

The background of the slide is a grayscale image of a hand wearing a textured work glove, with a stream of glowing blue cubes rising from the wrist. The cubes are semi-transparent and have a bright blue glow. The hand is positioned in the center, with fingers slightly curled. The overall aesthetic is industrial and technological.

# Intercept 1Q16 Earnings Presentation

*May 5<sup>th</sup>, 2016*

# Safe Harbor 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 our financial position, including expected adjusted operating expenses; the activities anticipated to be undertaken by us, including the potential regulatory approval and launch of OCA in PBC and the timelines related thereto; the initiation, enrollment, conduct and completion of clinical trials; the anticipated regulatory process and timetable with respect to our product candidates; our ongoing and anticipated buildout and hiring to support our growing business operations; the continued development of OCA and Intercept's other product candidates; and our 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: the initiation, cost, timing, progress and results of our development activities, preclinical studies and clinical trials; the timing of and our ability to obtain and maintain regulatory approval of OCA and any other product candidates we may develop, particularly the possibility that regulatory authorities may require clinical outcomes data (and not just results based on achievement of a surrogate endpoint) as a condition to any marketing approval for OCA, and any related restrictions, limitations, and/or warnings in the label of any approved product candidates; our plans to research, develop and commercialize our product candidates; our ability to obtain and maintain intellectual property protection for its product candidates; our ability to successfully commercialize our product candidates; the size and growth of the markets for our product candidates and our ability to serve those markets; the rate and degree of market acceptance of any future products, which may be affected by the reimbursement that our products receive from payors; the success of competing drugs that are or become available; regulatory developments in the United States and other countries; the performance of third-party suppliers and manufacturers; our collaborators' election to pursue research, development and commercialization activities; our ability to attract collaborators with development, regulatory and commercialization expertise; our need for and ability to obtain additional financing; our estimates regarding expenses, future revenues and capital requirements and the accuracy thereof; our use of cash and short term investments; our ability to 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.

# Agenda

- Mark Pruzanski, M.D., Chief Executive Officer
  - Corporate update
- Lisa Bright, Chief Commercial & Corporate Affairs Officer
  - Commercial Update
- Barbara Duncan, Chief Financial Officer
  - Financial Update
- Questions/Answers
  - Rachel McMinn, Ph.D., Chief Business and Strategy Officer
  - Richard Kim, SVP of US Commercial

# General Update

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Mark Pruzanski, M.D.

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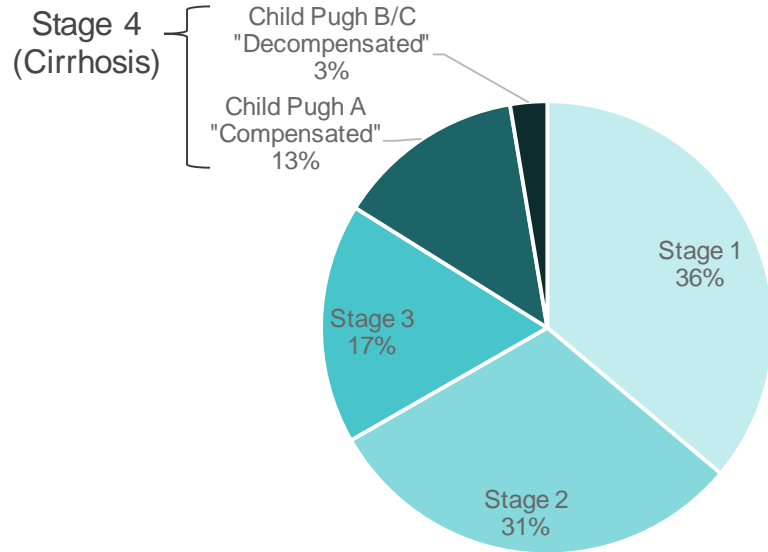
# 2016 has been eventful for Intercept

- Successful FDA advisory committee meeting
- EASL 2016: Our last medical meeting prior to PDUFA
- Brand name for OCA in PBC provisionally approved: Ocaliva™

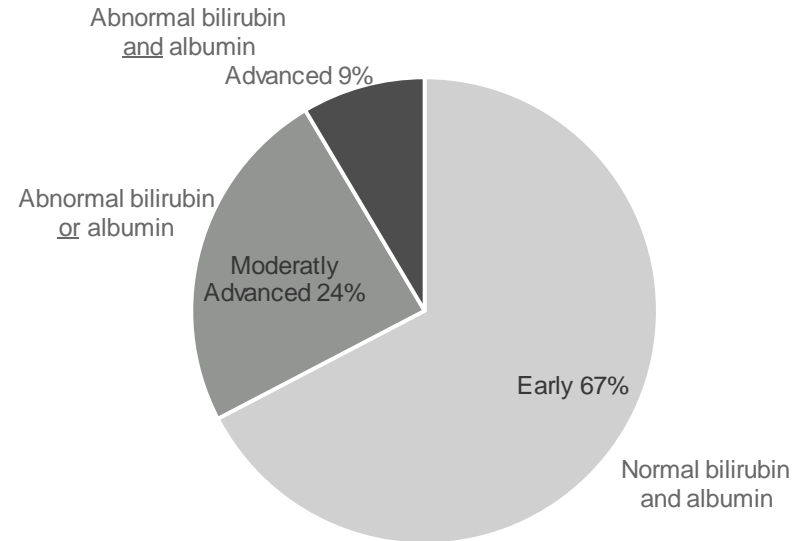


# Two methods for staging of PBC

Staged by Histology (Ludwig)<sup>1</sup>



Staged by Rotterdam<sup>2</sup>



Data from [Lammers et al. Gastroenterology. 2014](#), 1: For patients with available biopsy (25% of patients unavailable); [Ludwig et al. Virchows Arch A Pathol Anat Histol. 1978](#) - Stage 1: Portal inflammation with or without florid bile duct lesions. Stage 2: Gradual increase of periportal lesions extending into the hepatic parenchyma. Stage 3: Distortion of the hepatic architecture with numerous fibrosis septa. Stage 4: Cirrhosis with the existence of regenerative nodules; Child Pugh distribution assumptions based on: [Kim et al. Korean J Hepatol. 2010](#), [Malham World et al. J Gastro. 2011](#), [Kochel-Jankowska et al. J Physiol Pharmacol. 2013](#), [Kikuchi World et al. J Hepatol. 2013](#), [Chen Ann et al. Hepatol. 2013](#), [Nilsson et al. HBP \(Oxford\). 2010](#), [Su et al. Liver Int. 2008](#), [Aboutwera et al. Biochim Biophys Acta. 2003](#); 2: [ter Borg et al. Am J Gastro. 2006](#) - baseline values for patients with available data



# PBC & NASH are distinct progressive liver diseases

	PBC	NASH
Disease etiology	Autoimmune	Metabolic
Site of injury	Bile duct	Hepatocyte
Disease pathology	Cholestasis – Bile acid toxicity due to impaired bile flow	Fat accumulation Inflammation Ballooning
Lipid Profile <sup>1,2</sup>	HDL = 74 mg/dL LDL = 137 mg/dL Triglycerides = 111 mg/dL	HDL = 42 mg/dL LDL = 112 mg/dL Triglycerides = 177-195 mg/dL

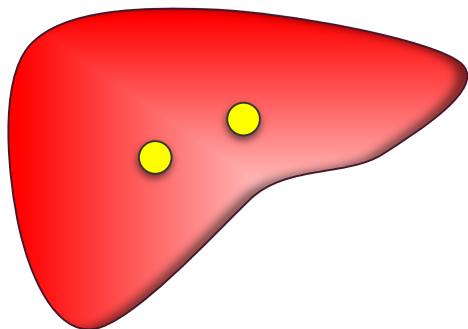
**While both PBC and NASH eventually may lead to fibrosis and cirrhosis, with risk of HCC and liver failure, the pathophysiology and natural history of the two diseases are quite distinct**

1: PBC data from the POISE trial (manuscript submitted); 2:NASH data from the FLINT trial, [Neuschwander-Tetri BA, et al. Lancet 2014](#); 45-51% of patients in FLINT had baseline lipid lowering medication

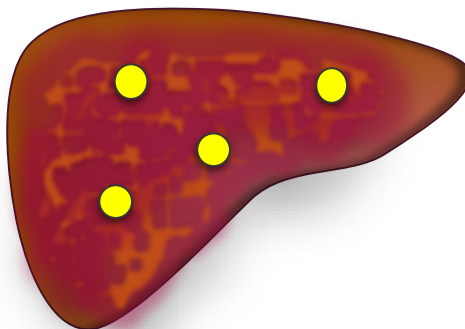
# Bile acid & OCA exposures are higher in a cholestatic liver

● Bile Acids/OCA

Healthy

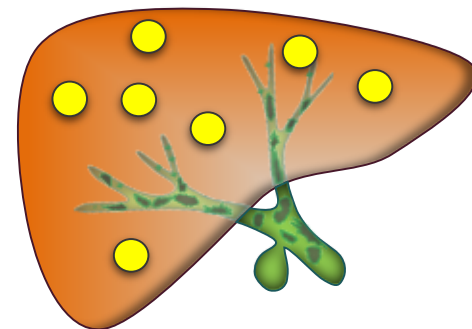


Non-Cholestatic Cirrhotic



Most patients have normal bile flow until advanced stage disease

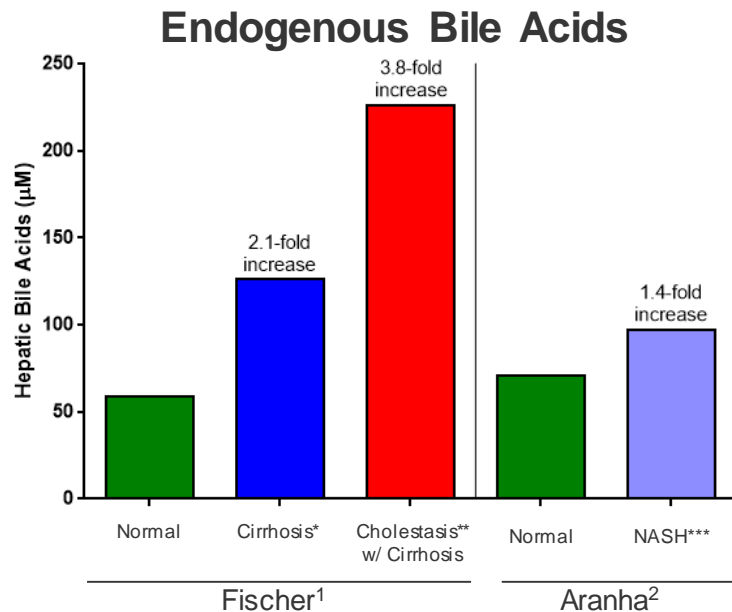
Cholestatic Cirrhotic  
(e.g. PBC)



Bile flow is progressively impaired, potentially resulting in harmful accumulation



# Bile acid concentrations are higher in cholestatic livers



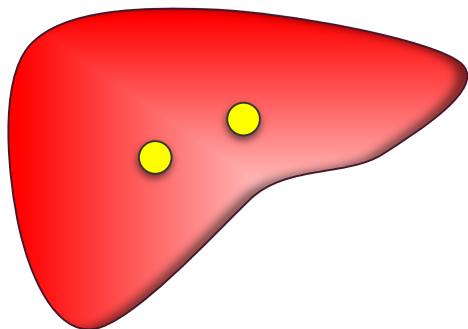
OCA exposure in the liver is predicted to be lower in NASH patients relative to cholestatic disease patients (e.g. PBC)

1: [Fischer et al. Clin Chim Acta. 1996](#); Data from livers of transplanted patients; \*2 alcoholic cirrhosis & 4 hepatic cirrhosis, \*\* 5 PBC & 1 PSC  
2: [Aranha et al. Eur. J. Gast & Hep. 2008](#) \*\*\*pre-cirrhotic NASH patients  
[Overmoyer et al. Arch Pathol Lab Med. 1987](#)

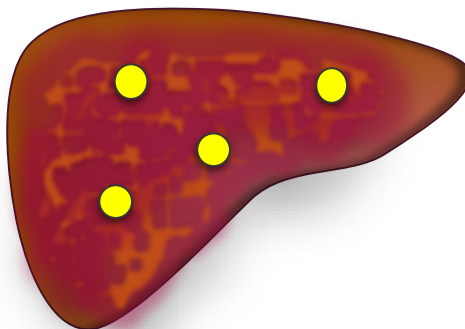
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● Bile Acids/OCA

Healthy



Non-Cholestatic Cirrhotic

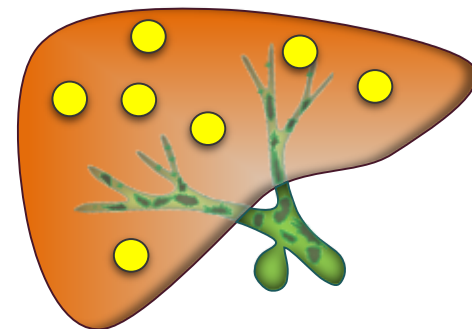


25 mg OCA dose



>50 mg effective OCA dose

Cholestatic Cirrhotic  
(e.g. PBC)



25 mg OCA dose



~90 mg effective OCA dose

# EASL 2016

- 8 clinical OCA abstracts presented
  - 4 PBC, 3 NASH, 1 BA
- Sponsored two satellite symposia:
  - Answering the Unmet Medical Need in Primary Biliary Cholangitis (PBC)
  - Understanding the Role of Evolving Targets in NASH
- Announced winners of Practice to Policy
  - Offers financial support to local and national projects in PBC that create valuable insights, evidence and learning for the wider healthcare community across the United States, Canada and Europe
  - 20 winning organizations (including academic centers, healthcare organizations and patient advocates) will receive grants in 2016

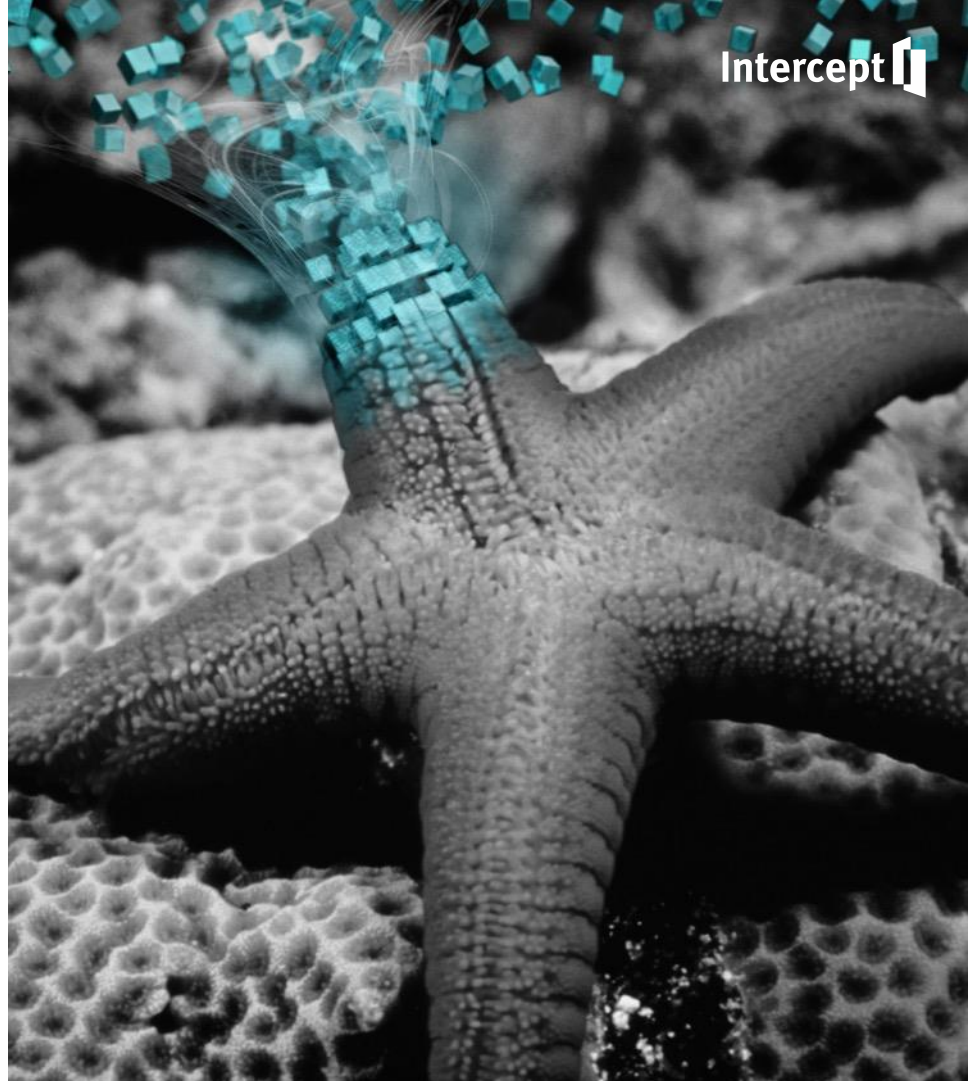


# PBC Commercial Update

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Lisa Bright

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# Our plan for a successful Ocaliva launch in PBC

**Communicate the  
tremendous scientific  
innovation for Ocaliva**

**Achieve broad payer  
coverage**

**Prioritize high volume  
prescribers**

**Establish a strong support  
system**

# Pre-launch US activity update

- 45 Territory Business Managers have been in the field since October 2015
  - Profiled >4000 of our core customers
  - >93 disease state programs, reaching ~800 key physicians
  - We've introduced our key customers to Intercept as a company
- Our managed market team has been hard at work
  - 3 National Advisory Boards
  - 2 National payer mock P&T simulations
  - >50 interactions w/ key regional and national payers
- Multiple Awareness Efforts Underway
  - Patient-directed PBC disease website ([LivingwithPBC.com](http://LivingwithPBC.com))
  - Physician-directed PBC disease website ([RethinkPBC.com](http://RethinkPBC.com))
  - Patient-directed App that tracks ALP and symptoms ([PBC Living](http://PBC Living))



# Financial update

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Barbara Duncan

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# Questions