

---

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT  
PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

**Date of Report (Date of earliest event reported): February 14, 2019**

**ALKERMES PUBLIC LIMITED COMPANY**

(Exact name of registrant as specified in its charter)

**Ireland**  
(State or other jurisdiction  
of incorporation)

**001-35299**  
(Commission  
File Number)

**98-1007018**  
(IRS Employer  
Identification No.)

**Connaught House, 1 Burlington Road  
Dublin 4, Ireland**

(Address of principal executive offices)

(Zip Code)

**(Registrant's telephone number, including area code): + 353-1-772-8000**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

---

---

## TABLE OF CONTENTS

[Item 2.02 Results of Operations and Financial Condition.](#)

[Item 9.01 Financial Statements and Exhibits.](#)

- Ex-99.1 Press release issued by Alkermes plc dated February 14, 2019 announcing financial results for the three and twelve months ended December 31, 2018 and financial expectations for the twelve months ending December 31, 2019.
- Ex-99.2 Investor presentation to be displayed by Alkermes plc on February 14, 2019.

[SIGNATURE](#)

**Item 2.02 Results of Operations and Financial Condition.**

On February 14, 2019, Alkermes plc (the “Company”) announced financial results for the three and twelve months ended December 31, 2018 and financial expectations for the twelve months ending December 31, 2019. A copy of the related press release is furnished hereto as Exhibit 99.1 and a copy of the investor presentation to be displayed during the Company’s conference call on February 14, 2019 discussing financial results for the three and twelve months ended December 31, 2018 and financial expectations for the twelve months ending December 31, 2019 is furnished hereto as Exhibit 99.2. This information, including Exhibits 99.1 and 99.2, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press release issued by Alkermes plc dated February 14, 2019 announcing financial results for the three and twelve months ended December 31, 2018 and financial expectations for the twelve months ending December 31, 2019.</a>
99.2	<a href="#">Investor presentation to be displayed by Alkermes plc on February 14, 2019.</a>

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: February 14, 2019

**ALKERMES PLC**

By: /s/ James M. Frates  
James M. Frates  
Senior Vice President and Chief Financial Officer (Principal  
Financial Officer)

Alkermes Contacts:

For Investors: Sandy Coombs +1 781 609 6377

For Media: Matthew Henson +1 781 609 6637

**Alkermes Plc Reports Financial Results for the Year Ended Dec. 31, 2018 and Provides Financial Expectations for 2019***— Record Revenues of \$1.09 Billion in 2018, Driven by 24% Year-Over-Year Growth of Proprietary Product Net Sales —**— Company Reports 2018 GAAP Net Loss per Share of \$0.90 and Diluted Non-GAAP**Earnings per Share of \$0.61 —**— 2019 Net Sales of Proprietary Products Expected to Grow Approximately 24%, Reflecting Continued Growth of VIVITROL® and ARISTADA®*

**DUBLIN, Ireland, Feb. 14, 2019** — Alkermes plc (Nasdaq: ALKS) today reported financial results for the year ended Dec. 31, 2018 and provided financial expectations for 2019.

“Our strong financial results in 2018 were driven by the growth of our proprietary commercial products and the continued strength and diversity of our royalty and manufacturing business,” commented James Frates, Chief Financial Officer of Alkermes. “As we enter 2019, our financial expectations reflect the continued growth of our proprietary products, VIVITROL® and ARISTADA®, as well as important investments in the future growth drivers of the company including our advancing development pipeline and commercial capabilities to support our expanding presence in schizophrenia.”

**Quarter Ended Sept. 30, 2018 Financial Highlights**

- Total revenues for the quarter were \$315.8 million. This compared to \$275.4 million for the same period in the prior year, representing an increase of 15%. Proprietary product net sales for VIVITROL and ARISTADA<sup>i</sup> were \$132.7 million for the quarter, reflecting a 28% increase compared to the same period in the prior year.
- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was \$9.7 million for the quarter, or a basic and diluted GAAP net loss per share of \$0.06. This compared to GAAP net loss of \$9.8 million, or a basic and diluted GAAP net loss per share of \$0.06, for the same period in the prior year.
- Non-GAAP net income was \$54.8 million for the quarter, or a non-GAAP basic earnings per share of \$0.35 and non-GAAP diluted earnings per share of \$0.34. This compared to non-GAAP net income of \$50.3 million, or a non-GAAP basic earnings per share of \$0.33 and non-GAAP diluted earnings per share of \$0.31, for the same period in the prior year.

The launch of ARISTADA INITIO<sup>ii</sup> continues to gain traction as payers and providers recognize the value proposition of this important new offering, particularly in combination with the ARISTADA two-month dose which provides the unique ability to fully dose a patient on day one for up to two months<sup>iii</sup>. With this offering, we are supporting continuity of care which is critically important for this patient population. We also continue to build the customized commercial capabilities necessary to navigate this complex treatment environment, including recent expansions of our field- and hospital-based teams,” stated Jim Robinson, President and Chief Operating Officer of Alkermes. “VIVITROL results for 2018 were in-line with our expectations and we are encouraged by solid growth trends across many states. As we enter 2019, we remain committed to increasing access to VIVITROL and driving increased adoption in order to meet the needs of patients with opioid and alcohol dependence.”

---

## **Quarter Ended Dec. 31, 2018 Financial Results**

### **Revenues**

- Net sales of VIVITROL were \$83.8 million, compared to \$75.6 million for the same period in the prior year, representing an increase of approximately 11%.
- Net sales of ARISTADA were \$48.8 million, compared to \$28.3 million for the same period in the prior year, representing an increase of approximately 72%.
- Manufacturing and royalty revenues from RISPERDAL CONSTA®, INVEGA SUSTENNA®/XEPLION® and INVEGA TRINZA®/TREVICTA® were \$81.4 million, compared to \$78.2 million for the same period in the prior year.
- Manufacturing and royalty revenues from AMPYRA/FAMPYRA<sup>®iv</sup> were \$38.8 million, compared to \$38.1 million for the same period in the prior year, which was above our expectations given generic entry into the market in 2018.
- Manufacturing and royalty revenues included \$26.7 million from Alkermes' share of proceeds from the sale of certain royalty streams by Zealand Pharma A/S, related to products using Alkermes' technology, to Royalty Pharma.
- Research and development revenues were \$15.6 million, of which \$14.4 million related to R&D reimbursement from the company's collaboration with Biogen for diroximel fumarate, or BIIB098.

### **Costs and Expenses**

- Operating expenses were \$315.7 million, compared to \$269.5 million for the same period in the prior year, primarily reflecting increased investment in the commercialization of ARISTADA and VIVITROL.

### **Calendar Year 2018 Financial Highlights**

- Total revenues increased 21% to \$1.09 billion in 2018, which included VIVITROL net sales of \$302.6 million and ARISTADA net sales of \$147.7 million. This compared to total revenues of \$903.4 million for 2017, which included VIVITROL net sales of \$269.3 million and ARISTADA net sales of \$93.5 million. Please see the tables at the end of this press release for a detailed breakdown of the revenues from our key commercial products.
- GAAP net loss was \$139.3 million, or a basic and diluted GAAP loss per share of \$0.90, for 2018. This compared to a GAAP net loss of \$157.9 million, or a basic and diluted GAAP loss per share of \$1.03, for 2017.
- Non-GAAP net income was \$97.8 million, or a non-GAAP basic earnings per share of \$0.63 and non-GAAP diluted earnings per share of \$0.61, for 2018. This compared to non-GAAP net income of \$27.8 million, or a non-GAAP basic earnings per share of \$0.18 and non-GAAP diluted earnings per share of \$0.17, for 2017.
- At Dec. 31, 2018, Alkermes recorded cash, cash equivalents and total investments of \$620.0 million, compared to \$590.7 million at Dec. 31, 2017. At Dec. 31, 2018, the company's total debt outstanding was \$279.3 million, compared to \$281.4 million at Dec. 31, 2017.

“Alkermes is defined by our commitment to making medicines that help address critical public health challenges, using our scientific insights to develop medicines that are designed with the real-world needs of patients in mind. Following the positive results of the ALKS 3831 ENLIGHTEN-2 pivotal study and the increasing traction of ARISTADA in the market, we continue to establish our emerging leadership position in the treatment of schizophrenia,” said Richard Pops, Chief Executive Officer of Alkermes. “2019 will be an important year for our late-stage pipeline highlighted by the planned submission of the

ALKS 3831 New Drug Application and the regulatory review of the recently submitted New Drug Application for diroximel fumarate for multiple sclerosis, with expected action in the fourth quarter. As development activities surrounding our ALKS 4230 immuno-oncology program gain momentum, we expect to have our first indications of ALKS 4230's anti-tumor response activity this year, and we look forward to updating you on our progress.”

#### **Recent Events:**

- ALKS 3831
  - In November 2018, Alkermes announced positive topline results from ENLIGHTEN-2, a pivotal phase 3 study of ALKS 3831 compared to olanzapine in patients with stable schizophrenia. In the study, ALKS 3831 met the pre-specified co-primary endpoints, demonstrating both a lower mean percent weight gain from baseline at six months compared to the olanzapine group and a lower proportion of patients who gained 10% or more of their baseline body weight at six months compared to the olanzapine group.
- Diroximel fumarate (BIIB098)
  - In December 2018, Alkermes and Biogen announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for diroximel fumarate, a novel oral fumarate in development for the treatment of relapsing forms of multiple sclerosis. If approved, Biogen intends to market diroximel fumarate under the brand name VUMERITY™. This name has been conditionally accepted by the FDA and will be confirmed upon approval.
- ALKS 4230
  - In November 2018, Alkermes presented initial clinical data from the ongoing dose-escalation stage of the phase 1 study for ALKS 4230 at the 2018 Society for Immunotherapy of Cancer (SITC) Annual Meeting.
- ALKS 5461
  - In January 2019, Alkermes received a Complete Response Letter from the FDA regarding the NDA for ALKS 5461 for the adjunctive treatment of major depressive disorder.

#### **Financial Expectations for 2019**

The following outlines the company's financial expectations for 2019, which include planned investments in the company's pipeline of development candidates and commercial infrastructure to support the company's expanding presence in schizophrenia.

- **Revenues:** The company expects total revenues to range from \$1.14 billion to \$1.19 billion, driven by expected growth of our proprietary products and an expected \$150 million milestone payment from Biogen in the fourth quarter related to the potential FDA approval of diroximel fumarate. Included in this total revenue expectation, Alkermes expects VIVITROL net sales to range from \$330 million to \$350 million, and ARISTADA net sales to range from \$210 million to \$230 million.
- **Cost of Goods Manufactured and Sold:** The company expects cost of goods manufactured and sold to range from \$180 million to \$190 million.
- **Research and Development (R&D) Expenses:** The company expects R&D expenses to range from \$450 million to \$480 million.
- **Selling, General and Administrative (SG&A) Expenses:** The company expects SG&A expenses to range from \$590 million to \$620 million.

- **Amortization of Intangible Assets:** The company expects amortization of intangibles to be approximately \$40 million.
- **Net Interest Expense:** The company expects net interest expense to range from \$5 million to \$10 million.
- **Income Tax Expense:** The company expects income tax expense to range from \$10 million to \$15 million.
- **GAAP Net Loss:** The company expects GAAP net loss to range from \$135 million to \$165 million, or a basic and diluted loss per share of \$0.87 to \$1.06, based on a weighted average basic and diluted share count of approximately 156 million shares outstanding.
- **Non-GAAP Net Income:** The company expects non-GAAP net income to range from \$40 million to \$70 million, or a non-GAAP basic earnings per share of \$0.26 to \$0.45, based on a weighted average basic share count of approximately 156 million shares outstanding and a non-GAAP diluted earnings per share of \$0.25 to \$0.43, based on a weighted average diluted share count of approximately 161 million shares outstanding.
- **Share-Based Compensation:** The company expects share-based compensation of approximately \$120 million.
- **Capital Expenditures:** The company expects capital expenditures to range from \$90 million to \$100 million.

### **Conference Call**

Alkermes will host a conference call and webcast presentation with accompanying slides at 8:30 a.m. ET (1:30 p.m. BST) on Thursday, Feb. 14, 2019, to discuss these financial results and provide an update on the company. The webcast may be accessed on the Investors section of Alkermes' website at [www.alkermes.com](http://www.alkermes.com). The conference call may be accessed by dialing +1 877 407 2988 for U.S. callers and +1 201 389 0923 for international callers. In addition, a replay of the conference call will be available from 11:00 a.m. ET (4:00 p.m. BST) on Thursday, Feb. 14, 2019, through Thursday, Feb. 21, 2019, and may be accessed by visiting Alkermes' website or by dialing +1 877 660 6853 for U.S. callers and +1 201 612 7415 for international callers. The replay conference ID is 13687392.

### **About Alkermes plc**

Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines for the treatment of central nervous system (CNS) diseases. The company has a diversified commercial product portfolio and a substantial clinical pipeline of product candidates for chronic diseases that include schizophrenia, depression, addiction and multiple sclerosis. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio. For more information, please visit Alkermes' website at [www.alkermes.com](http://www.alkermes.com).

### **Non-GAAP Financial Measures**

This press release includes information about certain financial measures that are not prepared in accordance with generally accepted accounting principles in the U.S. (GAAP), including non-GAAP net income (loss) and non-GAAP basic and diluted earnings (loss) per share. These non-GAAP measures are not based on any standardized methodology prescribed by GAAP and are not necessarily comparable to similar measures presented by other companies.

Non-GAAP net income (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.



The company's management and board of directors utilize these non-GAAP financial measures to evaluate the company's performance. The company provides these non-GAAP measures of the company's performance to investors because management believes that these non-GAAP financial measures, when viewed with the company's results under GAAP and the accompanying reconciliations, are useful in identifying underlying trends in ongoing operations. However, non-GAAP net income (loss) and non-GAAP basic and diluted earnings (loss) per share are not measures of financial performance under GAAP and, accordingly, should not be considered as alternatives to GAAP measures as indicators of operating performance. Further, non-GAAP net income (loss) and non-GAAP basic and diluted earnings (loss) per share should not be considered measures of our liquidity.

A reconciliation of GAAP to non-GAAP financial measures has been provided in the tables included in this press release.

### **Note Regarding Forward-Looking Statements**

Certain statements set forth in this press release constitute “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: the company’s future financial and operating performance, business plans or prospects; expectations concerning continued revenue growth from the company’s commercial products, including the growth of VIVITROL, ARISTADA and ARISTADA INITIO and the company’s expanding presence in the field of treatment of schizophrenia; expectations concerning the company’s continued investment in its commercial capabilities and the value that can be derived therefrom; the potential therapeutic and commercial value of the company’s marketed and development products, and patient access to and adoption of such products; expectations concerning the timing and results of clinical development and regulatory activities, including the anticipated presentation of data from the ENLIGHTEN-2 phase 3 clinical trial for ALKS 3831, the planned submission of an NDA for ALKS 3831, topline results from the EVOLVE-MS-2 head-to-head study of diroximel fumarate (BIIB098) compared to TECFIDERA, the FDA’s anticipated acceptance of, and action with respect to, the NDA for diroximel fumarate, topline results from the phase 3b clinical trial evaluating ARISTADA INITIO plus ARISTADA two-month dose alongside INVEGA SUSTENNA, the progress of, and presentation of initial data from, the ALKS 4230 phase 1 study, and the initiation of a subcutaneous dosing phase 1 study for ALKS 4230. The company cautions that forward-looking statements are inherently uncertain. Although the company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the forward-looking statements are neither promises nor guarantees and they are necessarily subject to a high degree of uncertainty and risk. Actual performance and results may differ materially from those expressed or implied in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: the unfavorable outcome of litigation, including so-called “Paragraph IV” litigation and other patent litigation, related to any of our products or products using our proprietary technologies, which may lead to competition from generic drug manufacturers; data from clinical trials may be interpreted by the FDA in different ways than we interpret it; the FDA may not agree with our regulatory approval strategies or components of our filings for our products, including our clinical trial designs, conduct and methodologies; clinical development activities may not be completed on time or at all; the results of our clinical development activities may not be positive, or predictive of real-world results or of results in subsequent clinical trials; regulatory submissions may not occur or be submitted in a timely manner; the company and its licensees may not be able to continue to successfully commercialize their products; there may be a reduction in payment rate or reimbursement for the company’s products or an increase in the company’s financial obligations to governmental payers; the FDA or regulatory authorities outside the U.S. may make adverse decisions regarding the company’s products; the company’s products may prove difficult to manufacture, be precluded from commercialization by the proprietary rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; and those risks and uncertainties described under the heading “Risk Factors” in the company’s most recent Annual Report on Form 10-K and in subsequent filings made by the company with the U.S. Securities and Exchange Commission (“SEC”), which are available on the SEC’s website at [www.sec.gov](http://www.sec.gov). Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release.

VIVITROL® is a registered trademark of Alkermes, Inc.; ARISTADA® and ARISTADA INITIO® are registered trademarks of Alkermes Pharma Ireland Limited; RISPERDAL CONSTA®, INVEGA SUSTENNA®, XEPLION®, INVEGA TRINZA® and TREVICTA® are registered trademarks of Johnson & Johnson; TECFIDERA® is a registered trademark of Biogen Inc.; and AMPYRA® and FAMPYRA® are registered trademarks of Acorda Therapeutics, Inc. (“Acorda”)

(tables follow)

i The term “ARISTADA” as used in this press release refers to ARISTADA and ARISTADA INITIO, unless the context indicates otherwise.

ii ARISTADA INITIO was approved by the FDA for the initiation of ARISTADA, a long-acting injectable atypical antipsychotic for the treatment of schizophrenia in adults. ARISTADA INITIO is to be administered with a single 30 mg dose of oral aripiprazole.

iii ARISTADA INITIO + single 30 mg oral dose of aripiprazole replaces need for concomitant three weeks of oral aripiprazole for initiation of ARISTADA, with relevant levels of aripiprazole concentration reached within four days.

iv AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg is developed and marketed in the U.S. by Acorda and outside the U.S. by Biogen Inc., under a licensing agreement with Acorda, as FAMPYRA® (prolonged-release fampridine tablets).

**Alkermes plc and Subsidiaries**  
**Selected Financial Information (Unaudited)**

Condensed Consolidated Statements of Operations - GAAP (In thousands, except per share data)	Three Months Ended December 31, 2018	Three Months Ended December 31, 2017
<b>Revenues:</b>		
Manufacturing and royalty revenues	\$ 167,422	\$ 138,700
Product sales, net	132,650	103,941
Research and development revenue	15,570	4,729
License revenues	120	28,000
Total Revenues	<u>315,762</u>	<u>275,370</u>
<b>Expenses:</b>		
Cost of goods manufactured and sold	49,117	38,507
Research and development	108,972	104,490
Selling, general and administrative	141,227	110,896
Amortization of acquired intangible assets	16,426	15,642
Total Expenses	<u>315,742</u>	<u>269,535</u>
Operating Income	<u>20</u>	<u>5,835</u>
<b>Other (Expense) Income, net:</b>		
Interest income	3,292	1,362
Interest expense	(3,478)	(3,192)
Change in the fair value of contingent consideration	(2,300)	5,700
Other expense, net	775	1,081
Total Other (Expense) Income, net	<u>(1,711)</u>	<u>4,951</u>
(Loss) Income Before Income Taxes	<u>(1,691)</u>	<u>10,786</u>
Provision for income taxes	8,022	20,575
<b>Net Loss — GAAP</b>	<u>\$ (9,713)</u>	<u>\$ (9,789)</u>
<b>Net (Loss) Earnings Per Share:</b>		
GAAP net loss per share — basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.06)</u>
Non-GAAP earnings per share — basic	<u>\$ 0.35</u>	<u>\$ 0.33</u>
Non-GAAP earnings per share — diluted	<u>\$ 0.34</u>	<u>\$ 0.31</u>
<b>Weighted Average Number of Ordinary Shares Outstanding:</b>		
Basic and diluted — GAAP	<u>155,506</u>	<u>153,865</u>
Basic — Non-GAAP	<u>155,506</u>	<u>153,865</u>
Diluted — Non-GAAP	<u>159,518</u>	<u>160,036</u>
An itemized reconciliation between net loss on a GAAP basis and non-GAAP net income is as follows:		
<b>Net Loss — GAAP</b>	\$ (9,713)	\$ (9,789)
<b>Adjustments:</b>		
Share-based compensation expense	29,314	20,581
Amortization expense	16,426	15,642
Depreciation expense	9,476	9,575
Fixed asset impairment	5,746	—
Change in the fair value of contingent consideration	2,300	(5,700)
Income tax effect related to reconciling items	1,533	(1,726)
Non-cash net interest expense	169	192
Change in the fair value of warrants and equity method investments	(410)	64
Income tax charge related to 2017 income tax reform (1)	—	21,453
<b>Non-GAAP Net Income</b>	<u>\$ 54,841</u>	<u>\$ 50,292</u>

**Alkermes plc and Subsidiaries**  
**Selected Financial Information (Unaudited)**

Condensed Consolidated Statements of Operations - GAAP (In thousands, except per share data)	Year Ended December 31, 2018	Year Ended December 31, 2017
<b>Revenues:</b>		
Manufacturing and royalty revenues	\$ 526,675	\$ 505,308
Product sales, net	450,334	362,834
Research and development revenues	68,895	7,232
License revenues	48,370	28,000
Total Revenues	<u>1,094,274</u>	<u>903,374</u>
<b>Expenses:</b>		
Cost of goods manufactured and sold	176,420	154,748
Research and development	425,406	412,889
Selling, general and administrative	526,408	421,578
Amortization of acquired intangible assets	65,168	62,059
Total Expenses	<u>1,193,402</u>	<u>1,051,274</u>
Operating Loss	<u>(99,128)</u>	<u>(147,900)</u>
Other (Expense) Income, net:		
Interest income	9,238	4,649
Interest expense	(15,437)	(12,008)
Change in the fair value of contingent consideration	(19,600)	21,600
Other expense, net	(2,040)	(9,615)
Total Other (Expense) Income, net	<u>(27,839)</u>	<u>4,626</u>
Loss Before Income Taxes	<u>(126,967)</u>	<u>(143,274)</u>
Provision for income taxes	12,344	14,671
<b>Net Loss — GAAP</b>	<u>\$ (139,311)</u>	<u>\$ (157,945)</u>
<b>Net (Loss) Earnings Per Share:</b>		
GAAP net loss per share — basic and diluted	<u>\$ (0.90)</u>	<u>\$ (1.03)</u>
Non-GAAP earnings per share — basic	<u>\$ 0.63</u>	<u>\$ 0.18</u>
Non-GAAP earnings per share — diluted	<u>\$ 0.61</u>	<u>\$ 0.17</u>
<b>Weighted Average Number of Ordinary Shares Outstanding:</b>		
Basic and diluted — GAAP	<u>155,112</u>	<u>153,415</u>
Basic — Non-GAAP	<u>155,112</u>	<u>153,415</u>
Diluted — Non-GAAP	<u>160,363</u>	<u>160,062</u>
An itemized reconciliation between net loss on a GAAP basis and non-GAAP net income is as follows:		
<b>Net Loss — GAAP</b>	\$ (139,311)	\$ (157,945)
Adjustments:		
Share-based compensation expense	105,357	83,917
Amortization expense	65,168	62,059
Depreciation expense	38,492	36,464
Change in the fair value of contingent consideration	19,600	(21,600)
Fixed asset impairment	5,746	—
Restructuring expense	3,598	—
Debt refinancing charge	2,298	—
Non-cash net interest expense	700	770
Change in the fair value of warrants and equity method investments	190	2,824
Income tax effect related to reconciling items	(4,002)	(10,622)
Income tax charge related to 2017 income tax reform (1)	—	21,453
Other-than-temporary impairment of equity method investment	—	10,471
<b>Non-GAAP Net Income</b>	<u>\$ 97,836</u>	<u>\$ 27,791</u>

(1) - On December 22, 2017, the Tax Cuts and Jobs Act of 2017 was signed into law and has resulted in significant changes to the U.S. corporate income tax system including a federal corporate rate reduction from 35% to 21%. The change in tax rate and tax law is accounted for in the period of enactment. Therefore, during the period ended December 31, 2017, we recorded a \$21.5 million tax expense related to our current estimate of the provisions of the Tax Cuts and Jobs Act of 2017.

**Alkermes plc and Subsidiaries**  
**Selected Financial Information (Unaudited)**

Condensed Consolidated Balance Sheets (In thousands)	December 31, 2018	December 31, 2017
Cash, cash equivalents and total investments	\$ 620,039	\$ 590,716
Receivables	292,223	233,590
Contract assets	8,230	—
Inventory	90,196	93,275
Prepaid expenses and other current assets	53,308	48,475
Property, plant and equipment, net	309,987	284,736
Intangible assets, net and goodwill	283,874	349,041
Other assets	167,150	197,394
<b>Total Assets</b>	<b>\$ 1,825,007</b>	<b>\$ 1,797,227</b>
Long-term debt — current portion	\$ 2,843	\$ 3,000
Other current liabilities	336,931	288,122
Long-term debt	276,465	278,436
Contract liabilities — long-term	9,525	5,657
Other long-term liabilities	27,958	19,204
Total shareholders' equity	1,171,285	1,202,808
<b>Total Liabilities and Shareholders' Equity</b>	<b>\$ 1,825,007</b>	<b>\$ 1,797,227</b>
Ordinary shares outstanding (in thousands)	155,757	154,009

This selected financial information should be read in conjunction with the consolidated financial statements and notes thereto included in Alkermes plc's Annual Report on Form 10-K for the year ended December 31, 2018, which the company intends to file in February 2019.

**Alkermes plc and Subsidiaries**  
**Revenues for Calendar Year 2018 and 2017**

(In thousands)	Three Months Ended March 31, 2018	Three Months Ended June 30, 2018	Three Months Ended September 30, 2018	Three Months Ended December 31, 2018	Year Ended December 31, 2018
<b>Revenues:</b>					
PARTNERED LONG-ACTING ANTIPSYCHOTICS (1)	\$ 68,790	\$ 85,181	\$ 77,202	\$ 81,372	\$ 312,545
VIVITROL	62,682	76,203	79,893	83,831	302,609
ARISTADA	29,160	33,604	36,142	48,819	147,725
AMPYRA/FAMPYRA	28,259	19,678	20,339	38,778	107,054
BYDUREON	9,749	13,510	11,944	10,572	45,775
<b>Key Commercial Product Revenues</b>	<b>198,640</b>	<b>228,176</b>	<b>225,520</b>	<b>263,372</b>	<b>915,708</b>
Legacy Product Revenues	7,803	9,872	6,926	36,700	61,301
License Revenue (2)	—	48,250	—	120	48,370
Research and Development Revenues	18,707	18,344	16,274	15,570	68,895
<b>Total Revenues</b>	<b>\$ 225,150</b>	<b>\$ 304,642</b>	<b>\$ 248,720</b>	<b>\$ 315,762</b>	<b>\$ 1,094,274</b>

(In thousands)	Three Months Ended March 31, 2017	Three Months Ended June 30, 2017	Three Months Ended September 30, 2017	Three Months Ended December 31, 2017	Year Ended December 31, 2017
<b>Revenues:</b>					
PARTNERED LONG-ACTING ANTIPSYCHOTICS (1)	\$ 60,003	\$ 82,169	\$ 79,443	\$ 78,238	\$ 299,853
VIVITROL	58,456	66,071	69,178	75,617	269,322
ARISTADA	18,000	22,685	24,503	28,324	93,512
AMPYRA/FAMPYRA	29,219	25,256	24,478	38,066	117,019
BYDUREON	12,266	11,635	10,095	11,700	45,696
<b>Key Commercial Product Revenues</b>	<b>177,944</b>	<b>207,816</b>	<b>207,697</b>	<b>231,945</b>	<b>825,402</b>
Legacy Product Revenues	13,191	10,192	8,661	10,696	42,740
License Revenue (3)	—	—	—	28,000	28,000
Research and Development Revenues	643	833	1,027	4,729	7,232
<b>Total Revenues</b>	<b>\$ 191,778</b>	<b>\$ 218,841</b>	<b>\$ 217,385</b>	<b>\$ 275,370</b>	<b>\$ 903,374</b>

- (1) - Includes RISPERDAL CONSTA, INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA.  
(2) - Includes a milestone payment allocated to the license sold to Biogen in connection with the BIIB098 collaboration.  
(3) - Includes the upfront payment allocated to the license sold to Biogen in connection with the BIIB098 collaboration.

**Alkermes plc and Subsidiaries**  
**2019 Guidance — GAAP to Non-GAAP Adjustments**

An itemized reconciliation between projected loss per share on a GAAP basis and projected earnings per share on a non-GAAP basis is as follows:

An itemized reconciliation between projected loss per share on a GAAP basis and projected earnings per share on a non-GAAP basis is as follows:

<b>(In millions, except per share data)</b>	Amount	Shares	(Loss) Earnings Per Share
Projected Net Loss — GAAP	\$ (165.0)	156	\$ (1.06)
Adjustments:			
Share-based compensation expense	120.0		
Amortization expense	55.0		
Depreciation expense	40.0		
Non-cash net interest expense	1.0		
Income tax effect related to reconciling items	4.0		
Projected Net Income — Non-GAAP	\$ 55.0	161	\$ 0.34

Projected GAAP and non-GAAP measures reflect mid-points within ranges of estimated guidance.





# Fourth Quarter and Year End 2018 Financial Results & Business Update

February 14, 2019

# Forward-Looking Statements and Non-GAAP Financial Information

Certain statements set forth in this presentation constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: the company's expectations with respect to its future financial and operating performance, business plans or prospects; expectations with respect to continued revenue growth from the company's commercial products, including VIVITROL<sup>®</sup>, ARISTADA<sup>®</sup> and ARISTADA INITIO<sup>®</sup>; VIVITROL growth driven by improvements to and modernization of the treatment ecosystem for substance use disorders, including related policy initiatives and state and federal funding; the therapeutic and commercial value of the company's marketed and development products and patient access to such products; expectations concerning the timing and results of clinical development activities relating to the company's products and product development candidates, including expansion of the ongoing phase 1 study for ALKS 4230 and initiation of a subcutaneous dosing study for ALKS 4230, topline data from the phase 3 elective study for diroxime fumarate ("DRF"), topline data from the phase 3b study evaluating ARISTADA and ARISTADA INITIO alongside INVEGA SUSTENNA<sup>®</sup>, the presentation of data relating to ALKS 3831 and submission of a new drug application ("NDA") for ALKS 3831 and the presentation and publication of data relating to detoxification and induction strategies; the company's expectations and timelines for regulatory interactions with the U.S. Food and Drug Administration ("FDA"), and actions by the FDA, relating to the company's NDA submission for DRF and planned NDA submission for ALKS 3831; the potential financial benefits that may be achieved under the license and collaboration agreement between the company and Biogen for DRF; Biogen's marketing plans for DRF; and expectations concerning the timing and results of commercial activities relating to the company's products and potential expansion of the company's commercial portfolio, including preparations for the potential launch of ALKS 3831 and investment in the company's commercial infrastructure. The company cautions that forward-looking statements are inherently uncertain. Although the company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the forward-looking statements are neither promises nor guarantees and they are necessarily subject to a high degree of uncertainty and risk. Actual performance and results may differ materially from those expressed or implied in the forward-looking statements due to various risks and uncertainties. These risks, assumptions and uncertainties include, among others: the unfavorable outcome of litigation, including so-called "Paragraph IV" litigation and other patent litigation, related to any of the company's products, which may lead to competition from generic drug manufacturers; data from clinical trials may be interpreted by the FDA in different ways than the company interprets it; the FDA may not agree with the company's regulatory approval strategies or components of the company's filings for its products, including its clinical trial designs, conduct and methodologies or the sufficiency of the results thereof to support approval; clinical development activities may not be completed on time or at all; the results of the company's clinical development activities may not be positive, or predictive of real-world results or of results in subsequent clinical trials; regulatory submissions may not occur or be submitted in a timely manner; the company and its licensees may not be able to continue to successfully commercialize their products; there may be a reduction in payment rate or reimbursement for the company's products or an increase in the company's financial obligations to governmental payers; the FDA or regulatory authorities outside the U.S. may make adverse decisions regarding the company's products; the company's products may prove difficult to manufacture, be precluded from commercialization by the proprietary rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; and those risks, assumptions and uncertainties described under the heading "Risk Factors" in the company's most recent Annual Report on Form 10-K and in subsequent filings made by the company with the U.S. Securities and Exchange Commission ("SEC"), which are available on the SEC's website at [www.sec.gov](http://www.sec.gov), and on the company's website at [www.alkermes.com](http://www.alkermes.com) in the "Investors - SEC filings" section. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this presentation.

**Non-GAAP Financial Measures:** This presentation includes information about certain financial measures that are not prepared in accordance with generally accepted accounting principles in the U.S. (GAAP), including non-GAAP net income/(loss) and non-GAAP earnings per share. These non-GAAP measures are not based on any standardized methodology prescribed by GAAP and are not necessarily comparable to similar measures presented by other companies. 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, 2019.

**Note Regarding Trademarks:** The company is the owner of various U.S. federal trademark registrations (®) and other trademarks (™), including ARISTADA<sup>®</sup>, VIVITROL<sup>®</sup> and ARISTADA INITIO<sup>®</sup>. Any other trademarks referred to in this presentation are the property of their respective owners. Appearances of such other trademarks herein should not be construed as any indicator that their respective owners will not assert their rights thereto.



# Transformational Progress Over the Past 5 Years

## Delivering Growth Across Multiple Dimensions

### Meaningful impact on patients



~380K patients<sup>1</sup> treated with VIVITROL® or ARISTADA®

### Enhanced scale of the business



Crossed \$1B in total revenue in 2018  
Increased annual proprietary product net sales by 527%<sup>2</sup>

### Sophisticated commercial infrastructure



Community and hospital sales organizations supported by extensive team, including: policy, patient access services, managed markets and marketing

### World-class science and late-stage pipeline



Expanded discovery and clinical development capabilities  
4 NDA submissions

### Specialized manufacturing capabilities



950M oral solid doses<sup>1</sup>  
30M sterile injectable doses<sup>1</sup>  
~1,000 employees in operations and quality

### Dedicated culture



~2,300 total employees in Ireland, MA, OH, and U.S.-based field sales force

1. Includes years 2014 through 2018  
2. FY2018 compared to FY2013

**Q4 & Year End 2018 Financial Results  
2019 Guidance**

**Jim Frates**  
Chief Financial Officer

**Commercial Update**

**Jim Robinson**  
President & Chief Operating Officer

**Business Update**

**Richard Pops**  
Chief Executive Officer

## Fourth Quarter 2018 Revenue Summary



In millions, except %	Q4'18	Q4'17	Δ Q4'18 vs. Q4'17
VIVITROL®	\$83.8	\$75.6	11%
ARISTADA®	\$48.8	\$28.3	72%
Manufacturing & Royalty Revenues*	\$167.4	\$138.7	21%
R&D Revenues	\$15.6	\$4.7	N/A
<b>Total Revenues</b>	<b>\$315.8</b>	<b>\$275.4</b>	<b>15%</b>

\*In Q4'18, Manufacturing and Royalty Revenues included a royalty payment of \$26.7 million from Zealand Pharma A/S ("Zealand") resulting from Zealand's sale to Royalty Pharma of certain royalty streams for products containing Alkermes technology.



# 2018 Revenue Summary



In millions, except %	FY 2018	FY 2017	Δ 2018 vs. 2017
VIVITROL®	\$302.6	\$269.3	12%
ARISTADA®	\$147.7	\$93.5	58%
Manufacturing & Royalty Revenues	\$526.7	\$505.3	4%
R&D Revenues	\$68.9	\$7.2	N/A
Total Revenues	\$1,094.3	\$903.4	21%



# Revenues From Proprietary Commercial Medicines



**ARISTADA INITIO<sup>®</sup>**  
aripiprazole lauroxil  
extended-release injectable suspension

675 mg

**ARISTADA<sup>®</sup>**  
aripiprazole lauroxil  
extended-release injectable suspension

441 mg 662 mg 882 mg 1064 mg

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





## VIVITROL® Performance



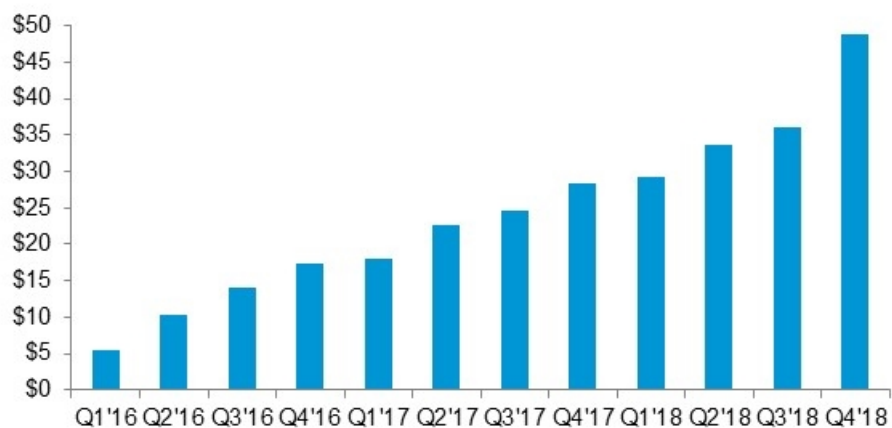
- ▶ **Q4 year-over-year net sales growth of 11%, driven by underlying unit growth of 11%**
  - Q4'18 results reflect estimated 49% Medicaid units
- ▶ **Net sales increased 5% sequentially, driven by unit growth**
  - Inventory in the channel increased by <1 week at year-end
  - Gross-to-net deductions of 46% in Q4'18, compared to 47% in Q3'18 and 46% in Q4'17
- ▶ **2019 net sales expectations of \$330M - \$350M**





## ARISTADA® Performance

ARISTADA Quarterly Net Sales (\$M)



- ▶ Q4 year-over-year net sales growth of **72%**
- ▶ Sequential growth of **35%** compared to Q3'18, driven by unit growth and favorable gross-to-net adjustments
  - Approximately 44% gross-to-net deductions, compared to 47% in Q3'18 and 42% in Q4'17
  - Inventory in the channel increased by ~1 week at year-end
- ▶ **2019 net sales expectations of \$210M - \$230M**



# Alkermes: 2019 Financial Expectations†

(in millions, except per share amounts)	Financial Expectations for Year Ending Dec. 31, 2019†	
Revenues	\$1,140 – 1,190	<b>Revenues:</b> <ul style="list-style-type: none"> <li>- VIVITROL® net sales of \$330M - \$350M               <ul style="list-style-type: none"> <li>- Q1 VIVITROL net sales of ~\$70M</li> </ul> </li> <li>- ARISTADA® net sales of \$210M - \$230M               <ul style="list-style-type: none"> <li>- Q1 ARISTADA net sales of ~\$40M</li> </ul> </li> <li>- License revenues: \$150M milestone anticipated upon FDA approval of diroximel fumarate (expected Q4 2019)</li> </ul>
COGS	\$180 – 190	
R&D Expense	\$450 – 480	
SG&A Expense	\$590 – 620	
Amortization of Intangible Assets	~\$40	
Net Interest Expense	\$5 to \$10	
Income Tax Expense	\$10 to \$15	
GAAP Net Loss	\$(135) – (165)	
GAAP Net Loss Per Share	\$(0.87) – (1.06)	
Non-GAAP Net Income‡	\$40 – 70	
Non-GAAP Earnings Per Share (Basic)	\$0.26 – 0.45	
Non-GAAP Earnings Per Share (Diluted)	\$0.25 – 0.43	

† This financial guidance, provided by Alkermes plc (the "Company") in its Current Report on Form 8-K filed with the SEC on Feb. 14, 2019, is effective only as of such date. The Company expressly disclaims any obligation to update or reaffirm this guidance. The Company only provides financial guidance in a Regulation FD compliant manner.

‡ Non-GAAP net income 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. Reconciliation of this non-GAAP financial measure to the most directly comparable GAAP financial measure can be found in the Alkermes plc Current Report on Form 8-K filed with the SEC on Feb. 14, 2019.



## Alkermes: 2019 Financial Expectations<sup>†</sup> - Operating Expenses

- ✔ **Investments in R&D to support current development programs and pipeline expansion**
  - R&D expected to be in the range of \$450M to \$480M, driven by:
    - Ongoing studies related to ARISTADA®, ALKS 3831 and diroximel fumarate that are carrying over from 2018, as well as life-cycle management initiatives related to ARISTADA and ALKS 3831
    - Intensified activity for the clinical development program for ALKS 4230
    - Investment in internal research and discovery efforts
- ✔ **Commercial infrastructure provides a platform to capture efficiencies as commercial portfolio expands, particularly as we prepare for the planned launch of ALKS 3831 in schizophrenia**
  - SG&A expected to be in the range of \$590M to \$620M, driven by:
    - Full-year impact of the expansion of the ARISTADA commercial team that took place at the end of 2018
    - Infrastructure investments to support long-term growth

<sup>†</sup>This financial guidance, provided by the Company in its Current Report on Form 8-K filed with the SEC on Feb. 14, 2019, is effective only as of such date. The company expressly disclaims any obligation to update or reaffirm this guidance. The company only provides financial guidance in a Regulation FD compliant manner.



© 2019 Alkermes. All rights reserved.

## VIVITROL®: Opportunities to Increase Utilization and Drive Growth

- State and federal dollars are being allocated; Funding slowly flowing into fragmented treatment system
- Improvements in accessibility of VIVITROL and implementation of public policy initiatives driving growth in bellwether states
  - Encouraged by new trends and initiatives in important states such as Pennsylvania, California, Florida, Kentucky and Michigan
    - Michigan example: First state to fully embrace provision of Comprehensive Addiction Recovery Act mandating that Opioid Treatment Programs offer all three FDA-approved forms of medication; Recent Michigan legislation requires courts to order an assessment for alcohol use disorder and possible medication-assisted treatment for people convicted of two or more DUI offenses
- State programs expanded to ~750 at the end of 2018, primarily driven by criminal justice re-entry and drug court programs
- Implemented new commercial capabilities to support continuity of care and accessibility

- ✔ **2018 was highlighted by the launch of ARISTADA INITIO®**
  - ARISTADA INITIO regimen\* in conjunction with two-month ARISTADA resonating with treatment providers and patients
    - Covered by the largest health plans and PBMs
    - Added to the formularies of 65 of the largest hospitals since launch
- ✔ **ARISTADA market share increased to 29% among new aripiprazole long-acting atypical prescriptions (months of therapy) in Q4'18<sup>1</sup>**
- ✔ **Recent expansion of ARISTADA field and hospital-based sales force**
  - In Q4'18, field and hospital-based sales force for ARISTADA expanded by ~60 sales representatives
  - To maximize impact and efficiency, newly created Field Reimbursement and Key Accounts teams will also support continuity of care for patients and engage with large, multi-site providers for ARISTADA
- ✔ **Topline results expected for phase 3b study evaluating ARISTADA INITIO plus the ARISTADA two-month dose alongside INVEGASUSTENNA® in H1 2019**

\*ARISTADA INITIO regimen consists of ARISTADA INITIO + single 30 mg dose of oral aripiprazole. ARISTADA INITIO regimen plus ARISTADA on day 1 of treatment yields relevant levels of aripiprazole concentration in the body within four days.

1. IMS NPA



**Program**

- Investigational, novel, once-daily, oral atypical antipsychotic drug candidate for the treatment of schizophrenia
- Designed to provide antipsychotic efficacy of olanzapine with a favorable weight profile

**Status**

- Reported positive topline results from ENLIGHTEN-2, a six-month phase 3 study assessing weight gain with olanzapine compared to ALKS 3831, in Q4'18

**Priorities**

- Data presentation of ENLIGHTEN-2 results expected at medical meetings in spring 2019
- Anticipated pre-NDA meeting to discuss key FDA requirements including efficacy, safety, weight and metabolic profile
- NDA submission planned for mid-2019



## Diroximel Fumarate (DRF, formerly BIIB098)

### Program

- Investigational product for the treatment of relapsing forms of multiple sclerosis (MS)
- License and collaboration agreement with Biogen announced in Q4'17

### Status

- Submitted NDA to the FDA in Q4'18
- Biogen intends to commercialize under the brand name VUMERITY™, which has been conditionally accepted by the FDA

### Priorities

- Topline results for EVOLVE-MS-2 head-to-head study of diroximel fumarate compared to TECFIDERA® expected in mid-2019

### Biogen License and Collaboration Agreement

- Granted Biogen exclusive, worldwide license to commercialize DRF
- Mid-teens percentage royalty to Alkermes on worldwide net sales of DRF
- \$150M milestone upon regulatory approval by FDA by 12/31/21
- Biogen responsible for development and commercial expenses (as of 1/1/18)

## Program

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

## Status

- Monotherapy dose-escalation stage of phase 1 study ongoing
- Initiated evaluation of safety and anti-tumor activity of ALKS 4230 in combination with pembrolizumab in Q3'18
- Presented initial clinical data from ongoing monotherapy dose-escalation stage of phase 1 study at Society for Immunotherapy of Cancer Meeting in Q4'18

## Priorities

- Initiate subcutaneous dosing study in Q1'19
- Complete monotherapy dose-escalation stage of phase 1 study to identify optimal dose and advance into monotherapy dose-expansion stage



# Significant News Flow Expected in 2019

## Schizophrenia

### ARISTADA®

- Report topline results for phase 3b ARISTADA-INVEGA SUSTENNA® study (H1)

### ALKS 3831

- Present ENLIGHTEN-2 data at medical meeting (H1)
- Submit NDA for schizophrenia (mid-year)

## Addiction

### VIVITROL®

- Present and publish data on detox and induction strategies

## Multiple Sclerosis

### Diroximel fumarate

- Report topline data for EVOLVE-MS-2 head-to-head vs. TECFIDERA® (mid-year)
- Expected FDA regulatory action

## Immuno-oncology

### ALKS 4230

- Initiate subcutaneous dosing study (Q1)
- Complete monotherapy dose-escalation stage of phase 1 study
- Initiate monotherapy dose-expansion stage of phase 1 study



---

 [www.alkermes.com](http://www.alkermes.com)

