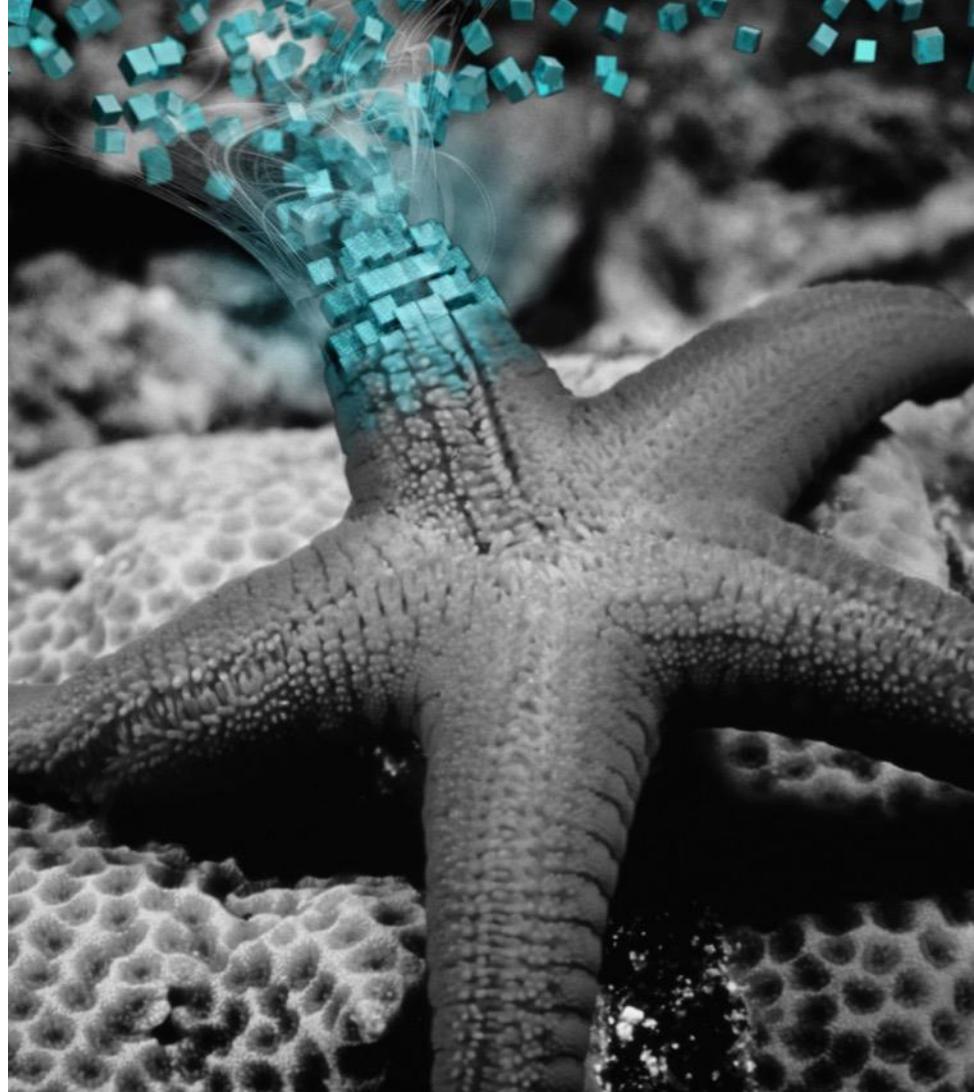


# Intercept Pharmaceuticals

Q3 2019 Earnings Call Presentation

November 5, 2019



# Cautionary Note Regarding Forward-Looking Statements

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This presentation contains forward-looking statements, including, but not limited to, statements regarding the progress, timing and results of Intercept's clinical trials, including its clinical trials for the treatment of nonalcoholic steatohepatitis ("NASH"), the safety and efficacy of Intercept's approved product, Ocaliva (obeticholic acid or "OCA") for primary biliary cholangitis ("PBC"), and Intercept's product development candidates, including OCA for NASH, the timing and acceptance of Intercept's potential regulatory filings and potential approval of OCA for NASH or any other indications in addition to PBC, the timing and potential commercial success of OCA and any other product candidates Intercept may develop and Intercept's strategy, future operations, future financial position, future revenue, projected costs, financial guidance, prospects, plans, objectives of management and expected market growth.

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 Intercept undertakes no obligation to update any forward-looking statement except as required by law. These forward-looking statements are based on estimates and assumptions by Intercept's 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 Intercept's forward-looking statements: Intercept's ability to successfully commercialize Ocaliva for PBC; Intercept's ability to maintain its regulatory approval of Ocaliva for PBC in the United States, Europe, Canada, Israel, Australia and other jurisdictions in which it has or may receive marketing authorization; the initiation, timing, cost, conduct, progress and results of Intercept's 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 it intends to seek approval or completing and timely reporting the results of its NASH or PBC clinical trials; Intercept's ability to timely and cost-effectively file for and obtain regulatory approval of its product candidates, including OCA for NASH, in the United States, Europe and its other target markets; 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 contained in the label of any of its products or product candidates; any potential side effects associated with Ocaliva for PBC, OCA for NASH or Intercept's 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; Intercept's ability to establish and maintain relationships with, and the performance of, third-party manufacturers, contract research organizations and other vendors upon whom it is substantially dependent for, among other things, the manufacture and supply of its products, including Ocaliva for PBC and, if approved, OCA for NASH, and its clinical trial activities; Intercept's ability to identify, develop and successfully commercialize its products and product candidates, including its ability to timely and successfully launch OCA for NASH, if approved; Intercept's ability to obtain and maintain intellectual property protection for its products and product candidates, including its 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 Intercept's products and product candidates and its ability to serve those markets; the degree of market acceptance of Ocaliva for PBC and, if approved, OCA for NASH or Intercept's other product candidates among physicians, patients and healthcare payors; the availability of adequate coverage and reimbursement from governmental and private healthcare payors for Intercept's products, including Ocaliva for PBC and, if approved, OCA for NASH, and its ability to obtain adequate pricing for such products; Intercept's 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; Intercept's ability to prevent system failures, data breaches or violations of data protection laws; costs and outcomes relating to any disputes, governmental inquiries or investigations, legal proceedings or litigation, including any securities, intellectual property, employment, product liability or other litigation; Intercept's collaborators' election to pursue research, development and commercialization activities; Intercept's ability to establish and maintain relationships with collaborators with development, regulatory and commercialization expertise; Intercept's need for and ability to generate or obtain additional financing; Intercept's estimates regarding future expenses, revenues and capital requirements and the accuracy thereof; Intercept's use of cash and short-term investments; Intercept's ability to acquire, license and invest in businesses, technologies, product candidates and products; Intercept's ability to attract and retain key personnel to manage its business effectively; Intercept's ability to manage the growth of its operations, infrastructure, personnel, systems and controls; Intercept's ability to obtain and maintain adequate insurance coverage; 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 with the U.S. Securities and Exchange Commission, including Intercept's Annual Report on Form 10-K for the year ended December 31, 2018.

## Q3 2019 Business Highlights

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Submitted NDA to the FDA for obeticholic acid (OCA) in patients with fibrosis due to NASH; On track to file MAA in EU in Q4 2019

OCA is positioned to become the foundational therapy in patients with advanced fibrosis due to NASH following its approval

Commercial foundation in PBC uniquely positions Intercept for success in NASH

Raising FY 2019 net sales guidance for Ocaliva to between \$245M and \$250M

# Strong Presence at AASLD 2019

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- More than 20 abstracts being presented in the general and late breaker sessions
  - Final results from the Phase 3 POISE Five-Year Open-Label trial
  - Phase 3 REGENERATE interim analysis results
  - PRO data from REGENERATE trial
  - First presentation of OCA's effect on non-invasive tests that are most commonly used by physicians for NASH patients



# Continuing to Advance Phase 3 NASH Clinical Development

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## REGENERATE

- Completed enrollment of the outcomes cohort of REGENERATE with close to 2,500 patients randomized
  - In Sept 2019, submitted NDA seeking accelerated approval for NASH to FDA
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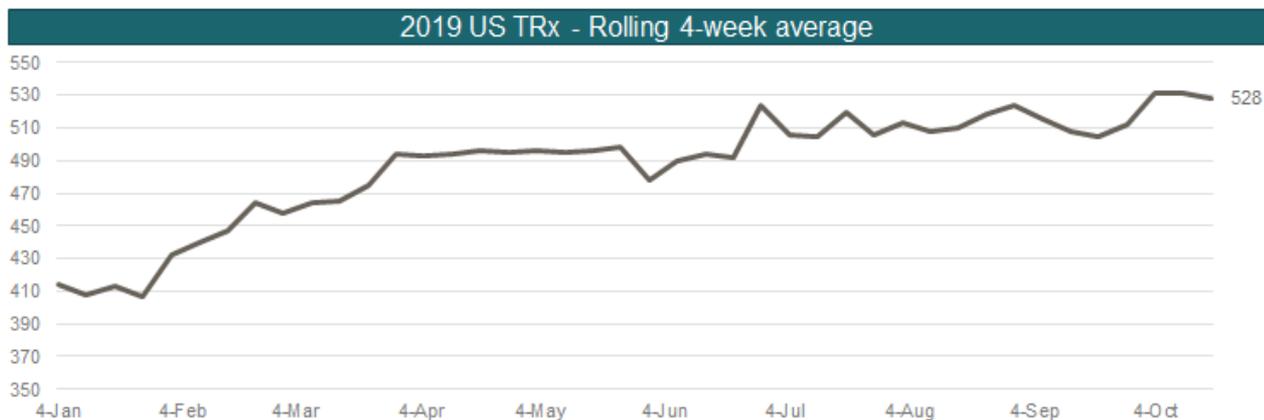
## REVERSE

- Continue to drive to the completion of enrollment of REVERSE, our Phase 3 trial in NASH patients with compensated cirrhosis
  - Study was expanded last quarter to target up to approximately 900 patients and extend the double-blind phase of REVERSE to 18 months
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# Strength in Commercial PBC Business Continues



- Worldwide Ocaliva net sales increased 32% year-over-year to \$61.5M in Q3 2019
  - U.S. net sales of \$45.2M; 23% growth year-over-year
  - International net sales of \$16.3M; 65% growth year-over-year



Note: Chart reflects U.S. IMS data only

# NASH Launch Preparations Underway

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## Significant Progress on NASH Launch Preparations

- Disease state education on early versus advanced fibrosis and non-invasive testing methods continues
  - New data suggests that the progression to cirrhosis can happen faster than previously anticipated\*
  - Launched NASH Truth unbranded disease education campaign
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## Payor Conversations Progressing Well

- Proactive discussions ongoing with payors regarding Phase 3 REGENERATE trial data
  - Prevention of cirrhosis and related complications are a key value driver
  - Expansion of payor team in the field nearly complete
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## Preparing for Specialty launch focused on advanced fibrosis

- Targeting approximately 15,000 hepatologists and GI specialists in the US
  - Expansion on track for 150 Intercept territory business managers by launch
  - Assembled a strong team with deep expertise and direct experience in leading the launch of numerous successful blockbuster drugs
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\*Source: 2019 AASLD abstract 2285.

# Q3 2019 Select Financial Highlights

Three Months Ended  
September 30,

	2019	2018
Total revenue	\$ 61.9M	\$ 47.0M
Ocaliva net sales – U.S.	45.2M	36.7M
Ocaliva net sales – ex-U.S.	16.3M	9.9M
Licensing revenue	0.4M	0.4M
GAAP operating expenses	137.5M	105.3M
Non-GAAP adjusted operating expenses	122.1M	92.2M
Cost of sales	0.5M	0.5M
SG&A Expenses	76.8M	56.8M
R&D Expenses	60.2M	47.9M
	9/30/19	12/31/18
Cash, cash equivalents & investment debt securities	\$ 712.4M	\$ 436.2M

# FY 2019 Financial Guidance

	Revised Guidance (November 5, 2019)	Prior Guidance (May 8, 2019)
Ocaliva Net Sales	\$245M - \$250M	\$235M - \$245M
Gross-to-Net Deductions	10% - 15%	10% - 15%
Non-GAAP Adjusted Operating Expenses	\$480M - \$500M	\$470M - \$500M

Note: 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.

# Appendix

# Non-GAAP Reconciliation

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## Reconciliation of Non-GAAP Adjusted Operating Expenses to Total Operating Expenses

*(Unaudited)*

*(In thousands)*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Total operating expenses	\$ 137,483	\$ 105,272	\$ 403,639	\$ 330,043
Adjustments:				
Stock-based compensation	13,130	11,994	42,809	38,415
Depreciation and amortization	2,203	1,123	6,813	3,551
Non-GAAP adjusted operating expenses	<u>\$ 122,150</u>	<u>\$ 92,155</u>	<u>\$ 354,017</u>	<u>\$ 288,077</u>