

A close-up photograph of a starfish on a rocky surface. The starfish's central disk is covered in a dense layer of small, glowing teal cubes. From the top of the starfish, a stream of these cubes is being ejected, floating in the air above it. The background is a blurred, textured rock surface.

# Intercept 3Q 2016 Earnings Presentation

*November 3<sup>rd</sup>, 2016*

# Safe Harbor & Disclaimer Statement

This presentation contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding Intercept's financial position, including expected adjusted operating expenses; the activities anticipated to be undertaken by Intercept, including the anticipated progression of the U.S. launch of Ocaliva® in PBC, the potential regulatory approval and launch of OCA in PBC outside the United States and the timelines related thereto; the initiation, enrollment, conduct and completion of clinical trials; the anticipated regulatory process and timetable with respect to Intercept's product candidates; Intercept's ongoing and anticipated buildout and hiring to support our growing business operations; the continued development of OCA and Intercept's other product candidates; and Intercept's strategic directives under the caption "About Intercept." 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 could 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: Intercept's ability to successfully commercialize Ocaliva in PBC, and Intercept's ability to maintain its regulatory approval of Ocaliva in the United States for Ocaliva 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 United States 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 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 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 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 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 our annual report on Form 10-K for the year ended December 31, 2015 filed on February 29, 2016 as well as any updates to these risk factors filed from time to time in our other filings with the Securities and Exchange Commission. All information in this presentation is as of the date of the release, 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 as the one-time net expense of \$45.0 million for the proposed settlement of the purported securities class action lawsuit, 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.

# 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 Update
- Sandip Kapadia, Chief Financial Officer
  - Financial Update
- Questions/Answers
  - Rachel McMinn, Ph.D., Chief Business and Strategy Officer

# Corporate Update

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Mark Pruzanski, M.D.

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# Corporate overview

- Completed our first full quarter of launch of Ocaliva in PBC
  - \$4.7M in U.S. Ocaliva sales for 3Q16
- Positive CHMP opinion in October for Ocaliva in PBC
- Advancing our NASH program
  - Completing interim cohort enrollment for REGENERATE remains top priority
  - Completed target enrollment in Phase 2 CONTROL trial
- Other key clinical trials
  - Completed target enrollment in Phase 2 AESOP trial in PSC
  - On track to complete INT-767 Phase 1 trial by year-end
- AASLD meeting starts next week

# Anticipated Upcoming Milestones

<b>OCA</b>	<b>PBC</b>	EU marketing approval decision for Ocaliva	YE 16
		Submission of updated COBALT Phase 4 protocol	YE 16
	<b>NASH</b>	Complete enrollment of interim cohort for Phase 3 REGENERATE trial	1H 17
		Report topline CONTROL results	2017
<b>PSC</b>	Report topline AESOP results	2017	
<b>INT-767</b>		Complete SAD/MAD Phase 1 trial	YE 16

# U.S. PBC Commercial Update

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Richard Kim

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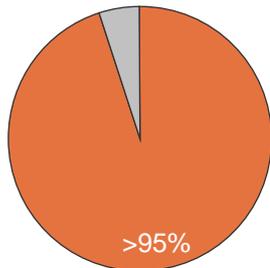
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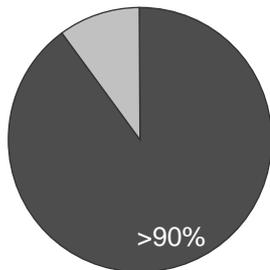
# U.S. Commercial Update

## Commercial

We have reached >90% of our target subscribers to date



Lead Targets



Total Targets

## Our Patients

Enrollment into Interconnect have been robust

A majority of patients match POISE criteria



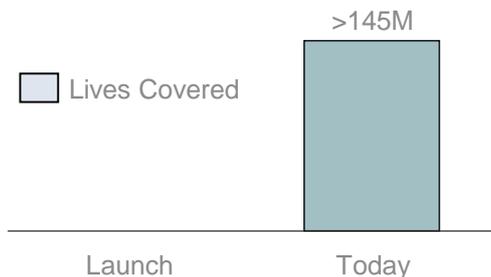
Nearly all patients are initiating Ocaliva on the 5mg dose



# U.S. Commercial Update (cont'd)

## Managed Markets

We have gained reimbursement across a large number of plans



- We believe recent flattening of IMS NRx is primarily the result of the shift from medical exception to full coverage based on prior authorization, which has slowed conversion of enrollments to prescription shipped
- We anticipate this to be short-term and will improve over time as published prior authorization criteria become available

## Prescription Data

IMS remains a good directional tool to monitor launch



- We expect NRx will become less reliable as a proxy for new patient demand going forward, as patients titrating from the 5mg to 10mg dose could be recorded as a NRx

# Future Growth Drivers

## Marketing Materials

Ocaliva marketing brand campaign was cleared by the FDA's OPDP division



## Medical Conferences

Recent and upcoming conferences are important opportunities to engage physicians



## POISE Publication

Important factor in accessing many large academic institutions

THE NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

A Placebo-Controlled Trial of Obeticholic Acid in Primary Biliary Cholangitis

## Managed Markets

Additional coverage decisions into the end of the year

We expect time from Rx to shipment to contract

# International PBC Commercial Update

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Lisa Bright

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# We are marking good progress for Ocaliva internationally

- Regulatory
  - Positive CHMP opinion in October; marketing approval expected by year-end
  - Filed New Drug Submission in Canada in September
- Launch Preparations
  - Salesforce recruitment in early launch countries underway
- Reimbursement/Pricing
  - Focus on cost effectiveness & budget impact
- Early Access Programs
  - ATU in France
  - Several patients in Switzerland, Austria and Denmark granted access under local regulations
- Revenues
  - Early launch countries to begin contributing to Ocaliva sales in 2017
  - Germany, France key early markets

# Financial Update

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Sandip Kapadia

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# Third Quarter 2016 Financial Results

	Quarter ended 6/30/2016	Quarter ended 9/30/2016
Product Revenue	\$0.75	\$4.7
GAAP Operating Expense	\$83.6	\$88.2
Adjusted Operating Expense <sup>1</sup>	\$78.5	\$75.0
2016 Operating Expense Guidance <sup>2</sup>	\$360-400	\$320-340
Cash Position	\$439.5	\$780.0 <sup>3</sup>

1: Excludes non-cash items such as stock-based compensation and other non-cash items; see reconciliation table on following slide 15

2: Excludes the one-time net expense of \$45.0 million for the settlement of the purported securities class action lawsuit, as well as non-cash items such as stock-based compensation

3: Includes ~\$409 million net proceeds from July 2016 convertible notes transaction

All values in millions

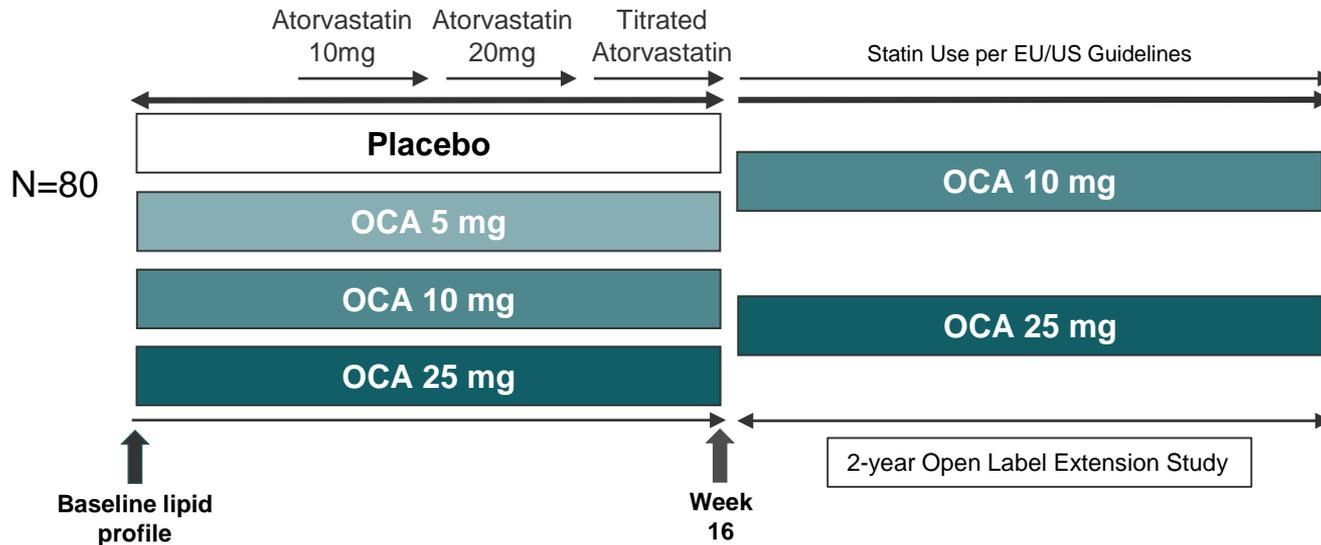
# Reconciliation Table

	Three Months Ended September 30		Nine Months Ended September 30	
	2016	2015	2016	2015
Total operating expense	<b>\$88.2</b>	<b>\$52.2</b>	<b>\$299.7</b>	<b>\$142.6</b>
Adjustments:				
Stock based compensation	<b>12.5</b>	<b>5.7</b>	<b>27.0</b>	<b>22.0</b>
Depreciation	<b>0.6</b>	<b>0.4</b>	<b>2.2</b>	<b>1.1</b>
Litigation settlement	<b>-</b>	<b>-</b>	<b>45.0</b>	<b>-</b>
Adjusted operating expense	<b>\$75.0</b>	<b>\$46.1</b>	<b>\$225.4</b>	<b>\$119.5</b>

All values in millions

# Appendix

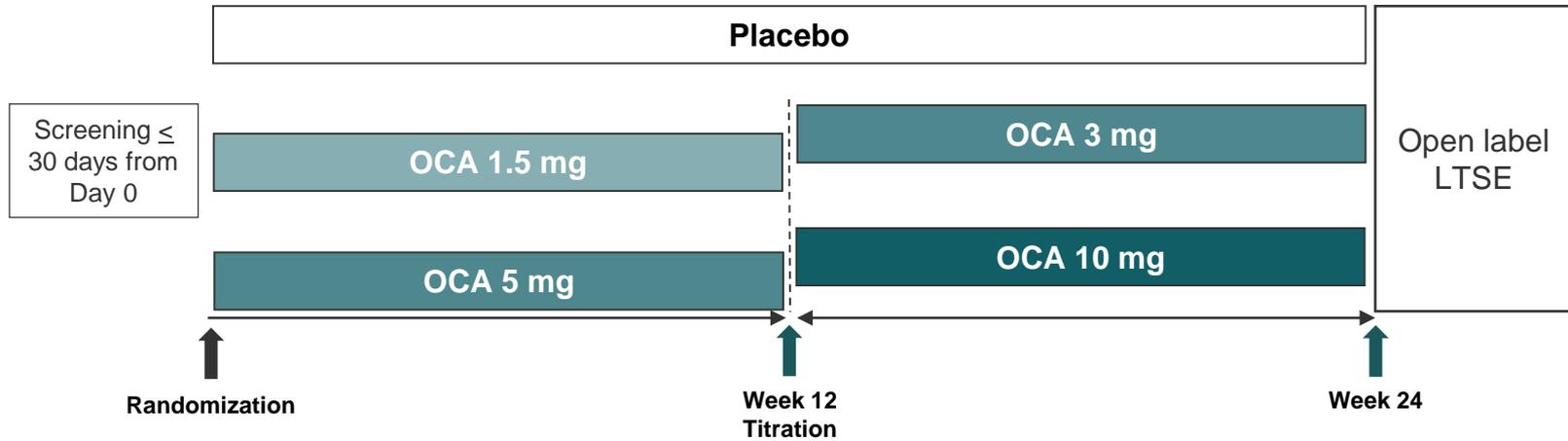
## Phase 2 CONTROL Trial : Combination of OCA And Statins for Monitoring Of Lipids



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



- 75 patients (target)
- Primary endpoints: change from baseline in ALP; safety
- Initiated in December 2014; expanded number of enrollment centers November 2015
- Completed enrollment September 2016