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**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): October 23, 2018**

**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 October 23, 2018.

[SIGNATURE](#)

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

On October 23, 2018, Alkermes plc (the “Company”) announced financial results for the three and nine months ended September 30, 2018 and updated financial expectations for the year ending December 31, 2018. 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 October 23, 2018 discussing financial results for the three and nine months ended September 30, 2018 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 October 23, 2018 announcing financial results for the three and nine months ended September 30, 2018 and updated financial expectations for the year ending December 31, 2018.</a>
99.2	<a href="#">Investor presentation to be displayed by Alkermes plc on October 23, 2018.</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: October 23, 2018

**ALKERMES PLC**

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

Alkermes Contacts:

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**Alkermes Plc Reports Third Quarter 2018 Financial Results**

— *Third Quarter Revenues Increased to \$248.7 Million, Driven by 24% Year-Over-Year Growth of Proprietary Product Net Sales* —

— *Company Reports GAAP Net Loss per Share of \$0.22 and Diluted Non-GAAP Earnings per Share of \$0.07* —

— *Company Increases Financial Expectations for 2018* —

**DUBLIN, Ireland, Oct. 23, 2018** — Alkermes plc (Nasdaq: ALKS) today reported financial results for the third quarter of 2018.

“Our solid results in the quarter were in-line with expectations, driven by the growth of our proprietary commercial products, the continued strength of our royalty and manufacturing business, and the important investments we are making in our late-stage pipeline and commercial organization,” commented James Frates, Chief Financial Officer of Alkermes. “Our diverse business is financially strong and we are well positioned to execute on our strategy to drive value and long-term growth. Based on our outlook for the remainder of the year, today we are raising our financial expectations for 2018, primarily driven by upside from AMPYRA® revenues.”

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

- Total revenues for the quarter were \$248.7 million. This compared to \$217.4 million for the same period in the prior year, representing an increase of 14%. Proprietary product net sales for VIVITROL® and ARISTADA® were \$116.0 million for the quarter, reflecting a 24% increase compared to the same period in the prior year.
- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was \$34.4 million for the quarter, or a basic and diluted GAAP net loss per share of \$0.22. This compared to GAAP net loss of \$36.3 million, or a basic and diluted GAAP net loss per share of \$0.24, for the same period in the prior year
- Non-GAAP net income was \$11.6 million for the quarter, or a non-GAAP basic and diluted earnings per share of \$0.07. This compared to non-GAAP net income of \$4.2 million, or a non-GAAP basic and diluted earnings per share of \$0.03, for the same period in the prior year.

“The third quarter was highlighted by the launch of ARISTADA INITIO®<sup>1</sup>, the newest addition to the ARISTADA product family. This new offering is resonating with healthcare providers and the early trends are encouraging. ARISTADA INITIO further differentiates ARISTADA in the market and provides an opportunity to address unmet patient need,” stated Jim Robinson, President and Chief Operating Officer of Alkermes. “We are also making important strides with VIVITROL as the product continues to grow and as policymakers continue to activate in their response to the opioid crisis. We look forward to providing updates on our progress.”

**Quarter Ended Sept. 30, 2018 Financial Results****Revenues**

- Net sales of VIVITROL were \$79.9 million, compared to \$69.2 million for the same period in the prior year, representing an increase of approximately 15%.
  - Net sales of ARISTADA were \$36.1 million, compared to \$24.5 million for the same period in the prior year, representing an increase of approximately 48%.
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- Manufacturing and royalty revenues from RISPERDAL CONSTA®, INVEGA SUSTENNA®/XEPLION® and INVEGA TRINZA®/TREVICTA® were \$77.2 million, compared to \$79.4 million for the same period in the prior year, reflecting the timing of RISPERDAL CONSTA manufacturing shipments.
- Manufacturing and royalty revenues from AMPYRA/FAMPYRA®<sup>2</sup> were \$20.3 million, compared to \$24.5 million for the same period in the prior year.
- Research and development revenues were \$16.3 million, of which \$15.7 million related to the collaboration with Biogen for BIIB098, or diroximel fumarate.

#### Costs and Expenses

- Operating expenses were \$285.9 million, compared to \$255.7 million for the same period in the prior year, primarily reflecting increased investment in the commercialization of VIVITROL and ARISTADA.

“Against the backdrop of the highly-anticipated upcoming regulatory interactions for ALKS 5461 for the adjunctive treatment of major depressive disorder and the ALKS 3831 ENLIGHTEN-2 pivotal study data in schizophrenia, we continue to make important progress across our other pipeline assets. BIIB098 for multiple sclerosis is on track for NDA submission by year-end and ALKS 4230, our immuno-oncology program, is gaining momentum, highlighted by the recent initiation of combination therapy evaluation,” said Richard Pops, Chief Executive Officer of Alkermes. “Our results this quarter demonstrate the strong and resilient company we have carefully built over the years, with important medicines driving an expected topline in excess of \$1 billion and a diverse development portfolio of late-stage product candidates, each with the potential to impact the practice of medicine and change the growth trajectory of the company. As we head into the fourth quarter, the business is well positioned for growth and the opportunities ahead.”

#### Recent Events:

- ARISTADA
  - Completed enrollment of six-month phase 3b study evaluating ARISTADA INITIO plus the ARISTADA two-month dose and INVEGA SUSTENNA in patients experiencing an acute exacerbation of schizophrenia
- ALKS 4230
  - Initiated clinical evaluation of ALKS 4230 in combination with PD-1 inhibitor pembrolizumab
  - Submitted new clinical protocol for subcutaneous dosing phase 1 study to the ALKS 4230 Investigational New Drug (IND) application

#### Upcoming Milestones:

The following outlines the company’s expected upcoming milestones.

- ALKS 5461
  - Joint meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee to review the ALKS 5461 New Drug Application (NDA) on Nov. 1, 2018
  - Prescription Drug User Fee Act (PDUFA) target action date on Jan. 31, 2019

- ALKS 3831
  - Topline results for ENLIGHTEN-2, a six-month weight study of ALKS 3831 compared to olanzapine in patients with stable schizophrenia in Q4 2018
- BIIB098 (diroximel fumarate)
  - Planned submission of the NDA for diroximel fumarate for the treatment of multiple sclerosis in Q4 2018
- ALKS 4230
  - Presentation of initial clinical data from ongoing dose-escalation stage of the phase 1 study at the 2018 Society for Immunotherapy of Cancer (SITC) Annual Meeting in November 2018
  - Initiation of subcutaneous dosing phase 1 study in early 2019

### **Financial Expectations for 2018**

Alkermes is updating its financial expectations for 2018 to reflect greater than expected revenues from AMPYRA. The following outlines Alkermes' updated financial expectations for 2018.

- **Revenues:** The company now expects total revenues to range from \$1.015 billion to \$1.045 billion, increased from its previous expectation of \$975 million to \$1.025 billion. This increase was driven by upside from AMPYRA following delayed generic competition in 2018. Included in this total revenue expectation, Alkermes continues to expect VIVITROL net sales to range from \$300 million to \$330 million, although closer to the lower end of this range, and ARISTADA net sales to range from \$140 million to \$160 million.
- **Cost of Goods Manufactured and Sold:** The company continues to expect cost of goods manufactured and sold to range from \$180 million to \$190 million.
- **Research and Development (R&D) Expenses:** The company continues to expect R&D expenses to range from \$415 million to \$445 million.
- **Selling, General and Administrative (SG&A) Expenses:** The company continues to expect SG&A expenses to range from \$515 million to \$545 million.
- **Amortization of Intangible Assets:** The company continues to expect amortization of intangibles to be approximately \$65 million.
- **Net Interest Expense:** The company continues to expect net interest expense to be approximately \$10 million.
- **Income Tax Expense:** The company continues to expect income tax expense of up to \$10 million.
- **GAAP Net Loss:** The company now expects GAAP net loss to range from \$180 million to \$210 million, or a basic and diluted loss per share of \$1.16 to \$1.35, based on a weighted average basic and diluted share count of approximately 155 million shares outstanding. This compares to previous expectations of GAAP net loss in the range of \$210 million to \$240 million, or a basic and diluted loss per share of \$1.35 to \$1.55, based on a weighted average basic and diluted share count of approximately 155 million shares outstanding.
- **Non-GAAP Net Income:** The company now expects non-GAAP results to range from non-GAAP net income of \$20 million to \$50 million, or a non-GAAP basic earnings per share of \$0.13 to \$0.32 and a non-GAAP diluted earnings per share of \$0.12 to \$0.31, based on a weighted average basic share count of approximately 155 million shares outstanding and a weighted average diluted share count of approximately 161 million shares outstanding. This compares to previous expectations of non-GAAP net results in the range of non-GAAP net loss of \$10 million to non-GAAP net income of \$20 million, or a basic and diluted non-

GAAP net loss per share of \$0.06 to a non-GAAP basic earnings per share of \$0.13 and a non-GAAP diluted earnings per share of \$0.12, based on a weighted average basic share count of approximately 155 million shares outstanding and a weighted average diluted share count of approximately 161 million shares outstanding .

- **Share-Based Compensation:** The company continues to expect share-based compensation of approximately \$120 million.
- **Capital Expenditures:** The company now expects capital expenditures to range from \$65 million to \$75 million, compared to a previous expectation in the range of \$80 million to \$90 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 Tuesday, Oct. 23, 2018, 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 +1 888 424 8151 for U.S. callers and +1 847 585 4422 for international callers. The conference call ID number is 6037988. In addition, a replay of the conference call will be available from 11:00 a.m. ET (4:00 p.m. BST) on Tuesday, Oct. 23, 2018, through 5:00 p.m. ET (9:00 p.m. GMT) on Tuesday, Oct. 30, 2018, and may be accessed by visiting Alkermes' website or by dialing +1 888 843 7419 for U.S. callers and +1 630 652 3042 for international callers. The replay access code is 6037988.

### **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.



### **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: future financial and operating performance, business plans or prospects; the likelihood of continued revenue growth from the company’s commercial products, including the growth of VIVITROL and ARISTADA; the potential therapeutic and commercial value of the company’s marketed and development products, and patient access to, and policy related to, such products; expectations concerning the timing and results of clinical development and regulatory activities, including the timing of the phase 3 clinical trial (ENLIGHTEN-2) data readout for ALKS 3831, the timing of the submission of the NDA for BIIB098, the timing of presentation of initial data from the ALKS 4230 phase 1 study and initiation of a subcutaneous dosing phase 1 study for ALKS 4230, and the outcome and timing of the FDA’s review of the NDA for ALKS 5461. 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 and, for ALKS 5461, evidence of efficacy and adequacy of bridging to buprenorphine; 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; AMPYRA® and FAMPYRA® are registered trademarks of Acorda Therapeutics, Inc.

<sup>1</sup> 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. The ARISTADA INITIO regimen consists of ARISTADA INITIO plus a single 30 mg dose of oral aripiprazole.

<sup>2</sup> AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg is developed and marketed in the U.S. by Acorda Therapeutics, Inc. and outside the U.S. by Biogen Idec, under a licensing agreement with Acorda Therapeutics, as FAMPYRA® (prolonged-release fampridine tablets).

(tables follow)

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

Condensed Consolidated Statements of Operations - GAAP  
(In thousands, except per share data)

	Three Months Ended	
	September 30, 2018	September 30, 2017
<b>Revenues:</b>		
Manufacturing and royalty revenues	\$ 116,411	\$ 122,677
Product sales, net	116,035	93,681
Research and development revenue	16,274	1,027
<b>Total Revenues</b>	<b>248,720</b>	<b>217,385</b>
<b>Expenses:</b>		
Cost of goods manufactured and sold	39,410	36,054
Research and development	101,265	104,411
Selling, general and administrative	128,777	99,633
Amortization of acquired intangible assets	16,426	15,643
<b>Total Expenses</b>	<b>285,878</b>	<b>255,741</b>
Operating Loss	(37,158)	(38,356)
<b>Other Income, net:</b>		
Interest income	2,561	1,173
Interest expense	(3,346)	(3,129)
Change in the fair value of contingent consideration	4,200	13,600
Other expense, net	(90)	(9,078)
<b>Total Other Income, net</b>	<b>3,325</b>	<b>2,566</b>
Loss Before Income Taxes	(33,833)	(35,790)
Income Tax Provision	611	486
<b>Net Loss — GAAP</b>	<b>\$ (34,444)</b>	<b>\$ (36,276)</b>
<b>Net (Loss) Earnings Per Share:</b>		
GAAP net loss per share — basic and diluted	\$ (0.22)	\$ (0.24)
Non-GAAP earnings per share — basic and diluted	\$ 0.07	\$ 0.03
<b>Weighted Average Number of Ordinary Shares Outstanding:</b>		
Basic and diluted — GAAP	155,328	153,684
Basic — Non-GAAP	155,328	153,684
Diluted — Non-GAAP	159,763	159,989
An itemized reconciliation between net loss on a GAAP basis and non-GAAP net income is as follows:		
<b>Net Loss — GAAP</b>	<b>\$ (34,444)</b>	<b>\$ (36,276)</b>
<b>Adjustments:</b>		
Share-based compensation expense	25,068	19,487
Amortization expense	16,426	15,643
Depreciation expense	9,842	9,394
Non-cash net interest expense	170	192
Change in the fair value of warrants and equity method investments	(367)	(303)
Change in the fair value of contingent consideration	(4,200)	(13,600)
Income tax effect related to reconciling items	(869)	(844)
Other-than-temporary impairment of equity method investment	—	10,471
<b>Non-GAAP Net Income</b>	<b>\$ 11,626</b>	<b>\$ 4,164</b>

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

Condensed Consolidated Statements of Operations - GAAP  
(In thousands, except per share data)

	Nine Months Ended	
	September 30, 2018	September 30, 2017
<b>Revenues:</b>		
Manufacturing and royalty revenues	\$ 359,253	\$ 366,608
Product sales, net	317,684	258,893
Research and development revenues	53,325	2,503
License revenues	48,250	—
<b>Total Revenues</b>	<b>778,512</b>	<b>628,004</b>
<b>Expenses:</b>		
Cost of goods manufactured and sold	127,303	116,241
Research and development	316,434	308,399
Selling, general and administrative	385,181	310,682
Amortization of acquired intangible assets	48,742	46,417
<b>Total Expenses</b>	<b>877,660</b>	<b>781,739</b>
<b>Operating Loss</b>	<b>(99,148)</b>	<b>(153,735)</b>
<b>Other Expense, net:</b>		
Interest income	5,946	3,287
Interest expense	(11,959)	(8,816)
Change in the fair value of contingent consideration	(17,300)	15,900
Other expense, net	(2,815)	(10,696)
<b>Total Other Expense, net</b>	<b>(26,128)</b>	<b>(325)</b>
<b>Loss Before Income Taxes</b>	<b>(125,276)</b>	<b>(154,060)</b>
<b>Income Tax Provision (Benefit)</b>	<b>4,322</b>	<b>(5,904)</b>
<b>Net Loss — GAAP</b>	<b>\$ (129,598)</b>	<b>\$ (148,156)</b>
<b>Net (Loss) Earnings Per Share:</b>		
GAAP net loss per share — basic and diluted	\$ (0.84)	\$ (0.97)
Non-GAAP earnings (loss) per share — basic	\$ 0.28	\$ (0.15)
Non-GAAP earnings (loss) per share — diluted	\$ 0.27	\$ (0.15)
<b>Weighted Average Number of Ordinary Shares Outstanding:</b>		
Basic and diluted — GAAP	154,979	153,263
Basic — Non-GAAP	154,979	153,263
Diluted — Non-GAAP	160,224	153,263
An itemized reconciliation between net loss on a GAAP basis and non-GAAP net income (loss) is as follows:		
<b>Net Loss — GAAP</b>	<b>\$ (129,598)</b>	<b>\$ (148,156)</b>
<b>Adjustments:</b>		
Share-based compensation expense	76,043	63,336
Amortization expense	48,742	46,417
Depreciation expense	29,016	26,889
Change in the fair value of warrants and equity method investments	600	2,760
Non-cash net interest expense	531	578
Change in the fair value of contingent consideration	17,300	(15,900)
Income tax effect related to reconciling items	(5,535)	(8,896)
Other-than-temporary impairment of equity method investment	—	10,471
Restructuring expense	3,598	—
Debt refinancing charge	2,298	—
<b>Non-GAAP Net Income (Loss)</b>	<b>\$ 42,995</b>	<b>\$ (22,501)</b>

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

Condensed Consolidated Balance Sheets (In thousands)	September 30, 2018	December 31, 2017
Cash, cash equivalents and total investments	\$ 578,543	\$ 590,716
Receivables	250,913	233,590
Contract assets	13,476	—
Inventory	88,018	93,275
Prepaid expenses and other current assets	50,265	48,475
Property, plant and equipment, net	303,087	284,736
Intangible assets, net and goodwill	300,299	349,041
Other assets	176,109	197,394
<b>Total Assets</b>	<b>\$ 1,760,710</b>	<b>\$ 1,797,227</b>
Long-term debt — current portion	\$ 2,843	\$ 3,000
Other current liabilities	301,945	288,122
Long-term debt	277,007	278,436
Contract liabilities — long-term	5,010	5,657
Other long-term liabilities	23,190	19,204
Total shareholders' equity	1,150,715	1,202,808
<b>Total Liabilities and Shareholders' Equity</b>	<b>\$ 1,760,710</b>	<b>\$ 1,797,227</b>
Ordinary shares outstanding (in thousands)	155,364	154,009

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 September 30, 2018, which the company intends to file in October 2018.

**Alkermes plc and Subsidiaries**  
**2018 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:

<b>(In millions, except per share data)</b>	Amount	Shares	(Loss) Earnings Per Share
Projected Net Loss — GAAP	\$ (195.0)	155	\$ (1.26)
Adjustments:			
Share-based compensation expense	120.0		
Amortization expense	65.0		
Depreciation expense	42.5		
Non-cash net interest expense	1.0		
Income tax effect related to reconciling items	(3.5)		
Other (including debt refinancing & restructuring charges)	5.0		
Projected Net Income — Non-GAAP	\$ 35.0	161	\$ 0.22

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



# Third Quarter 2018 Financial Results & Update

October 23, 2018

# 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 future financial and operating performance, business plans or prospects of the company; the continued growth of the long-acting injectable antipsychotic market and revenue from the company's commercial products, including VIVITROL<sup>®</sup>, ARISTADA<sup>®</sup> and ARISTADA INITIO<sup>®</sup>; improvements to and modernization of the treatment ecosystem for opioid dependence, including related policy initiatives and the company's engagement with policymakers; the timing, funding, results and feasibility of clinical development activities, including the timing of the phase 3 data readout for ALKS 3831, the timing of the presentation of initial phase 1 data for ALKS 4230, expansion of the phase 1 study for ALKS 4230, and initiation of a phase 1 subcutaneous dosing study for ALKS 4230, the timing of topline data from the phase 3 elective study for BILBO98, the timing of topline data from the phase 3b study evaluating ARISTADA<sup>®</sup> and INVEGA SUSTENNA<sup>®</sup>, the timing of completion of the registration packages and submission of the new drug applications ("NDAs") for each of BILBO98 and ALKS 3831, and the timing of the company's potential nomination of new development candidates; whether the studies conducted for ALKS 5461, ALKS 3831 and BILBO98 will meet the U.S. Food and Drug Administration's ("FDA") requirements for approval; the company's expectations and timelines for regulatory interactions with the FDA, and actions by the FDA, relating to its review of the NDA submission for ALKS 5461; expectations concerning the timing, results and nature of commercial activities, including preparations for the anticipated launch of ALKS 5461, activities related to the launch of ARISTADA INITIO<sup>®</sup> and timing of the potential launch by Biogen of BILBO98, the potential financial benefits that may be achieved under the license and collaboration agreement between the company and Biogen for BILBO98; the therapeutic value and commercial potential of the company's commercial products and development candidates; and funding for, payer coverage of, and patient access to and awareness of, the company's commercial products and development candidates. Although the company believes that such forward-looking 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, assumptions 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 our products or partnered products, 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 and, for ALKS 5461, evidence of efficacy and adequacy of bridging to buprenorphine; 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, 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 Oct. 23, 2018.

**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.



Q3 Financial Results & 2018 Guidance

**Jim Frates**  
Chief Financial Officer

Commercial Update

**Jim Robinson**  
President & Chief Operating Officer

Business Update

**Richard Pops**  
Chief Executive Officer





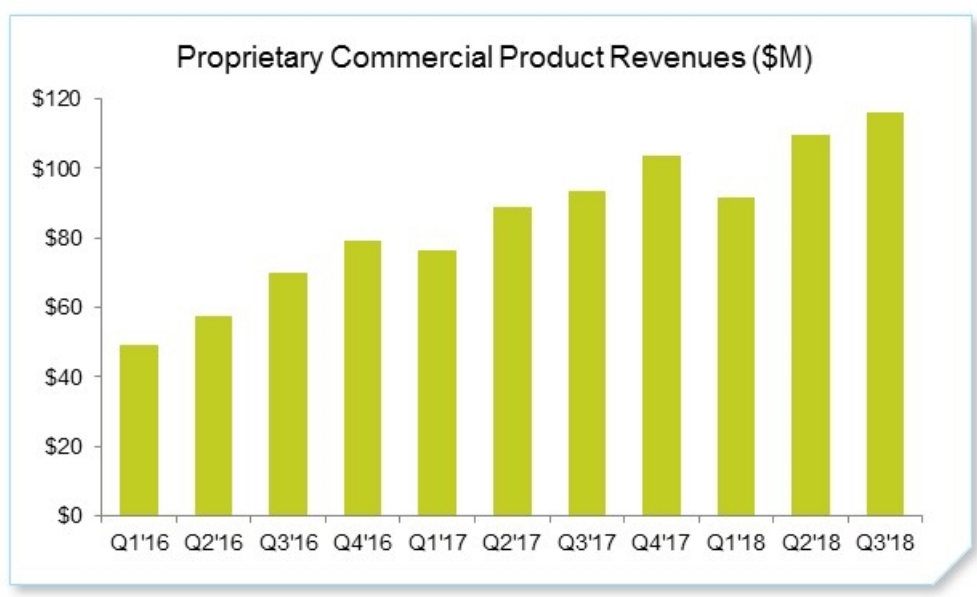
# Third Quarter 2018 Revenue Summary



In millions, except %	Q3'18	Q3'17	Δ Q3'18 VS. Q3'17
VIVITROL®	\$79.9	\$69.2	15%
ARISTADA®	\$36.1	\$24.5	48%
Manufacturing & Royalty Revenues	\$116.4	\$122.7	-5%
R&D Revenues	\$16.3	\$1.0	
<b>Total Revenues</b>	<b>\$248.7</b>	<b>\$217.4</b>	<b>14%</b>



# Revenues From Proprietary Commercial Medicines



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

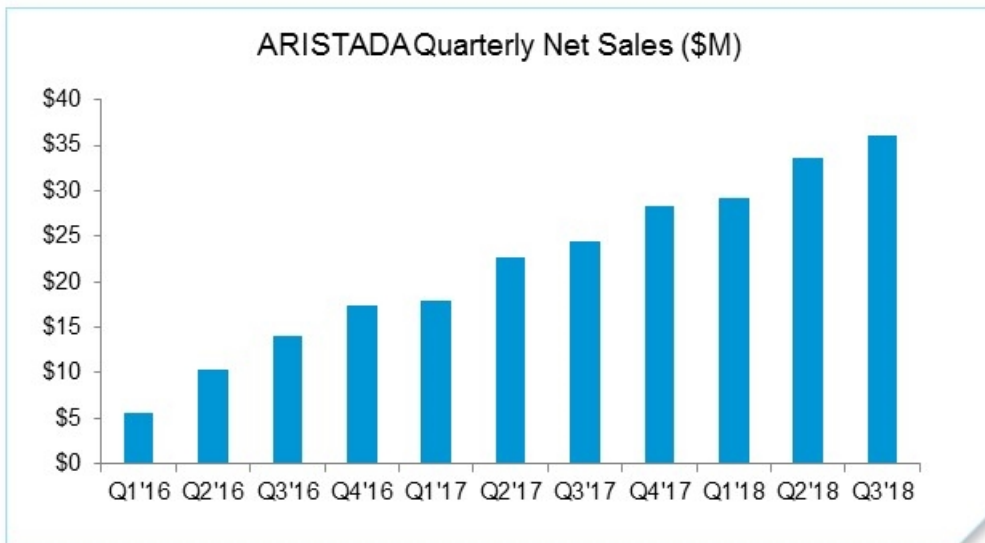
**Vivitrol**<sup>®</sup>  
(naltrexone for extended-release  
injectable suspension)



## VIVITROL® Performance



- ▶ Q3 year-over-year net sales growth of 15%, driven by underlying unit growth of 18%
  - Q3'18 results reflect estimated 48% Medicaid units
  - Net sales increased 5% sequentially, driven by favorable gross-to-net variability
  - Gross-to-net deductions of 47% in Q3'18, compared to 49% in Q2'18 and 45% in Q3'17
- ▶ 2018 net sales expected toward lower end of \$300M - \$330M guidance range



- ▶ Q3 year-over-year net sales growth of 48%
- ▶ Sequential growth of 8% compared to Q2'18
  - Approximately 47% gross-to-net deductions, compared to 43% in Q2'18 and 41% in Q3'17
- ▶ 2018 net sales expectations of \$140M - \$160M

# Alkermes: Updated 2018 Financial Expectations†

(in millions, except per share amounts)	Financial Expectations for Year Ending Dec. 31, 2018†
Revenues	\$1,015 – 1,045
COGS	\$180 – 190
R&D Expense	\$415 – 445
SG&A Expense	\$515 – 545
Amortization of Intangible Assets	~\$65
Net Interest Expense	~\$10
Income Tax Expense	\$0 – 10
GAAP Net Loss	\$(180) – (210)
GAAP Net Loss Per Share	\$(1.16) – (1.35)
Non-GAAP Net Income‡	\$20 – 50
Non-GAAP Earnings Per Share (Basic)	\$0.13 – 0.32
Non-GAAP Earnings Per Share (Diluted)	\$0.12 – 0.31

## Revenues:

- VIVITROL® net sales of \$300M - \$330M
- ARISTADA® net sales of \$140M - \$160M
- AMPYRA®/FAMPYRA® manufacturing & royalty revenue of ~\$80 million due to delayed generic competition in 2018

## Operating Expenses:

- Investments in advancing the development pipeline, the ARISTADA INITIO® launch and preparations for potential launch of ALKS 5461 in 2019

†This financial guidance, provided by Alkermes plc (the "Company") in its Current Report on Form 8-K filed with the SEC on Oct. 23, 2018, 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 October 23, 2018.



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

- ▶ **State and federal dollars are being allocated; Funding slowly flowing into fragmented treatment system**
  - ~\$2B of federal funding has been distributed to states via block grants
    - Small percentage has flowed from the states into changing the treatment system
  - New opioid legislation, SUPPORT for Patients and Communities Act, expected to be signed into law imminently
    - Extends State Targeted Response Grant program for another three years: \$500M per year 2019-2021
    - Includes provision for Comprehensive Opioid Recovery Centers, which provides funding to develop federally qualified treatment centers that utilize the full range of FDA-approved medications: \$50M over five years to provide comprehensive, patient-centered treatment including detoxification and wrap-around services
- ▶ **Improvements in accessibility of VIVITROL and implementation of public policy initiatives driving strong growth in certain states**
  - Pennsylvania, California, Florida, Michigan, Kentucky
- ▶ **State programs expanded to ~730 at the end of Q3'18, primarily driven by criminal justice re-entry and drug court programs**



## ARISTADA®: Gaining Traction With Launch of ARISTADA INITIO®

- ARISTADA INITIO now available
  - ARISTADA INITIO regimen\* provides an opportunity to initiate patients onto any dose of ARISTADA on day 1
  - ARISTADA INITIO in conjunction with two-month ARISTADA resonating with treatment providers and patients
    - Early coverage additions to key hospital and Medicare Part D formularies
    - Two-month ARISTADA unit growth accelerating with 26% sequential growth in Q3'18, up from 17% sequential growth in Q2'18
      - Two-month dose represented 15% of total ARISTADA units in Q3'18
- ARISTADA market share increased to 28% among new aripiprazole long-acting atypical prescriptions (months of therapy) in Q3'18<sup>1</sup>

\*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 product for adjunctive treatment of major depressive disorder (MDD)
- Opioid system modulator represents a new mechanism of action for the treatment of MDD

**Status**

- Regulatory review underway, PDUFA target action date Jan. 31, 2019
- FDA Advisory Committee meeting scheduled for Nov. 1, 2018

**Priorities**

- Continued scientific exchange with medical community; Presentations at Psych Congress, Neuroscience Education Institute Congress
- Preparations for potential launch
  - Investment in manufacturing, senior leadership and necessary commercial infrastructure



## Program

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

## Status

- Positive results from ENLIGHTEN-1 pivotal antipsychotic efficacy study announced June 2017
- Presented data from phase 1 translational medicine study evaluating metabolic profile of ALKS 3831 compared to olanzapine in May 2018

## Priorities

- Complete ENLIGHTEN-2, a six-month phase 3 study assessing weight gain with olanzapine compared to ALKS 3831; Topline data expected Q4'18
  - Enrollment of ENLIGHTEN-2 completed April 2018

## BIIB098 (Diroximel Fumarate)

### Program

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

### Status

- Received \$50M payment from Biogen following its preliminary review of GI tolerability data from ongoing clinical program in Q2'18
- Enrollment ongoing in elective EVOLVE-MS-2 head-to-head study versus TECFIDERA; Data expected mid-2019

### Priorities

- On track for planned NDA submission by year-end 2018

### Biogen License and Collaboration Agreement

- Granted Biogen exclusive, worldwide license to commercialize BIIB098
- Mid-teens percentage royalty to Alkermes on worldwide net sales of BIIB098
- \$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

**Priorities**

- ✔ Presentation of initial clinical data from ongoing dose-escalation stage of the phase 1 study at upcoming Society for Immunotherapy of Cancer Meeting
- ✔ Initiate subcutaneous dosing phase 1 study in early 2019
- ✔ 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 2018

### **ARISTADA®: New initiation product approved**

- ✓ ARISTADAINITIO® approved June 29

### **ALKS 5461: Regulatory review underway**

- ✓ NDA accepted for filing
- ☐ Advisory Committee meeting scheduled for Nov. 1

### **ALKS 3831: Data from second pivotal study**

- ✓ ENLIGHTEN-2 weight study enrollment completion
- ✓ Metabolic study data presentation
- ☐ ENLIGHTEN-2 topline results (Q4)

### **BIIB098 (diroximel fumarate): NDA submission**

- ✓ Receipt of \$50M payment following preliminary review of GI tolerability data from ongoing clinical program
- ☐ Planned NDA submission for treatment of MS (Q4)

### **ALKS 4230: Clinical proof-of-concept**

- ☐ Present initial dose-escalation data at medical meeting (Q4)
- ✓ Initiate evaluation in combination with pembrolizumab



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

