
**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): April 25, 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.

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Ex-99.2 Investor presentation to be displayed by Alkermes plc on April 25, 2019.

[SIGNATURE](#)

Item 2.02 Results of Operations and Financial Condition.

On April 25, 2019, Alkermes plc (the “Company”) announced financial results for the three months ended March 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 April 25, 2019 discussing financial results for the three months ended March 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

Exhibit No.	Description
99.1	Press release issued by Alkermes plc dated April 25, 2019 announcing financial results for the three months ended March 31, 2019.
99.2	Investor presentation to be displayed by Alkermes plc on April 25, 2019.

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: April 25, 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 First Quarter 2019 Financial Results*— First Quarter Revenues of \$223.1 Million, Primarily Driven by ~8% Year-Over-Year Growth of Proprietary Product Net Sales —**— Company Reports GAAP Net Loss per Share of \$0.62 and Non-GAAP Net Loss per Share of \$0.17 —**— Company Reiterating Financial Expectations for 2019 —***DUBLIN, Ireland, Apr. 25, 2019** — Alkermes plc (Nasdaq: ALKS) today reported financial results for the first quarter of 2019.

“Our first quarter results reflect the diversity of our business, as the growth of VIVITROL® net sales and royalty revenues from INVEGA SUSTENNA® offset a decline in AMPYRA® royalties, following generic entry in the market. As is typical, during the first quarter we saw the effect of seasonal inventory fluctuations and deductible resets for commercial payer plans impact net sales of our proprietary commercial products, which decreased sequentially. In particular, ARISTADA® net sales were impacted more than anticipated by inventory fluctuations which masked underlying prescription growth of approximately 5% compared to last quarter,” commented James Frates, Chief Financial Officer of Alkermes. “Today, we are reiterating our financial expectations for 2019, as we continue to position VIVITROL and ARISTADA for long-term growth, invest in our development pipeline and prepare for the potential launch of ALKS 3831.”

“The first few months of 2019 were highlighted by the presentation of important new data from large clinical trials of both ALKS 3831 and ARISTADA at the 2019 Congress of the Schizophrenia International Research Society. These innovative studies demonstrated the clear antipsychotic efficacy of our medicines along with our intended patient-focused attributes relating to safety and tolerability. Our recently announced ALPINE study results also provide information useful to clinicians making treatment decisions for their patients,” commented Richard Pops, Chief Executive Officer of Alkermes. “Looking ahead, we are focused on executing both commercially and across our development pipeline. With the planned submission of the New Drug Application for ALKS 3831 mid-year, expected regulatory action for diroximel fumarate for multiple sclerosis in the fourth quarter, and increasing momentum in the ALKS 4230 immunology program, we have a number of key milestones ahead and look forward to updating you on our progress throughout the year.”

Quarter Ended Mar. 31, 2019 Financial Highlights

- Total revenues for the quarter were \$223.1 million, compared to \$225.2 million for the same period in the prior year, reflecting the growth in our proprietary product net sales and an offsetting decrease in AMPYRAⁱ revenues following generic entry into the market in 2018.
 - Net loss according to generally accepted accounting principles in the U.S. (GAAP) was \$96.4 million for the quarter, or a basic and diluted GAAP net loss per share of \$0.62. This compared to GAAP net loss of \$62.5 million, or a basic and diluted GAAP net loss per share of \$0.40 for the same period in the prior year.
 - Non-GAAP net loss was \$26.0 million for the quarter, or a non-GAAP basic and diluted net loss per share of \$0.17. This compared to non-GAAP net loss of \$14.2 million, or a non-GAAP basic and diluted net loss per share of \$0.09 for the same period in the prior year.
-

Quarter Ended Mar. 31, 2019 Financial Results

Revenues

- Net sales of VIVITROL were \$69.2 million, compared to \$62.7 million for the same period in the prior year, representing an increase of approximately 10%.
- Net sales of ARISTADAⁱⁱ were \$30.3 million, compared to \$29.2 million for the same period in the prior year, representing an increase of approximately 4%.
- Manufacturing and royalty revenues from RISPERDAL CONSTA[®], INVEGA SUSTENNA[®]/XEPLION[®] and INVEGA TRINZA[®]/TREVICTA[®] were \$75.6 million, compared to \$68.8 million for the same period in the prior year.
- Manufacturing and royalty revenues from AMPYRA/FAMPYRA[®] were \$12.2 million, compared to \$28.3 million for the same period in the prior year due to generic competition to AMPYRA entering the market in late 2018.
- Research and development revenues from the collaboration with Biogen for diroximel fumarate (BIIB098) were \$13.9 million, compared to \$17.5 million for the same period in the prior year.

Costs and Expenses

- Operating expenses were \$299.1 million, compared to \$287.0 million for the same period in the prior year, primarily reflecting increased investment in the commercialization of VIVITROL and ARISTADA.
- Other expense during the quarter included a \$22.6 million charge due to a decrease in the fair value of contingent consideration, related to Recro Pharma, Inc.'s receipt of a second complete response letter from the United States (U.S.) Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for IV Meloxicam.

Financial Expectations for 2019

Alkermes reiterates its financial expectations for 2019 set forth in its press release dated Feb. 14, 2019.

Recent Events:

- Leadership
 - Appointed Todd Nichols to the role of Senior Vice President of Sales and Marketing. Mr. Nichols joins Alkermes from Celgene and his responsibilities will include leading global commercial activities, including marketing and sales of VIVITROL and ARISTADA, as well as developing and executing the commercial strategy for ALKS 3831 and other development candidates.
- ARISTADA
 - The U.S. Department of Veterans Affairs recently added ARISTADA and ARISTADA INITIO[®] to its National Formulary at parity with other long-acting injectable atypical antipsychotics.
 - Announced positive topline results from ALPINE (Aripiprazole L^uauroxil and P^alipiperidone palmitate: Iⁿitiation E^ffectiveness), a six-month study evaluating the efficacy, safety and tolerability of ARISTADA and INVEGA SUSTENNA, when used to initiate patients experiencing an acute exacerbation of schizophrenia in the hospital and maintain treatment in an outpatient setting. Results were presented at the 2019 Congress of the Schizophrenia International Research Society (SIRS).
- ALKS 3831
 - Presented new data at SIRS from the phase 3 ALKS 3831 ENLIGHTEN-2 six-month weight study and interim results from the ENLIGHTEN-2 52-week safety extension

study.

- Diroximel fumarate
 - Announced that the FDA accepted for review the NDA for diroximel fumarate. If approved, Biogen intends to market diroximel fumarate under the brand name VUMERITY™, which has been conditionally accepted by the FDA and would be confirmed upon approval.
- ALKS 4230
 - Initiated ARTISTRY-2, a new clinical study of ALKS 4230 administered subcutaneously as monotherapy and in combination with the PD-1 inhibitor KEYTRUDA® (pembrolizumab) in patients with advanced solid tumors.
 - Announced a research collaboration with Clovis to evaluate ALKS 4230 in combination with rucaparib, Clovis' marketed PARP inhibitor, and lucitanib, Clovis' investigational tyrosine kinase inhibitor.

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, Apr. 25, 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. 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, Apr. 25, 2019, through Thursday, May 2, 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 access code is 13690081.

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, multiple sclerosis and oncology. 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.

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 loss and non-GAAP basic and diluted 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 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 loss and non-GAAP basic and diluted 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 loss and non-GAAP basic and diluted 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; expectations concerning the company’s continued investment in its development pipeline and commercial capabilities and the value that can be derived therefrom; the potential therapeutic and commercial value of the company’s marketed and development products; expectations concerning the timing and results of clinical development and regulatory activities, including the planned submission of an NDA for ALKS 3831, the FDA’s anticipated action with respect to the NDA for diroximel fumarate, and increasing momentum in the ALKS 4230 development program; and expectations concerning investment in commercial activities, including the potential launch of ALKS 3831. 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. 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 and VUMERITY™ is a trademark of Alkermes Pharma Ireland Limited; RISPERDAL CONSTA®, INVEGA SUSTENNA®, XEPLION®, INVEGA TRINZA® and TREVICTA® are registered trademarks of Johnson & Johnson; KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp.; and AMPYRA® and FAMPYRA® are registered trademarks of Acorda Therapeutics, Inc.

(tables follow)

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

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

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Statements of Operations - GAAP (In thousands, except per share data)	Three Months Ended March 31, 2019	Three Months Ended March 31, 2018
Revenues:		
Manufacturing and royalty revenues	\$ 108,915	\$ 114,601
Product sales, net	99,481	91,842
Research and development revenue	14,706	18,707
Total Revenues	<u>223,102</u>	<u>225,150</u>
Expenses:		
Cost of goods manufactured and sold	45,361	44,476
Research and development	102,570	108,346
Selling, general and administrative	141,220	118,147
Amortization of acquired intangible assets	9,952	16,069
Total Expenses	<u>299,103</u>	<u>287,038</u>
Operating Loss	<u>(76,001)</u>	<u>(61,888)</u>
Other Expense, net:		
Interest income	3,570	1,485
Interest expense	(3,500)	(5,487)
Change in the fair value of contingent consideration	(22,600)	(1,900)
Other expense, net	(1,721)	792
Total Other Expense, net	<u>(24,251)</u>	<u>(5,110)</u>
Loss Before Income Taxes	<u>(100,252)</u>	<u>(66,998)</u>
Income Tax Benefit	(3,854)	(4,493)
Net Loss — GAAP	<u>\$ (96,398)</u>	<u>\$ (62,505)</u>
Net Loss Per Share:		
GAAP net loss per share — basic and diluted	<u>\$ (0.62)</u>	<u>\$ (0.40)</u>
Non-GAAP net loss per share — basic and diluted	<u>\$ (0.17)</u>	<u>\$ (0.09)</u>
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and diluted — GAAP and Non-GAAP	<u>156,336</u>	<u>154,424</u>
An itemized reconciliation between net loss on a GAAP basis and non-GAAP net loss is as follows:		
Net Loss — GAAP	\$ (96,398)	\$ (62,505)
Adjustments:		
Share-based compensation expense	24,616	20,042
Amortization expense	9,952	16,069
Depreciation expense	9,690	9,653
Change in the fair value of contingent consideration	22,600	1,900
Income tax effect related to reconciling items	2,972	(5,178)
Non-cash net interest expense	169	191
Change in the fair value of warrants and equity method investments	433	(302)
Restructuring expense	—	3,598
Debt refinancing charge	—	2,298
Non-GAAP Net Loss	<u>\$ (25,966)</u>	<u>\$ (14,234)</u>

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Balance Sheets (In thousands)	March 31, 2019	December 31, 2018
Cash, cash equivalents and total investments	\$ 625,133	\$ 620,039
Receivables	222,811	292,223
Contract assets	8,447	8,230
Inventory	92,861	90,196
Prepaid expenses and other current assets	56,492	53,308
Property, plant and equipment, net	320,004	309,987
Intangible assets, net and goodwill	273,922	283,874
Other assets	156,866	167,150
Total Assets	\$ 1,756,536	\$ 1,825,007
Long-term debt — current portion	\$ 2,843	\$ 2,843
Other current liabilities	324,842	336,931
Long-term debt	275,923	276,465
Contract liabilities — long-term	11,342	9,525
Other long-term liabilities	39,445	27,958
Total shareholders' equity	1,102,141	1,171,285
Total Liabilities and Shareholders' Equity	\$ 1,756,536	\$ 1,825,007
Ordinary shares outstanding (in thousands)	156,885	155,757

This selected financial information should be read in conjunction with the consolidated financial statements and notes thereto included in Alkermes plc's Quarterly Report on Form 10-Q for the three months ended March 31, 2019, which the company intends to file in April 2019.



First Quarter 2019 Financial Results & Business Update

April 25, 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 potential VIVITROL[®] growth driven by state policy initiatives and federal funding and potential ARISTADA[®] and ARISTADA INITIO[®] growth driven by expansion of the company's commercial organization, addition of such products to a key formulary and results from the ALPINE study; 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, the presentation of data relating to diroxime fumarate ("DRF") and topline data from the phase 3 elective study for DRF, 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. 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, and on the company's website at 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 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[®], ARISTADA INITIO[®], VIVITROL[®] and VUMERITY[™]. 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.



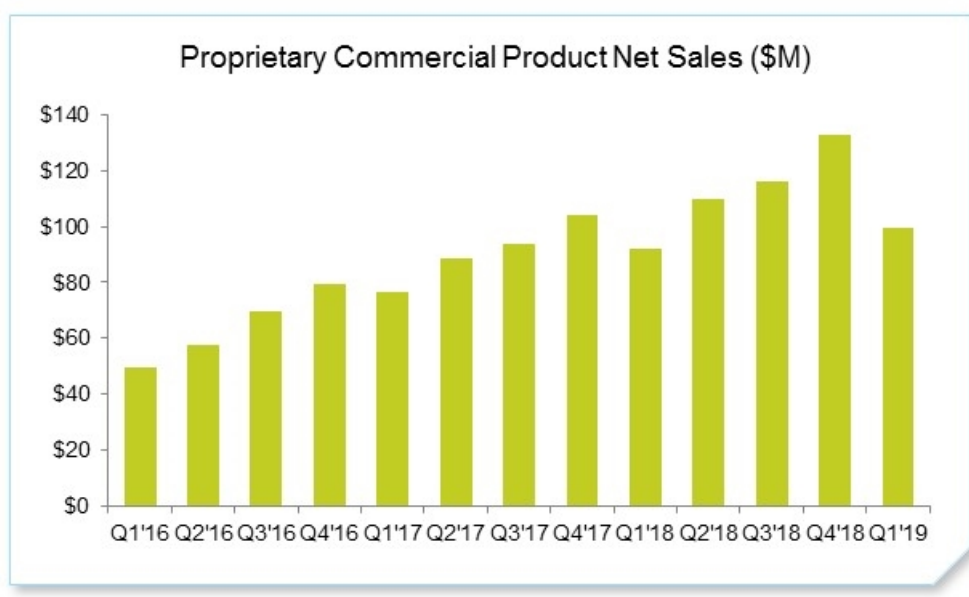
Q1 2019 Financial Results	Jim Frates Chief Financial Officer
Pipeline and R&D Update	Craig Hopkinson Chief Medical Officer
Business Update	Richard Pops Chief Executive Officer

In millions, except %	Q1'19	Q1'18	Δ Q1'19 vs. Q1'18
VIVITROL®	\$69.2	\$62.7	10%
ARISTADA®	\$30.3	\$29.2	4%
Manufacturing & Royalty Revenues	\$108.9*	\$114.6	(5%)
R&D Revenues	\$14.7	\$18.7	(21%)
Total Revenues	\$223.1	\$225.2	(1%)

*These results reflect a \$17.9 million decline in revenues from AMPYRA® following generic market entry near the end of 2018.



Revenues From Proprietary Commercial Medicines



ARISTADA INITIO[®]
aripiprazole lauroxil
extended-release injectable suspension

675 mg

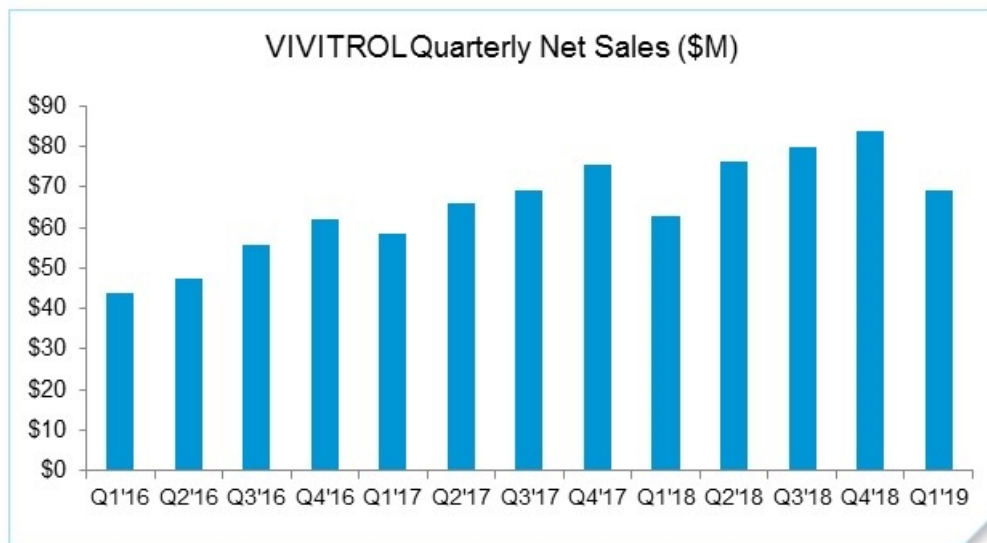
ARISTADA[®]
aripiprazole lauroxil
extended-release injectable suspension

441 mg 662 mg 882 mg 1064 mg

Vivitrol[®]
(naltrexone for extended-release
injectable suspension)



VIVITROL® Performance



- ▶ Q1 year-over-year net sales growth of **10%**, driven by underlying unit growth of **8%**
 - Gross-to-net deductions of 49% in Q1'19, compared to 46% in Q4'18 and 50% in Q1'18
- ▶ Sequential decrease in net sales driven by seasonal inventory fluctuations
 - Inventory drawdown of ~\$5M in quarter
- ▶ 2019 full year net sales expectations of **\$330M - \$350M**

ARISTADA® Performance



- ▶ Q1 year-over-year net sales growth of **4%**
 - Gross-to-net deductions of 49%, compared to 44% in Q4'18 and 43% in Q1'18
- ▶ Sequential decrease in net sales driven by seasonal inventory fluctuations
 - Inventory drawdown of ~\$10M in quarter
 - Total prescriptions increased by 5% sequentially during the quarter¹
- ▶ 2019 full year net sales expectations of **\$210M - \$230M**

1. IMS NPA



Alkermes: 2019 Financial Expectations†

<i>(in millions, except per share amounts)</i>	Financial Expectations for Year Ending Dec. 31, 2019†
Revenues	\$1,140 – 1,190
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

Revenues:

- VIVITROL® net sales of \$330M - \$350M
- ARISTADA® net sales of \$210M - \$230M
- License revenues: \$150M milestone anticipated upon FDA approval of diroximel fumarate (expected Q4'19)

† This financial guidance was initially provided by Alkermes plc (the "Company") in its Current Report on Form 8-K filed with the SEC on Feb. 14, 2019. This financial guidance was reiterated by the Company in its Current Report on Form 8-K filed with the SEC on Apr. 25, 2019 and is effective only as of such date. The Company expressly disclaims any obligation to update or reaffirm this guidance. The Company only provides 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.



VIVITROL®: Opportunities to Increase Utilization and Drive Growth

- ▶ Federal grant dollars related to 21st Century Cures and SUPPORT for Patients and Communities Acts continue to be allocated
 - Funding slowly flowing into fragmented treatment system
- ▶ States have adopted more targeted policies in criminal justice and community settings, and have passed legislation to remove certain barriers that limit access to medications
 - California, Texas, Pennsylvania, New Jersey and Kentucky
- ▶ VIVITROL net sales continue to be concentrated geographically
 - Top five states represented 44% of volume during Q1'19
 - Pennsylvania, Ohio, Massachusetts, New York, California



ARISTADA®: Potential New Growth Drivers

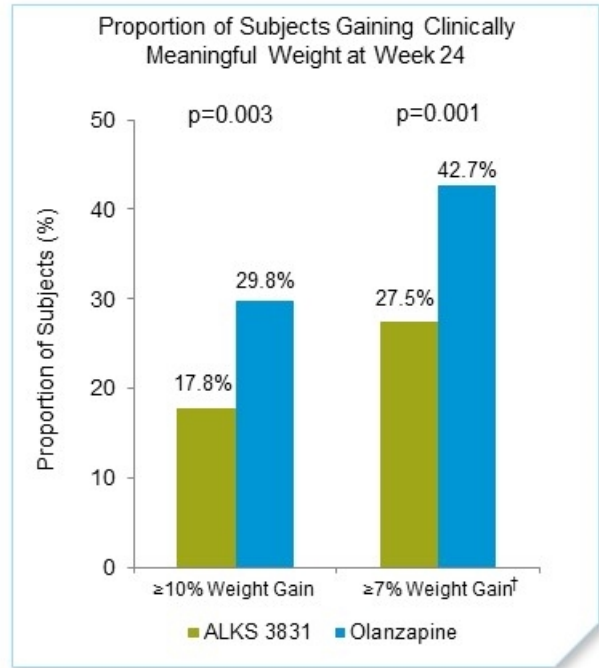
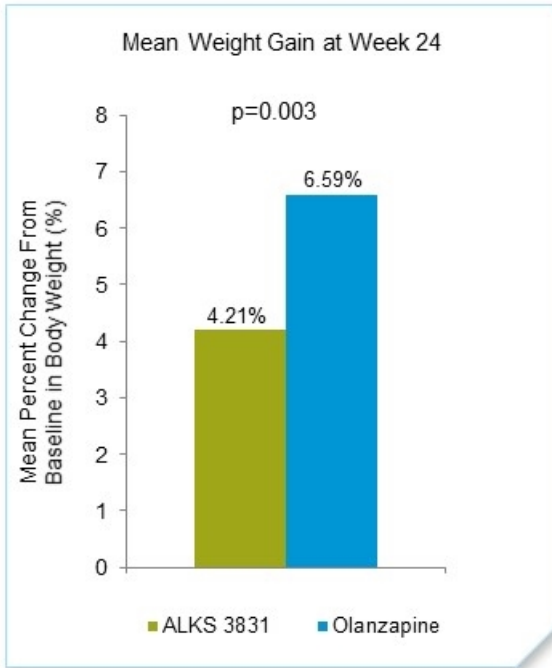
- ✔ Commercial organization expansion completed in Q1'19
 - 60 new community and hospital-based sales representatives recently onboarded
- ✔ Positive topline results from ALPINE study demonstrated efficacy, safety and tolerability of both ARISTADA and the current market-leader, INVEGA SUSTENNA®
 - Plan to publish data in peer-reviewed journal and present at upcoming medical meetings
- ✔ ARISTADA product family, including ARISTADA INITIO®* recently added to the U.S. Department of Veterans Affairs' National Formulary at parity with other atypical LAIs
- ✔ ARISTADA market share was 29% of new aripiprazole long-acting atypical prescriptions (months of therapy) in March 2019¹

*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

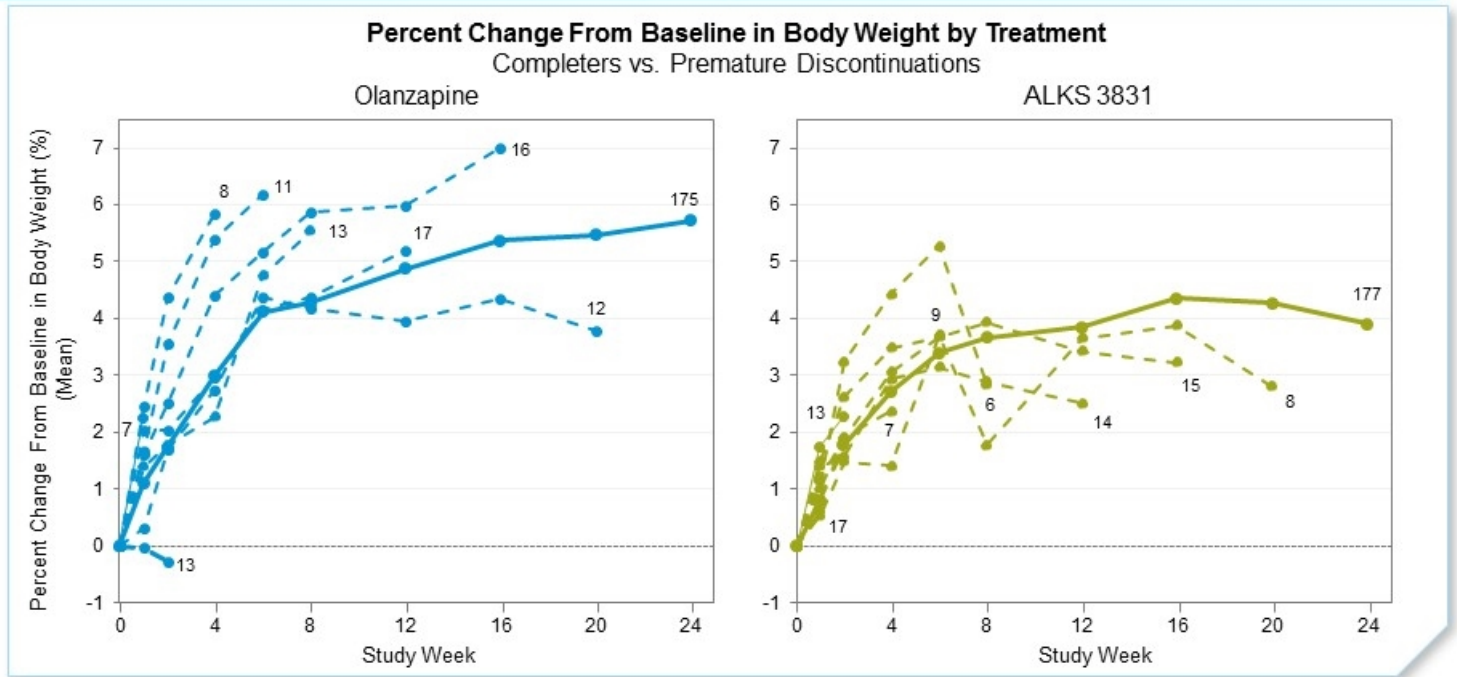


▶ ALKS 3831: ENLIGHTEN-2 and Interim Results From
Ongoing ENLIGHTEN-2-EXT Open-Label Safety Study



†Prespecified key secondary endpoint

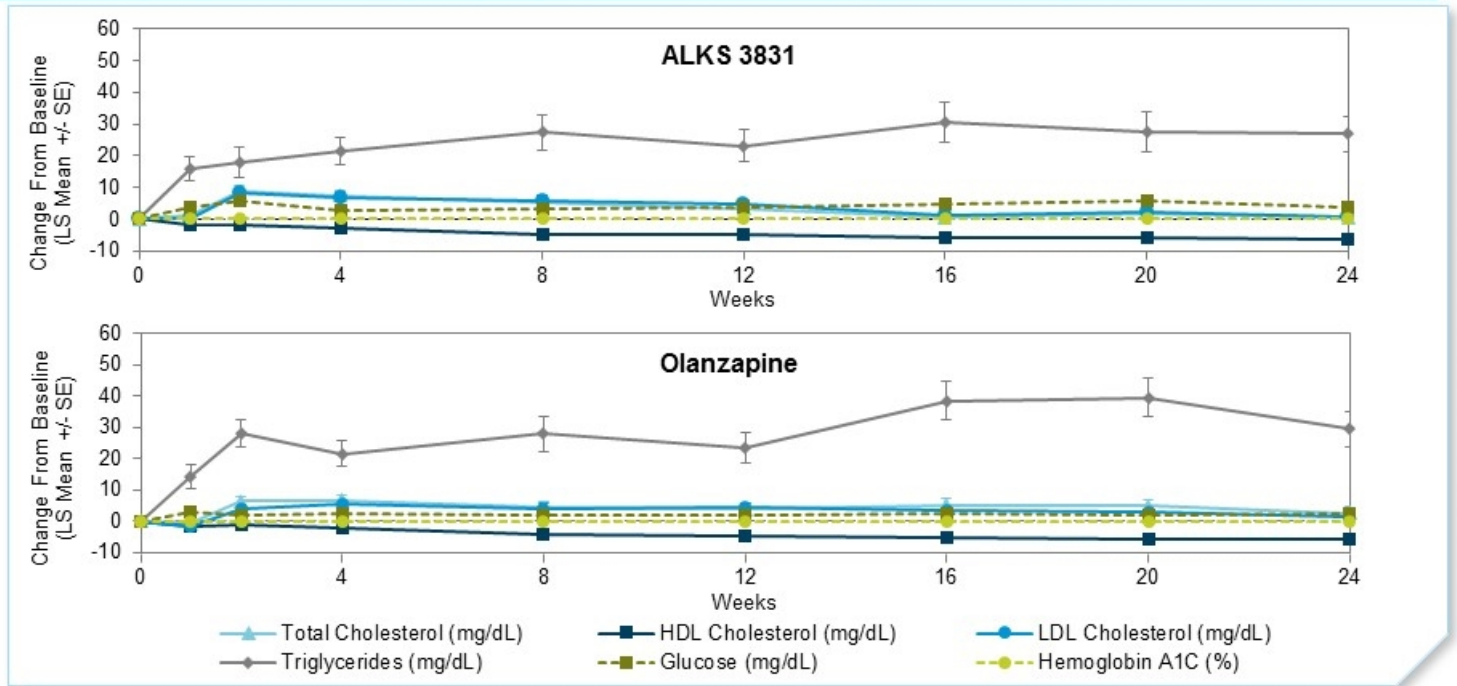
ENLIGHTEN-2: Weight Gain Trajectory of Early Discontinuations



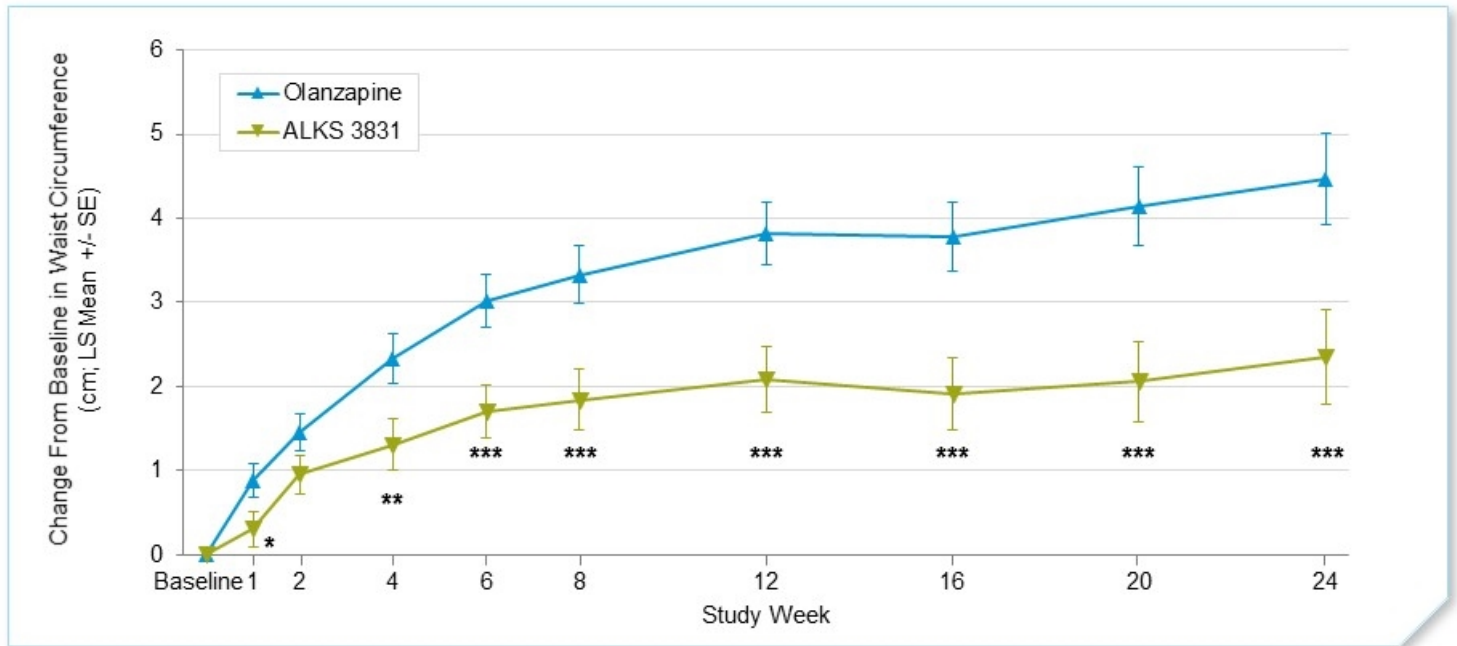
Solid lines denote the weight gain curve of patients who completed the study. Dashed lines denote weight gain curves of subjects who prematurely discontinued at given visits. Numbers of patients summarized in each curve are noted.

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ENLIGHTEN-2 Metabolic Parameters: Changes Were Generally Small for Both ALKS 3831 and Olanzapine



ENLIGHTEN-2: Early and Significant Impact on Waist Circumference



Note: Waist circumference curve based on ANCOVA approach using MI for missing data

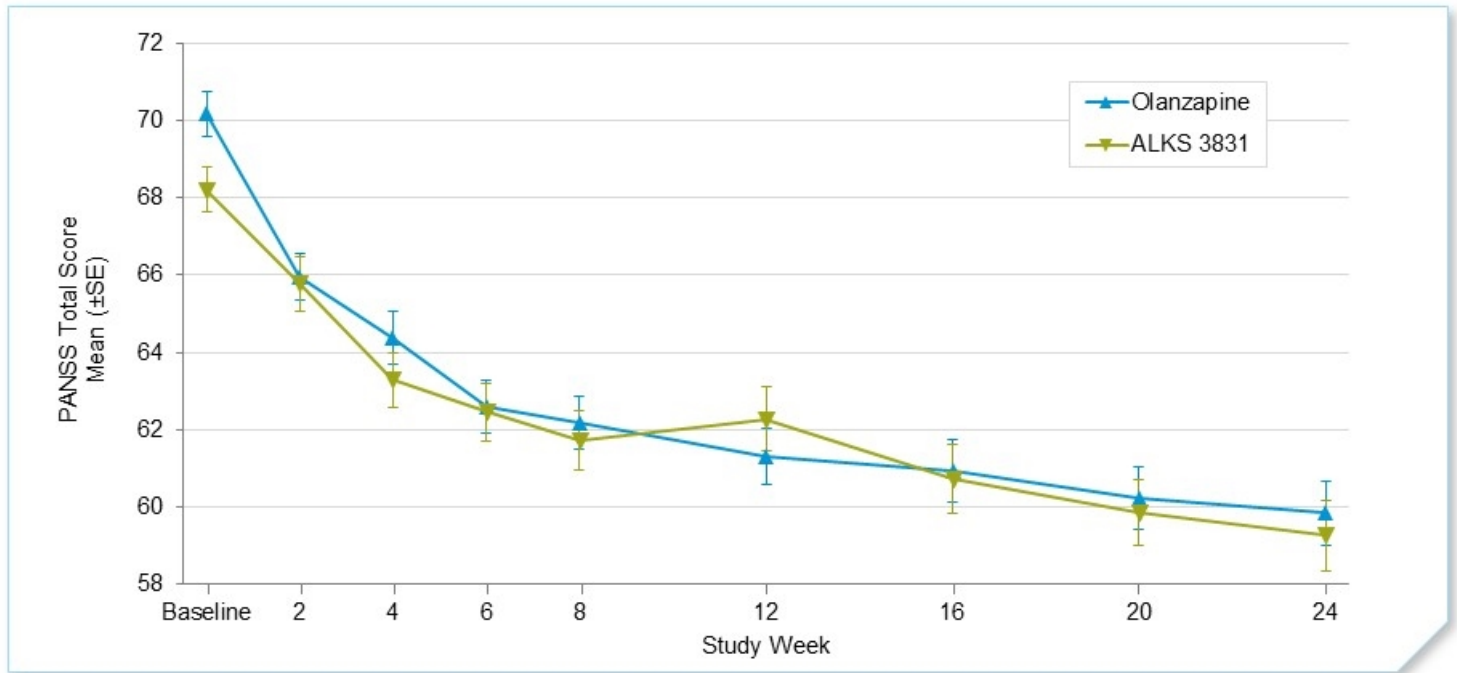
*p<0.05 vs. olanzapine; **p<0.01 vs. olanzapine; ***p<0.001 vs. olanzapine



ENLIGHTEN-2-EXT Open-Label, Safety Extension Study Interim Results: 16 Weight Remains Stable Over 52 Weeks



PANSS Scores Show Continuous Improvement in Stable Patients



ENLIGHTEN-2: Most Common Adverse Events

	ALKS 3831 (N=274) n (%)	Olanzapine (N=276) n (%)
Serious Adverse Events†	10 (3.6)	7 (2.5)
Any Adverse Event (≥5%)	203 (74.1)	227 (82.2)
Weight increased	68 (24.8)	100 (36.2)
Somnolence	58 (21.2)	50 (18.1)
Dry mouth	35 (12.8)	22 (8.0)
Increased appetite	30 (10.9)	34 (12.3)
Waist circumference increased	17 (6.2)	22 (8.0)
Blood creatine phosphokinase increased	14 (5.1)	12 (4.3)
Extra dose administered	14 (5.1)	17 (6.2)

- Similar safety profile observed to date in ongoing extension safety study (ENLIGHTEN-2-EXT)

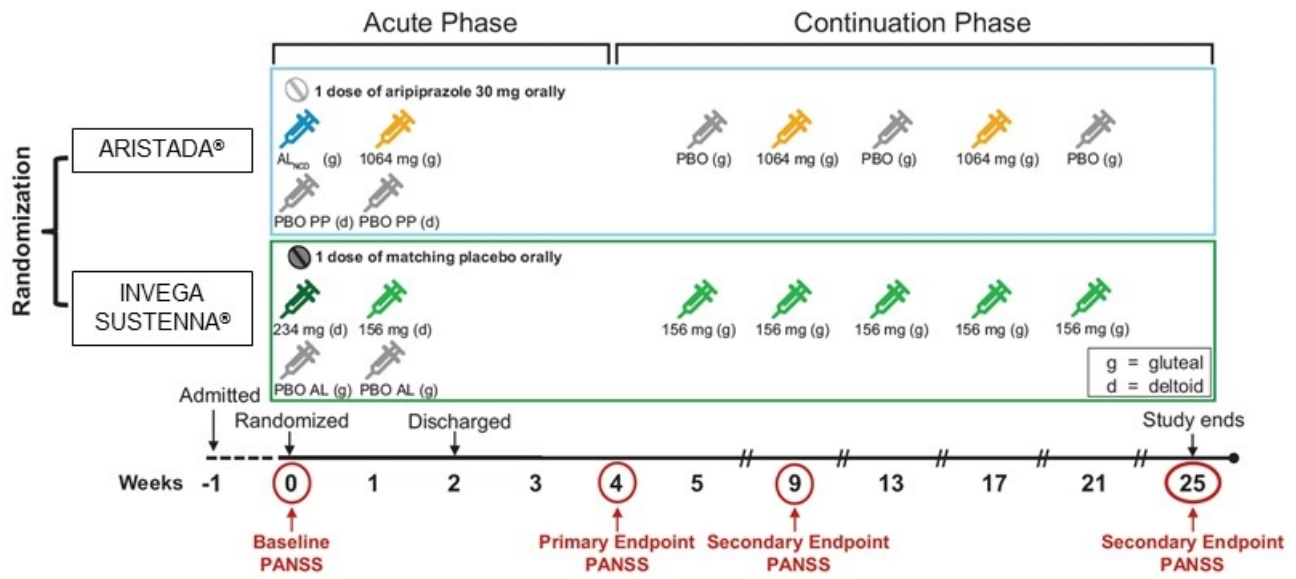
†Only 1 serious adverse event in each group deemed to be study-drug related



 ALPINE Study

Aripiprazole Lauroxil and Paliperidone Palmitate:
Initiation Effectiveness

ALPINE: Study Design



AL=aripiprazole lauroxil; NCD=NanoCrystal® Dispersion; PBO=placebo; PP=paliperidone palmitate.

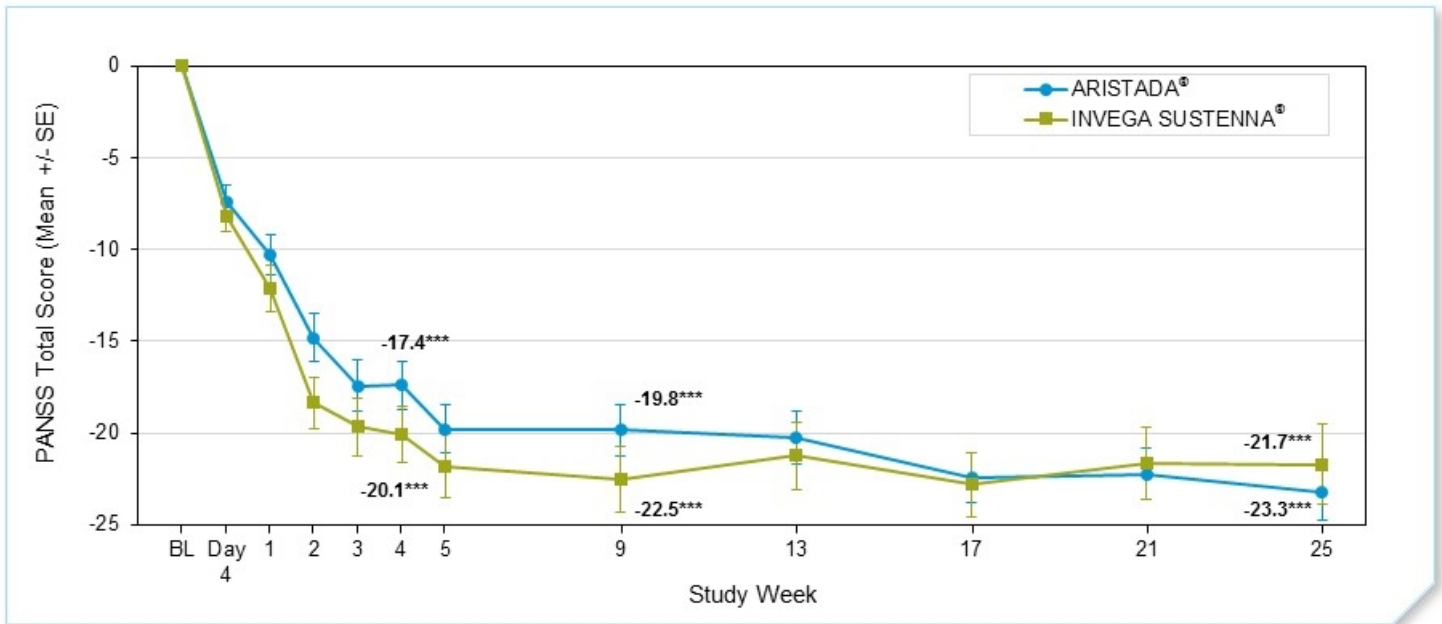
ALPINE: Demographics and Baseline Characteristics

	ARISTADA® (n=99)	INVEGA SUSTENNA® (n=101)
Age, mean (SD), y	43.5 (9.7)	43.4 (10.8)
Male, n (%)	73.0 (73.7)	76.0 (75.2)
Weight, mean (SD), kg	84.8 (19.8)	85.0 (18.8)
BMI, mean (SD), kg/m ²	28.2 (5.5)	27.9 (5.1)
PANSS total score, mean (SD) [†]	94.1 (9.0)	94.6 (8.4)
CGI-S score, mean (SD) [†]	4.8 (0.7)	4.9 (0.7)

BMI=body mass index; CGI-S=Clinical Global Impression-Severity; PANSS=Positive and Negative Syndrome Scale

[†]Based on patients who received ≥1 post-baseline PANSS assessment (ARISTADA, n=96; INVEGA SUSTENNA n=99)

ALPINE: Change From Baseline in PANSS Total Score



***p<0.001 (change from baseline within group)
Primary endpoint was the change from baseline in PANSS total scores at Week 4 within each treatment group

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ALPINE: Study Retention

	ARISTADA® (n=99)	INVEGA SUSTENNA® (n=101)
Subjects Who Completed the Treatment Period, n (%)	56 (56.6)	43 (42.6)
Subjects Who Discontinued Study, n (%)	43 (43.4)	58 (57.4)
Most Common Reasons for Discontinuation, n (%)		
Withdrawal by Subject	20 (20.2)	31 (30.7)
Adverse Event	10 (10.1)	11 (10.9)
Lost to Follow-up	8 (8.1)	9 (8.9)

ALPINE: Most Common Adverse Events

Most Common Adverse Events, n (%)	ARISTADA® (n=99)	INVEGA SUSTENNA® (n=101)
AEs ≥ 5%		
Injection site pain	17 (17.2)	25 (24.8)
Weight increased	9 (9.1)	17 (16.8)
Akathisia	9 (9.1)	11 (10.9)
Headache	8 (8.1)	8 (7.9)
Somnolence	4 (4.0)	7 (6.9)
Dystonia	3 (3.0)	6 (5.9)
Schizophrenia	5 (5.1)	2 (2.0)

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
- Presented data from ENLIGHTEN-2 and ENLIGHTEN-2-EXT at SIRS* in April 2019

Priorities

- Anticipated pre-NDA meeting to discuss key FDA requirements including efficacy, safety, weight and metabolic profile
- NDA submission planned for mid-2019



*Congress of the Schizophrenia International Research Society

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Diroximel Fumarate (DRF, formerly BIIB098)

<p>Program</p>	<ul style="list-style-type: none"> ➤ Investigational product for the treatment of relapsing forms of multiple sclerosis (MS) ➤ License and collaboration agreement with Biogen announced in Q4'17 	<p>Biogen License and Collaboration Agreement</p>
<p>Status</p>	<ul style="list-style-type: none"> ➤ NDA filed; PDUFA date in Q4'19 ➤ Biogen intends to commercialize under the brand name VUMERITY™, which has been conditionally accepted by the FDA 	<ul style="list-style-type: none"> ➤ 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)
<p>Priorities</p>	<ul style="list-style-type: none"> ➤ Additional data on DRF to be presented at spring medical meetings ➤ Topline results for EVOLVE-MS-2 head-to-head study of diroximel fumarate compared to TECFIDERA® expected in mid-2019 	

Program	<ul style="list-style-type: none">✔ Novel immuno-oncology candidate✔ Designed to selectively activate intermediate-affinity IL-2 receptors to enhance tumor-killing immune cells
Status	<ul style="list-style-type: none">✔ 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✔ Initiated subcutaneous dosing study in Q1'19✔ Announced preclinical research collaboration with Clovis to evaluate ALKS 4230 in combination with rucaparib, Clovis' marketed PARP inhibitor, and lucitanib, Clovis' investigational tyrosine kinase inhibitor, in Q1'19
Priorities	<ul style="list-style-type: none">✔ 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 ALPINE phase 3b study (Q2)

ALKS 3831

- ✓ Present ENLIGHTEN-2 data at medical meeting (Q2)
- ☐ 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 (Q4)

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



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