Intercept

Intercept Full Year 2016 Earnings Presentation

February 23rd 2017



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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.

Overview

Summary of 2016 Accomplishments

- Approval of Ocaliva® (obeticholic acid or OCA) in both U.S. and Europe
- Transitioned to commercial organization \$18.2M in U.S. Ocaliva sales for 2016
 - \$13.4M in U.S. Ocaliva sales for 4Q 2016
- Progress on Phase 3 REGENERATE trial
- Continued expansion of our clinical program
 - Completed enrollment in both AESOP & CONTROL trials
 - Completed Phase 1 trial for INT-767

2017 Corporate Priorities

- Continue to grow Ocaliva sales in U.S. and Europe
- Advance our NASH clinical development program
 - Complete interim cohort enrollment for REGENERATE by mid-2017
 - Report Phase 2 CONTROL trial data
 - Initiate Phase 3 NASH cirrhosis trial
- Further advance our understanding of OCA in cholestatic liver disease
 - Report Phase 2 AESOP trial in primary sclerosing cholangitis (PSC)
- Initiate Phase 2 trial of INT-767 in NASH with fibrosis



Updated REGENERATE Phase 3 Trial Design

		Interim Analysis				End of Study				
		Updated			Unchanged			Unchanged		
		N	Primary Endpoints ¹	Definition of NASH Resolution	Inclusion	Treatment Arms	Treatment Duration	N	Primary Endpoint	Treatment Duration
	Current Study Design	~750	Fibrosis improvement <u>OR</u> NASH resolution	Hepatocyte ballooning score of 0 & residual or no inflammation ²	Biopsy proven NASH ³ with fibrosis stage 2 or 3 ⁴	OCA 25mg	72 weeks	~2,000	Occurrence of pre-specified number of clinical events comprising a composite outcomes endpoint	Event driven
	Original Study Design	~1,400	Fibrosis improvement <u>AND</u> NASH resolution	Not defined		OCA 25mg Placebo I I I I I I I I I I I I I I I I I I I				

⁴NASH patients with stage 1 liver fibrosis with comorbid risk factors (defined as diabetes, obesity or active liver inflammation (ALT >1.5X ULN)) also being enrolled as an exploratory cohort



¹Primary endpoints defined as fibrosis improvement with no worsening of NASH <u>OR</u> NASH resolution with no worsening of fibrosis

²"Objective definition" of NASH resolution

 $^{^3}$ Central pathologist assessment of definite NASH and NAFLD Activity Score (NAS) ≥ 4

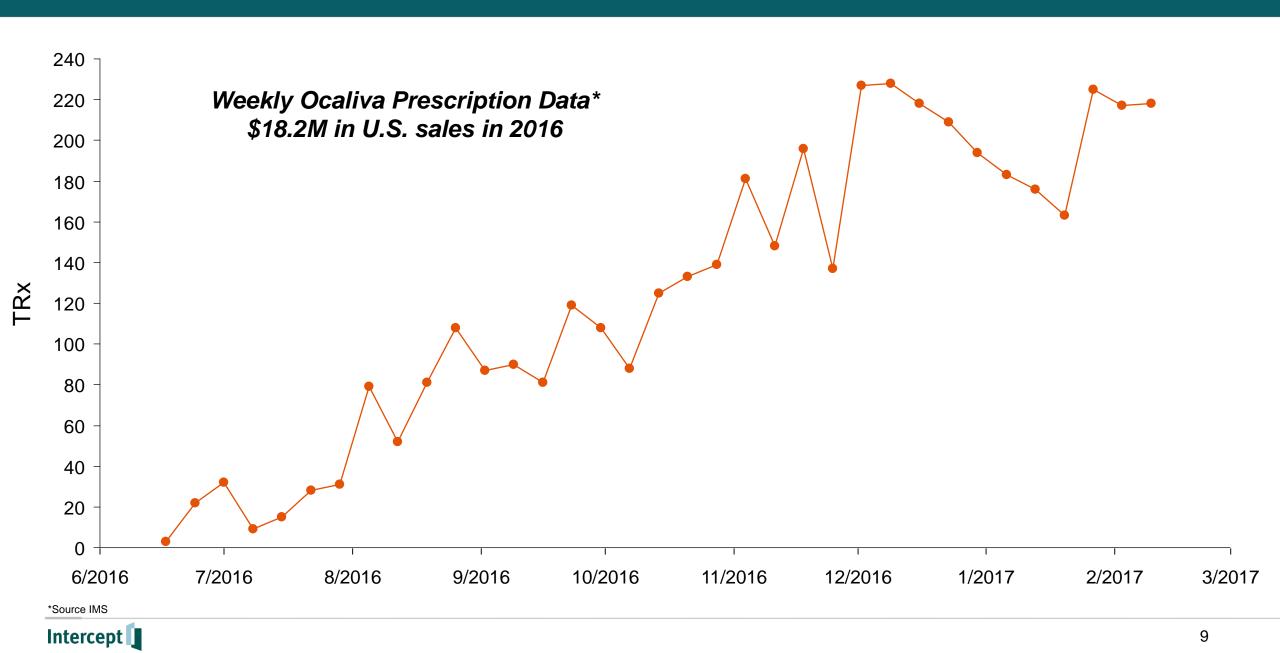
Key Anticipated 2017 Milestones

PBC	Ongoing Ocaliva U.S. launch and European launches in key markets
	Complete Phase 3 REGENERATE trial interim cohort enrollment (by mid-2017)
NACH	Report Phase 2 CONTROL results
NASH	Initiate Phase 3 OCA cirrhosis trial
	Initiate INT-767 Phase 2 trial
PSC	Report Phase 2 AESOP results

U.S. Commercial Update

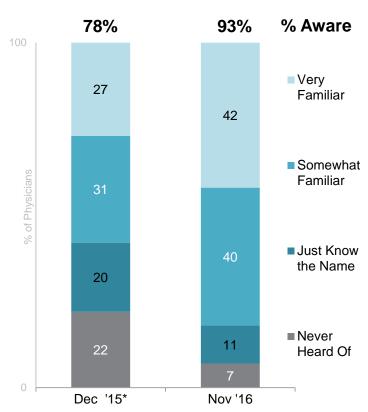
Richard Kim

U.S Commercial Update



Physicians Insights on Ocaliva

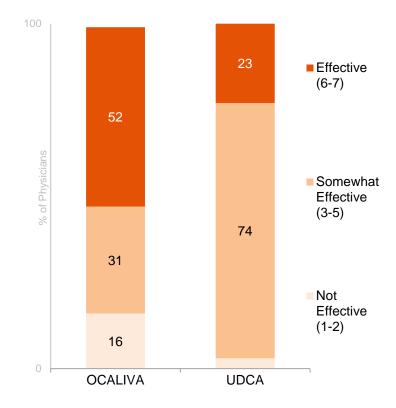
Aided Awareness of Ocaliva* (PBC Indication)



^{*} Note: prior to approval, awareness was gauged for obeticholic acid

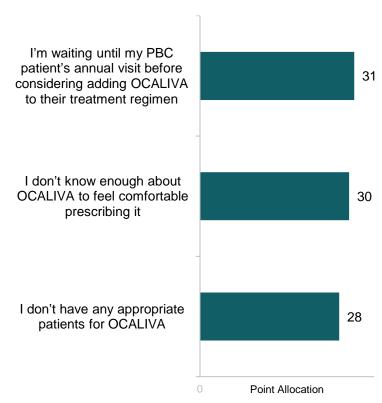
Total Physicians: Dec '15 (n=100), Nov '16 (n=121) How familiar are you with each of the following pharmaceuticals that are currently in development or available for PBC?

Perceived Efficacy



Total Physicians who have treated patients currently/previously on OCALIVA/UDCA —Dec '15 (n=100), Nov '16 (n=67/120) Thinking about the clinical outcomes you use to define treatment success, how effective would you say UDCA and OCALIVA are in treating PBC?

Top Reasons for Not Prescribing Ocaliva (Aided)



Physicians without patients on OCALIVA Total Physicians –Nov '16 (n=54) Which of the following reasons best explains why you do not have any patients currently on OCALIVA?



International PBC Commercial Update

Lisa Bright



We Are Making Good Progress for Ocaliva Internationally

- Regulatory
 - European Commission granted Ocaliva Marketing Authorization in December 2016
 - New Drug Submission under priority regulatory review in Canada
- Pricing & Reimbursement
 - Submitted pricing and reimbursements dossiers in 13 countries across Europe
- Early access
 - ATU in France
 - Programs underway/planned in other countries where local regulations permit
- Launch preparations
 - Salesforce recruitment and training completed in early launch countries
- Revenues
 - Early launch countries to contribute modestly Ocaliva sales in 2017; Germany & France key markets



Financial Update

Sandip Kapadia

Full Year 2016 Financial Results

	Year Ended 12/31/2016	2017 Guidance
Net Product Revenue	\$18.2	
Gross : Net	10-15%	10-15%
COGs	De minimis	De minimis
Interest Expense	\$14.2	~\$30.0
GAAP Operating Expense	\$427.5	
Adjusted Operating Expense ¹	\$332.5 ²	\$380 - \$420
Cash Position	\$689.4	

All values in millions



¹Excludes non-cash items such as stock-based compensation and other non-cash items; see reconciliation table on slide 15 ²Excludes the one-time net expense of \$45.0 million for the settlement of the purported class action lawsuit

Reconciliation Table

Total operating expense (GAAP)

Three Mon Decem		Year Ended December 31		
2016	2015	2016	2015	
\$127.8	\$89.3	\$427.5	\$231.9	

Adjustments:

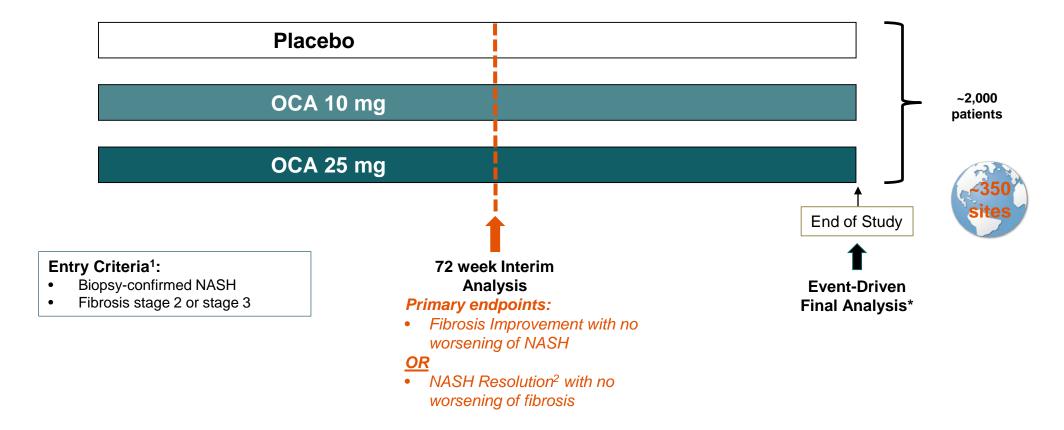
Stock based compensation	19.2	12.2	46.2	34.2
Depreciation	1.6	0.6	3.8	1.7
Litigation settlement	-	-	45.0	-
Adjusted operating expense	\$107.0	\$76.6	\$332.5	\$196.1

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 (complete enrollment of interim analysis cohort targeted by mid-2017)

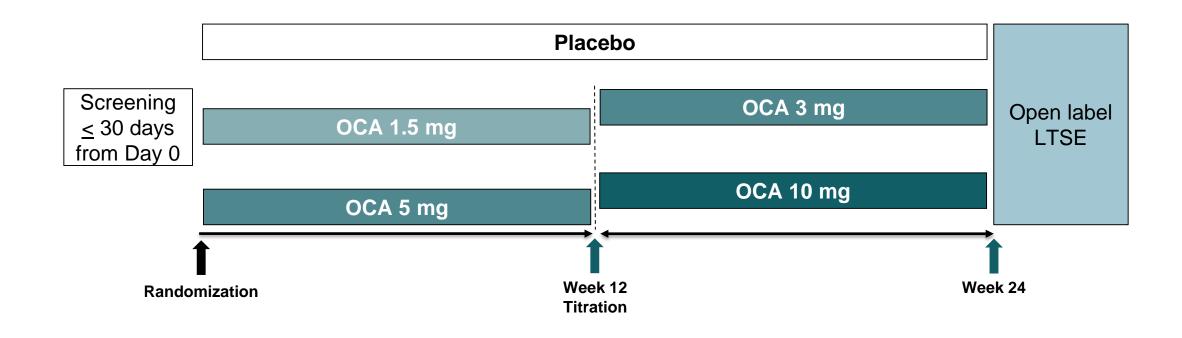
*EOS endpoint: Occurrence of pre-specified number of clinical events

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



¹Exploratory 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

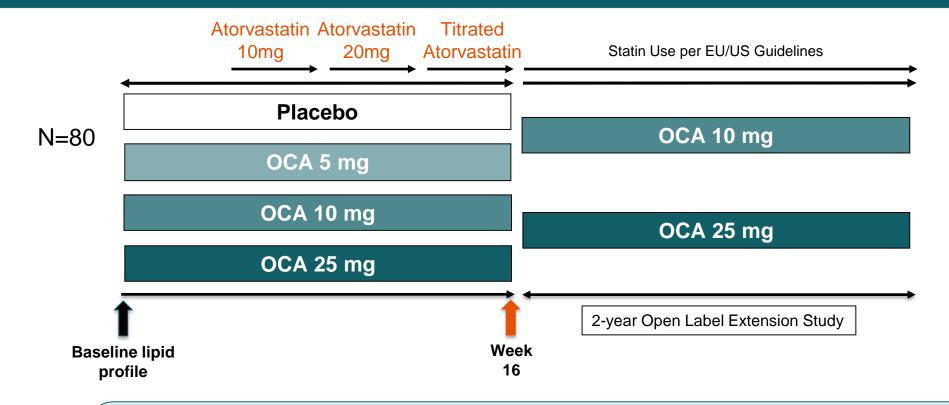
Phase 2 AESOP Trial: Assessment of Efficacy and Safety of OCA in PSC



- ~75 patients
- Primary endpoints: change from baseline in ALP; safety
- Completed enrollment Sept 2016



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



- 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
- Completed enrollment Nov 2016