



# Fourth Quarter and Year-End 2017 Financial Results

FEBRUARY 14, 2018

# Forward-Looking Statements and Non-GAAP Financial Information

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# Fourth Quarter Overview and Recent Events

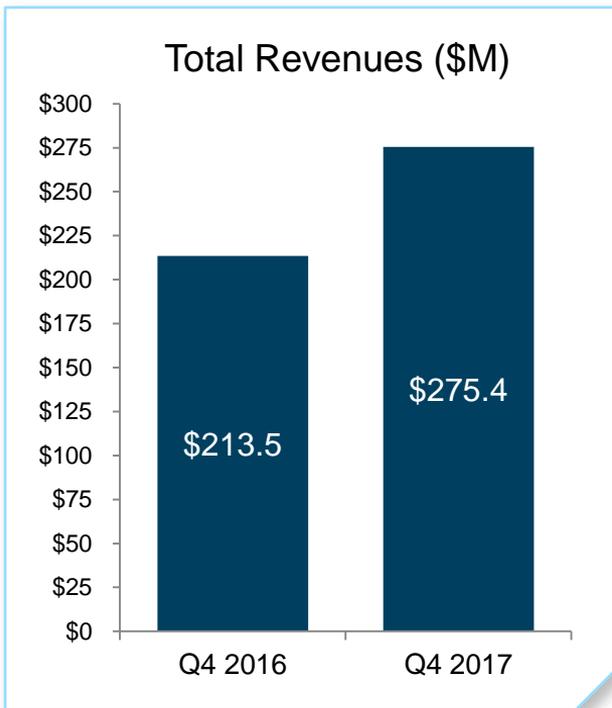
## Financial Results

- ✔ Q4 total revenues increased 29% year-over-year to \$275.4M
  - VIVITROL® net sales increased 22% year-over-year to \$75.6M
  - ARISTADA® net sales increased 64% year-over-year to \$28.3M
  - Recognized \$28.0M upfront payment related to Biogen collaboration announced 11/27/17
- ✔ GAAP net loss of \$9.8M, compared to a GAAP net loss of \$21.1M for Q4 2016
- ✔ Non-GAAP net income of \$50.3M, compared to non-GAAP net income of \$23.3M for Q4 2016

## Clinical / Regulatory

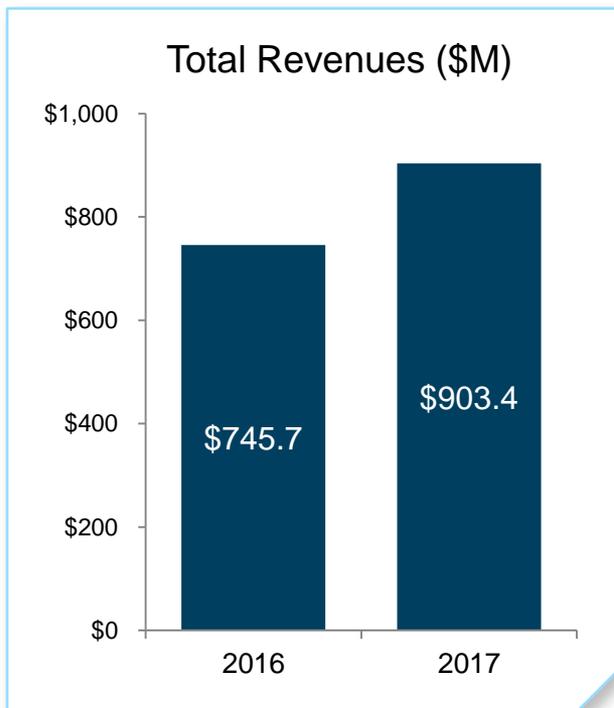
- ✔ ALKS 5461: Submitted New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for ALKS 5461 for the adjunctive treatment of major depressive disorder (MDD)
- ✔ BIIB098 (formerly ALKS 8700): Biogen and Alkermes announced a license and collaboration agreement to develop and commercialize BIIB098 for the treatment of Multiple Sclerosis (MS)
- ✔ ARISTADA: NDA was filed with the FDA for Aripiprazole Lauroxil NanoCrystal® Dispersion (AL<sub>NCD</sub>), a novel, investigational product designed for initiation onto ARISTADA
- ✔ VIVITROL: Results from NIDA-funded X:BOT study, comparing VIVITROL and buprenorphine-naloxone, were published in *The Lancet*; The data demonstrated that, once treatment was initiated, both medications were equally safe and effective in the treatment of opioid dependence.
- ✔ ALKS 4230: Preclinical data was presented at the Society of Immunotherapy of Cancer (SITC) Annual Meeting

# Q4 2017 Revenue Summary



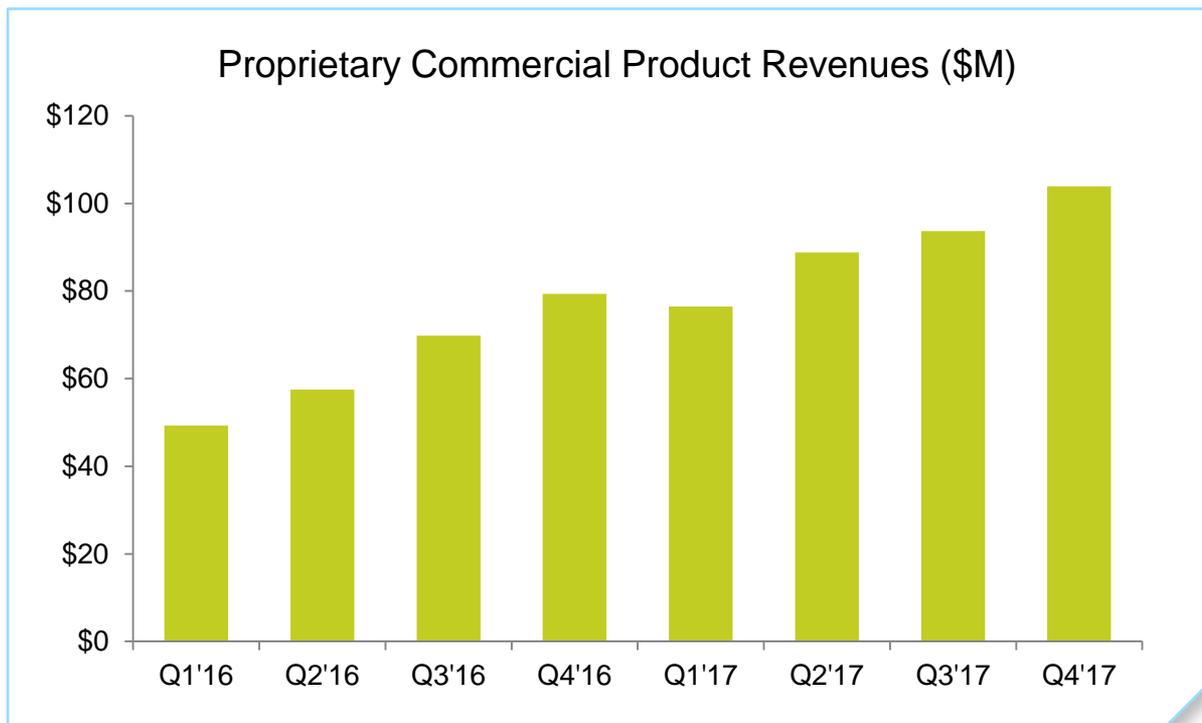
In millions, except %	Q4'17	Q4'16	Δ Q4'17 VS. Q4'16	Q3'17	Δ Q4'17 VS. Q3'17
VIVITROL®	\$75.6	\$62.1	22%	\$69.2	9%
ARISTADA®	\$28.3	\$17.3	64%	\$24.5	16%
Manufacturing & Royalty Revenue	\$138.7	\$133.8	4%	\$122.7	13%
License Revenue	\$28.0	-	-	-	-
<b>Total Revenue</b>	<b>\$275.4</b>	<b>\$213.5</b>	<b>29%</b>	<b>\$217.4</b>	<b>27%</b>

# 2017 Revenue Summary



In millions, except %	FY 2017	FY 2016	Δ 2017 VS. 2016
VIVITROL®	\$269.3	\$209.0	29%
ARISTADA®	\$93.5	\$47.2	98%
Manufacturing & Royalty Revenue	\$505.3	\$487.2	4%
License Revenue	\$28.0	-	-
<b>Total Revenue</b>	<b>\$903.4</b>	<b>\$745.7</b>	<b>21%</b>

# Growing Revenues From Proprietary Commercial Medicines

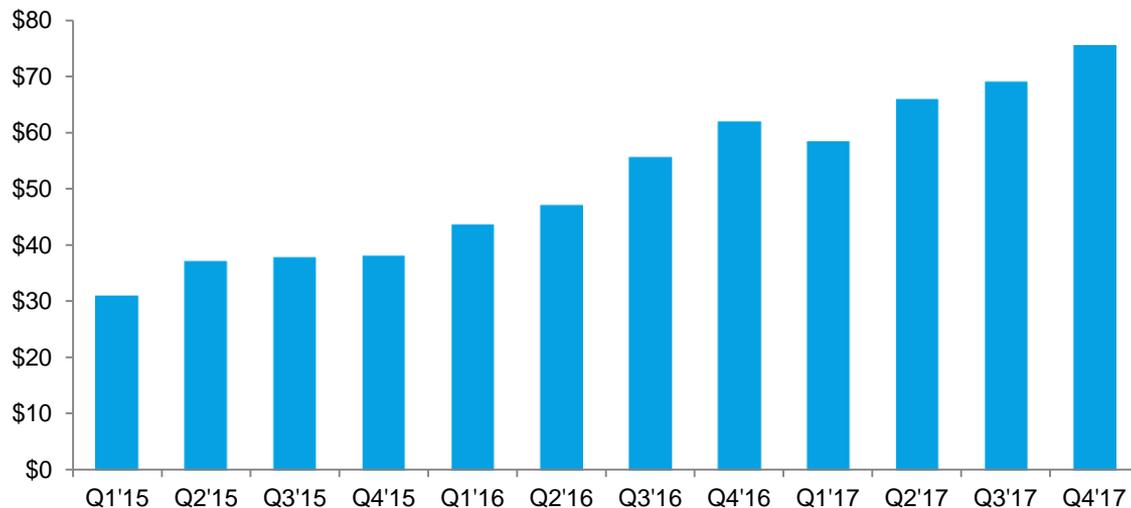


**ARISTADA**<sup>®</sup>  
aripiprazole lauroxil  
extended-release injectable suspension  
441mg · 662mg · 882mg · 1064mg

**Vivitrol**<sup>®</sup>  
(naltrexone for extended-release  
injectable suspension)

# VIVITROL® Fourth Quarter Performance

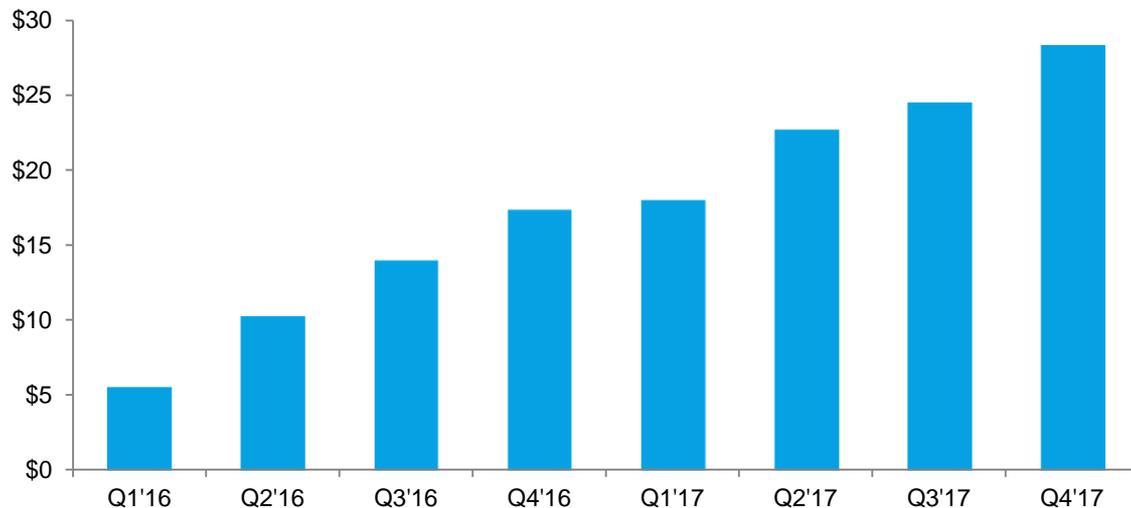
VIVITROL Quarterly Net Sales (\$M)



- ▶ Q4 year-over-year net sales growth of 22%
  - 9% sequential net sales growth compared to Q3'17
  - Q4 results reflect estimated 46% Medicaid units and 54% non-Medicaid units
- ▶ State programs expanded from ~560 at the end of Q3'17 to ~630 at the end of Q4'17
- ▶ 2018 financial expectations of \$300M - \$330M

# ARISTADA® Growing in Volume and Gaining Market Share

ARISTADA Quarterly Net Sales (\$M)



- ▶ Sequential unit growth of 16% compared to Q3'17
  - 41.5% gross-to-net deductions
- ▶ ARISTADA market share increased to 24% among new aripiprazole long-acting atypical prescriptions (months of therapy) in Q4'17, compared to 17% in Q4'16<sup>1</sup>
- ▶ 2018 financial expectations of \$140M - \$160M

1. IMS NPA

# Alkermes: 2018 Financial Expectations†

(in millions, except per share amounts)	Financial Expectations for Year Ending Dec. 31, 2018†
Revenues	\$975 – 1,025
COGS	\$180 – 190
R&D Expense	\$415 – 445
SG&A Expense	\$555 – 585
Amortization of Intangible Assets	~\$65
Net Interest Expense	~\$10
Income Tax Expense	\$0 – 10
GAAP Net Loss	\$(250) – (280)
Non-GAAP Net Loss‡	\$(5) – (35)
GAAP Net Loss Per Share	\$(1.61) – (1.81)
Non-GAAP Loss Per Share	\$(0.03) – (0.23)

## Revenue:

- VIVITROL® net revenue of \$300M - \$330M
- ARISTADA® net revenue of \$140M - \$160M
- License and R&D Revenue: \$50M payment and reimbursement of BIIB098 R&D expenses from Biogen
- AMPYRA®/FAMPYRA® royalty & manufacturing revenue of \$40M - \$50M; Generic competition for AMPYRA expected in July 2018

## Operating Expenses:

- Investment in ALKS 5461 launch (~200 reps) beginning mid-year

† This financial guidance, provided by Alkermes plc in its Current Report on Form 8-K filed with the SEC on Feb. 14, 2018, is effective only as of such date. The company expressly disclaims any obligation to update or reaffirm guidance, and this presentation is not a reaffirmation or update of previously provided historical guidance. The company only provides guidance in a Regulation FD compliant manner.

‡ Non-GAAP loss adjusts for one-time and non-cash charges by excluding from GAAP results: share-based compensation expense; amortization; depreciation; non-cash net interest expense; certain other one-time or non-cash items; and the income tax effect of these reconciling items. Reconciliations of these non-GAAP financial measures to the most directly comparable GAAP financial measures can be found in the Alkermes, plc Current Report on Form 8-K filed with the SEC on Feb. 14, 2018.

# VIVITROL®: Confluence of Data, Policy and Funding Being Integrated Into Response to Opioid Crisis

- Data underscore utility of VIVITROL for opioid dependence
  - Results from NIDA's X:BOT study, comparing extended-release naltrexone (VIVITROL) and buprenorphine-naloxone, were published in *The Lancet*
  - Data from the study demonstrated that, once treatment was initiated, both medicines were equally safe and effective in the treatment of opioid dependence
- Policymakers activating to address opioid epidemic at national level
  - Focus on implementation of Comprehensive Addiction and Recovery Act
  - FDA taking steps to promote more widespread use of medication-assisted treatment (MAT)
- State and federal dollars are being allocated; funding slow to reach treatment system
  - Federal budget passed last week included \$6B to address the opioid epidemic and mental health programs
  - Last year's 21<sup>st</sup> Century Cures Act provided \$1B; Have not yet seen that funding flow from the states into changing the treatment system

## ARISTADA®: Focused on Patient-Centered Treatment Options

- ▶ NDA submitted to FDA for Aripiprazole Lauroxil NanoCrystal® Dispersion (AL<sub>NCD</sub>) for initiation onto ARISTADA
  - PDUFA date of June 30, 2018
  - New initiation regimen designed to replace need for concomitant three weeks of oral aripiprazole
  - Provides an extended-release aripiprazole lauroxil formulation having a smaller particle size than ARISTADA, enabling faster dissolution and leading to more rapid achievement of therapeutic levels of aripiprazole
- ▶ New phase 3b study utilizing AL<sub>NCD</sub> plus two-month ARISTADA compared to current market leader INVEGA SUSTENNA® initiated in November 2017
- ▶ Two-month ARISTADA dose gaining traction
  - 9% of total ARISTADA prescriptions in Q4

# ALKS 5461

## Program

- ▶ Investigational product for adjunctive treatment of major depressive disorder
- ▶ Opioid system modulator with new mechanism of action
- ▶ FDA Fast Track status granted

## Status

- ▶ Submitted NDA, awaiting assignment of PDUFA target action date
- ▶ Publication of data and comprehensive scientific education ongoing

## Priorities

- ▶ Regulatory
  - Prepare for expected Advisory Committee meeting
- ▶ Preparations underway for anticipated launch
  - Scientific education about endogenous opioid system and dysregulation within the context of MDD
  - Planned hiring of commercial field organization in mid-2018 (~200 reps)

# ALKS 3831

## Program

- ✔ Novel, oral broad-spectrum antipsychotic drug candidate for the treatment of schizophrenia
- ✔ Designed to provide antipsychotic efficacy of olanzapine and a differentiated safety profile with favorable weight and metabolic properties

## Status

- ✔ Positive results from ENLIGHTEN-1 pivotal antipsychotic efficacy study announced June 2017
- ✔ Nearing anticipated completion of patient enrollment for ENLIGHTEN-2, a six-month phase 3 study assessing weight gain with olanzapine compared to ALKS 3831

## Priorities

- ✔ Complete ENLIGHTEN-2
  - Topline data expected in Fall 2018
- ✔ Share data from phase 1 translational medicine study evaluating metabolic profile of ALKS 3831 compared to olanzapine

# BIIB098 (Formerly ALKS 8700)

## Program

- Investigational product for the treatment of relapsing forms of multiple sclerosis
- License and collaboration agreement with Biogen announced in Q4 2017

## Status

- Long-term safety study ongoing; initial data showing low rates of GI AEs presented atECTRIMS\*
- Pharmacokinetic bridging studies and clinical requirements for registration complete

## Priorities

- Complete remaining clin/pharm studies for registration package
- Planned NDA submission in 2H 2018

## Biogen License and Collaboration Agreement

- Granted Biogen exclusive, worldwide license to commercialize BIIB098
- Mid-teens percentage royalty to Alkermes on worldwide net sales
- Clinical and regulatory milestones of up to \$200M
- Biogen responsible for all development and commercial expenses (as of 1/1/18)

\*European Committee for Treatment and Research in Multiple Sclerosis

# ALKS 4230

## Program

- ✔ Novel immuno-oncology candidate
- ✔ Designed to selectively activate intermediate-affinity IL-2 receptors to enhance tumor-killing immune cells

## Status

- ✔ Dose-escalation stage of phase 1 study ongoing
- ✔ Preclinical data presented at the SITC Annual Meeting
  - Data showed that treatment with ALKS 4230 significantly delayed tumor growth and led to accumulation of tumor-killing T cells in the tumor microenvironment in individualized and humanized melanoma xenograft models of tumor immunology

## Priorities

- ✔ Complete dose-escalation stage and advance into dose-expansion stage in 2018
- ✔ Planned submission of Investigational New Drug (IND) application for subcutaneous dosing phase 1 study



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