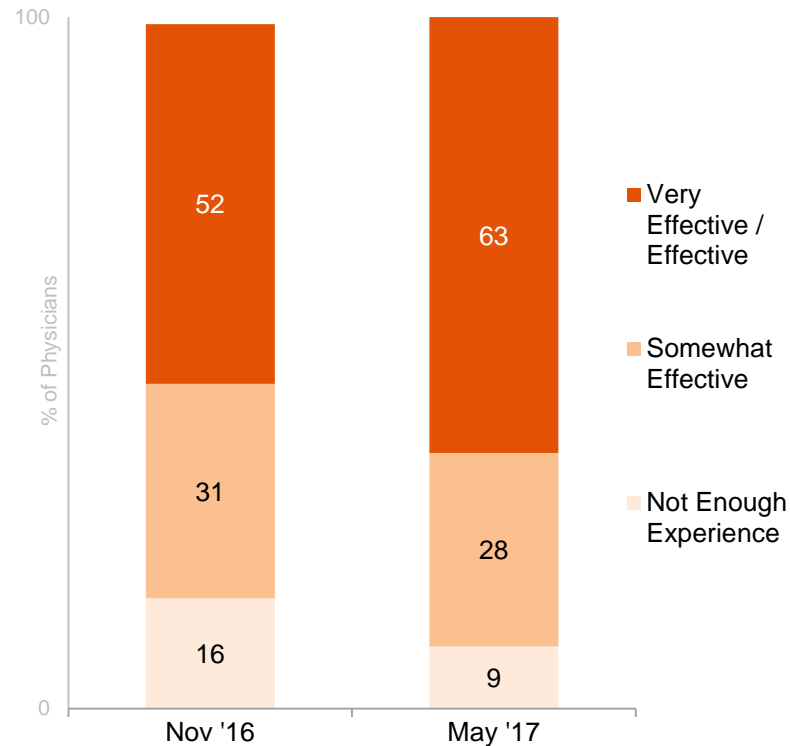
# Physicians Insights on Ocaliva

## Unaided Awareness of OCALIVA for PBC\*

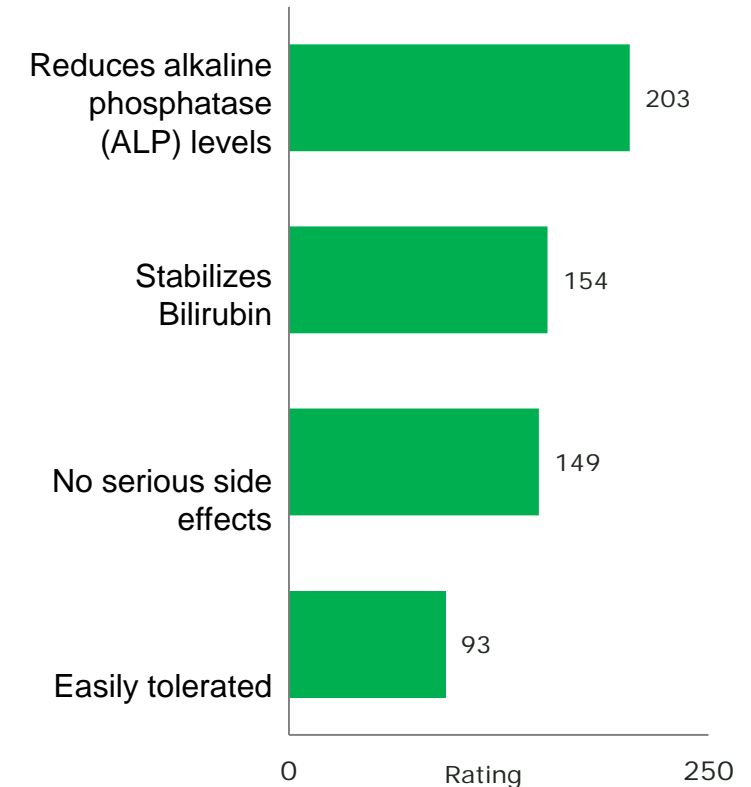


\* Unaided awareness tested in target call list physicians

## Perceived Efficacy Of OCALIVA



## Top Motivators to Prescribe OCALIVA (out of 8)



Source: Intercept Internal Market Research (HCP ATU) Results, May 2017

# Financial Update

Sandip Kapadia

# Second Quarter 2017 Financial Results

	Quarter Ended 6/30/2017	2017 Guidance
Net Product Revenue	<b>\$30.4</b>	
Gross : Net	<b>10-15%</b>	<b>Lower end 10-15%</b>
COGs	<b>De minimis</b>	<b>De minimis</b>
Interest Expense	<b>\$7.3</b>	<b>~\$30.0</b>
GAAP Operating Expense	<b>\$111.4</b>	
Adjusted Operating Expense <sup>1</sup>	<b>\$96.0</b>	<b>\$380 - \$420</b>
Cash Position	<b>\$550.3</b>	

<sup>1</sup>Excludes non-cash items such as stock-based compensation and other non-cash items; see reconciliation table on slide 12  
All values in millions

# Reconciliation Table

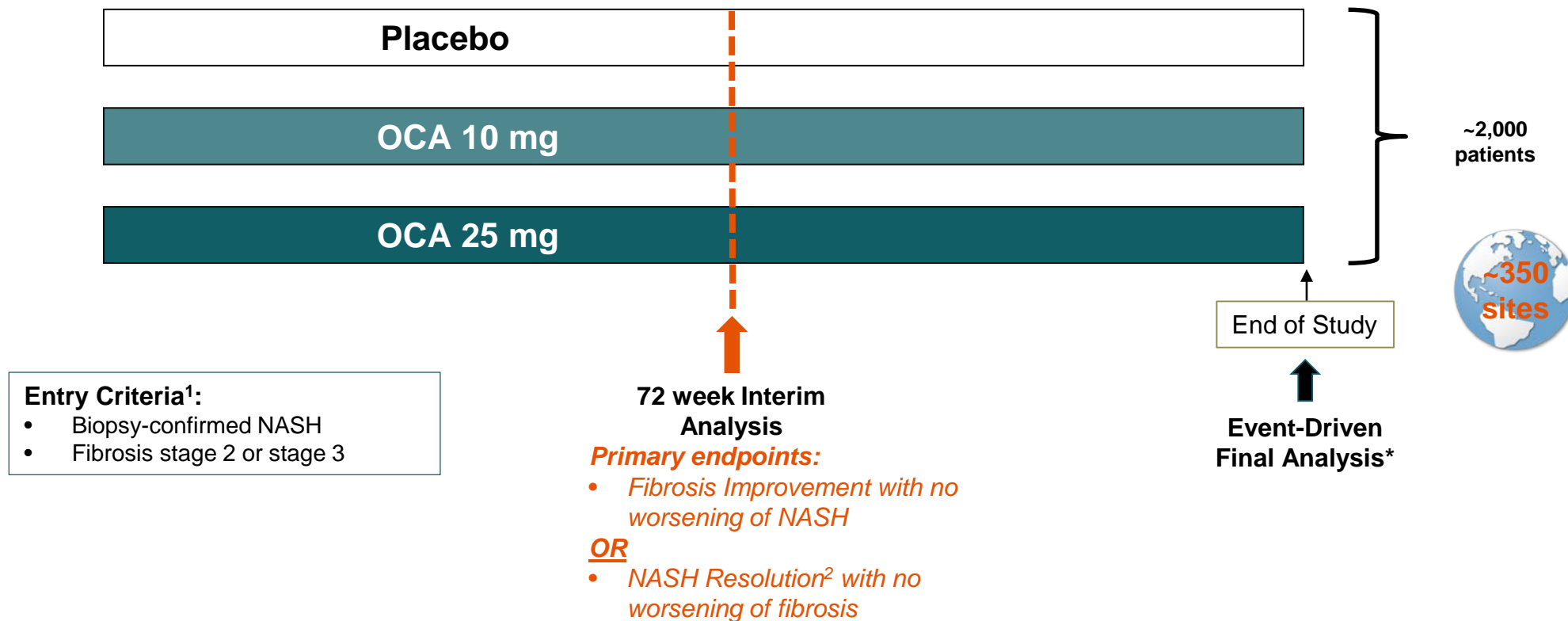
	Three Months Ended June 30	
	2017	2016
Total operating expense (GAAP)	\$111.4	\$83.6
Adjustments:		
Stock based compensation	14.3	4.3
Depreciation	1.1	0.9
Adjusted operating expense	\$96.0	\$78.5

All values in millions

# Appendix



# REGENERATE: Randomized Global Phase 3 Trial to Evaluate the Impact on NASH with Fibrosis of Obeticholic Acid Treatment



**Interim histology analysis at 72 weeks in ~750 patients planned to serve as basis for filing for approval  
Announced interim analysis complete enrollment in May 2017; Data expected in 1H 2019**

**\*EOS endpoint: Occurrence of pre-specified number of clinical events**

<sup>1</sup>Exploratory group of NASH patients with stage 1 liver fibrosis with comorbid risk factors (defined as diabetes, obesity or active liver inflammation (ALT >1.5X ULN)) will also be enrolled, but not included in the primary endpoint analyses

<sup>2</sup>Hepatocyte ballooning score of 0 & residual or no inflammation ("objective definition")