



Alkermes Plc Reports First Quarter 2018 Financial Results

April 26, 2018

- First Quarter Revenues Increase to \$225.2 Million, Primarily Driven by 20% Year-Over-Year Growth of Proprietary Product Net Sales --
- Company Reports GAAP Net Loss per Share of \$0.40 and Non-GAAP Net Loss per Share of \$0.09 --
- ALKS 5461 NDA Accepted for Regulatory Review; Assigned Jan. 31, 2019 PDUFA Date --
- Company Updating Financial Expectations for 2018 --

DUBLIN, April 26, 2018 /PRNewswire/ -- [Alkermes plc](#) (Nasdaq: ALKS) today reported financial results for the first quarter of 2018.

"Our first quarter results were in line with our expectations and reflect the solid growth of our proprietary commercial products and the continued strength of our royalty and manufacturing business," commented James Frates, Chief Financial Officer of Alkermes. "Today, we are updating our financial expectations for 2018, driven primarily by the timing of investments we will make in our commercial organization in preparation for the potential launch of ALKS 5461 in 2019. We remain well positioned to execute on our strategy to drive long-term value through important investments in our development pipeline and the growth of VIVITROL® and ARISTADA®."

Quarter Ended Mar. 31, 2018 Financial Highlights

- Total revenues for the quarter were \$225.2 million. This compared to \$191.8 million for the same period in the prior year, representing an increase of 17%.
- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was \$62.5 million for the quarter, or a basic and diluted GAAP net loss per share of \$0.40. This compared to GAAP net loss of \$68.9 million, or a basic and diluted GAAP net loss per share of \$0.45 for the same period in the prior year.
- Non-GAAP net loss was \$14.2 million for the quarter, or a non-GAAP basic and diluted net loss per share of \$0.09. This compared to non-GAAP net loss of \$27.9 million, or a non-GAAP basic and diluted net loss per share of \$0.18 for the same period in the prior year.

"VIVITROL® and ARISTADA® continue to demonstrate solid growth year-over-year and we have made significant progress in making these important medicines available to patients. We continue to focus on initiatives to promote broad and seamless access for patients," stated Jim Robinson, President and Chief Operating Officer of Alkermes. "The upcoming potential approval and launch of Aripiprazole Lauroxil NanoCrystal® Dispersion (ALNCD), a novel, investigational product designed for initiation onto ARISTADA, is an opportunity to address unmet patient need and expand the ARISTADA product family. Similarly, against the backdrop of new data, funding and policy being implemented to address the opioid epidemic, we have an opportunity to further expand patient access to VIVITROL, increase utilization and drive growth."

Quarter Ended Mar. 31, 2018 Financial Results

Revenues

- Net sales of VIVITROL were \$62.7 million, compared to \$58.5 million for the same period in the prior year, representing an increase of approximately 7%.
- Net sales of ARISTADA were \$29.2 million, compared to \$18.0 million for the same period in the prior year, representing an increase of approximately 62%.
- Manufacturing and royalty revenues from RISPERDAL CONSTA®, INVEGA SUSTENNA®/XEPLION® and INVEGA TRINZA®/TREVICTA® were \$68.8 million, compared to \$60.0 million for the same period in the prior year.
- Manufacturing and royalty revenues from AMPYRA®/FAMPYRA®¹ were \$28.3 million, compared to \$29.2 million for the same period in the prior year.
- Research and development revenues from the collaboration with Biogen for BII098 (formerly ALKS 8700) were \$17.5 million.

Costs and Expenses

- Operating expenses were \$287.0 million, compared to \$262.6 million for the same period in the prior year, primarily reflecting increased investment in the commercialization of VIVITROL and ARISTADA.
- Net interest expense during the quarter was \$4.0 million and included a \$2.3 million charge related to the refinancing of the company's term loan. The company refinanced its term loan to extend the maturity to 2023 and reduce the interest rate by 0.5%.

"Alkermes is entering the final stages of development for three of our pipeline candidates. The regulatory review of ALKS 5461 is back on track and we continue to prepare for potential approval and launch in 2019. For ALKS 3831, we recently completed enrollment of the ENLIGHTEN-2 pivotal study, with topline data expected in the fourth quarter of 2018. For BII098, preparation of the regulatory submission has begun and we are on track to

submit the NDA toward year-end," said Richard Pops, Chief Executive Officer of Alkermes. "We are on the threshold of our next phase of growth. Our dedication and determination to bring these important new medicines to patients are steadfast and we look forward to sharing our progress throughout the year."

Recent Events:

- **ALKS 5461:** New Drug Application (NDA) accepted for filing by U.S. Food and Drug Administration (FDA) for the adjunctive treatment of major depressive disorder (MDD) in patients with inadequate response to standard antidepressant therapy. A target action date of Jan. 31, 2019 was assigned under the Prescription Drug User Fee Act (PDUFA).
- **ALKS 3831:** Enrollment completed for ENLIGHTEN-2, a six-month weight study compared to olanzapine in patients with stable schizophrenia. Topline results are expected in the fourth quarter of 2018.
- **BIIB098:** MRI and relapse results from the phase 3 EVOLVE-MS-1 study in patients with relapsing and remitting multiple sclerosis were presented at the 70th annual meeting of the American Academy of Neurology (AAN).
- **James (Jim) Robinson** appointed to the role of President and Chief Operating Officer of Alkermes. Mr. Robinson's responsibilities include leading Alkermes' global Commercial, Operations, Business Development and Human Resources functions.

Financial Expectations for 2018

Alkermes is updating its financial expectations for 2018 to reflect the expected timing of potential approval and launch of ALKS 5461 in 2019. The following outlines Alkermes' updated financial expectations for 2018.

- **Revenues:** The company continues to expect total revenues to range from \$975 million to \$1.025 billion, driven by continuing growth of VIVITROL and ARISTADA. Included in this total revenue expectation, Alkermes continues to expect VIVITROL net sales to range from \$300 million to \$330 million, 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 now expects SG&A expenses to range from \$515 million to \$545 million, reduced from a previous expectation of \$555 million to \$585 million. This reduction is driven by the shift into 2019 of certain launch-related expenditures including the hiring of the ALKS 5461 sales force, and share-based compensation expense related to certain company-wide performance-based restricted stock unit awards, which vest upon FDA approval of ALKS 5461.
- **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 \$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. This compares to previous expectations of GAAP net loss in the range of \$250 million to \$280 million, or a basic and diluted loss per share of \$1.61 to \$1.81, based on a weighted average basic and diluted share count of approximately 155 million shares outstanding.
- **Non-GAAP Net Income (Loss):** The company now expects non-GAAP results to range from a non-GAAP net loss of \$10 million to a non-GAAP net income of \$20 million, or a non-GAAP basic and diluted loss per share of \$0.06 to 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. This compares to previous expectations of non-GAAP net loss in the range of \$5 million to \$35 million, or a basic and diluted non-GAAP net loss per share of \$0.03 to \$0.23, based on a weighted average basic and diluted share count of approximately 155 million shares outstanding.
- **Share-Based Compensation:** The company now expects share-based compensation of approximately \$120 million, reduced from approximately \$140 million. This reflects the anticipated timing of vesting of certain company-wide performance-based restricted stock unit awards, which vest upon FDA approval of ALKS 5461.
- **Capital Expenditures:** The company continues to expect capital expenditures to range from \$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 Thursday, Apr. 26, 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. 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 Thursday, Apr. 26, 2018, through 5:00 p.m. ET (10:00 p.m. BST) on Thursday, May 3, 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.

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: 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 such products; expectations concerning the timing and results of clinical development 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 BII098, and the outcome and timing of the FDA's review of the NDAs for AL_{NCD} and ALKS 5461; and expectations concerning the timing and results of commercial activities, including the expected launches of AL_{NCD} and 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. 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 NanoCrystal® 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.

¹AMPYRA® (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)

Three Months Ended March 31,	Three Months Ended March 31,
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Condensed Consolidated Statements of Operations - GAAP

(In thousands, except per share data)	2018	2017
Revenues:		
Manufacturing and royalty revenues	\$ 114,601	\$ 114,679
Product sales, net	91,842	76,456
Research and development revenues	18,707	643
Total Revenues	225,150	191,778
Expenses:		
Cost of goods manufactured and sold	44,476	40,412
Research and development	108,346	104,835
Selling, general and administrative	118,147	102,099
Amortization of acquired intangible assets	16,069	15,302
Total Expenses	287,038	262,648
Operating Loss	(61,888)	(70,870)
Other Expense, net:		
Interest income	1,485	943
Interest expense	(5,487)	(2,764)
Change in the fair value of contingent consideration	(1,900)	1,600
Other income (expense), net	792	(1,499)
Total Other Expense, net	(5,110)	(1,720)
Loss Before Income Taxes	(66,998)	(72,590)
Income Tax Benefit	(4,493)	(3,709)
Net Loss — GAAP	\$ (62,505)	\$ (68,881)

Net Loss Per Share:

GAAP net loss per share — basic and diluted	\$ (0.40)	\$ (0.45)
Non-GAAP net loss per share — basic and diluted	\$ (0.09)	\$ (0.18)

Weighted Average Number of Ordinary Shares Outstanding:

Basic and diluted — GAAP and Non-GAAP	154,424	152,704
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An itemized reconciliation between net loss on a GAAP basis and non-GAAP net loss is as follows:

Net Loss — GAAP	\$ (62,505)	\$ (68,881)
Adjustments:		
Share-based compensation expense	20,042	21,169
Amortization expense	16,069	15,302
Depreciation expense	9,653	8,461
Change in the fair value of contingent consideration	1,900	(1,600)
Non-cash net interest expense	191	193
Change in the fair value of warrants and equity method investments	(302)	1,452
Income tax effect related to reconciling items	(5,178)	(3,950)
Restructuring expense	3,598	—
Debt refinancing charge	2,298	—
Non-GAAP Net Loss	\$ (14,234)	\$ (27,854)

**Condensed Consolidated Balance Sheets
(In thousands)**

	March 31, 2018	December 31, 2017
Cash, cash equivalents and total investments	\$ 542,035	\$ 590,716
Receivables and contract assets	240,229	233,590
Inventory	84,884	93,275
Prepaid expenses and other current assets	46,463	48,475
Property, plant and equipment, net	289,621	284,736
Intangible assets, net and goodwill	332,972	349,041
Other assets	200,354	197,394
Total Assets	\$ 1,736,558	\$ 1,797,227
Long-term debt — current portion	\$ 2,843	\$ 3,000
Other current liabilities	271,687	288,122
Long-term debt	278,088	278,436
Contract liabilities — long-term	6,166	5,657
Other long-term liabilities	21,883	19,204
Total shareholders' equity	1,155,891	1,202,808
Total Liabilities and Shareholders' Equity	\$ 1,736,558	\$ 1,797,227

Ordinary shares outstanding (in thousands)	155,004	154,009
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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-Q for the three months ended March 31, 2018, which the company intends to file in April 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:

<u>(In millions, except per share data)</u>	<u>Amount</u>	<u>Shares</u>	<u>(Loss) Income Per Share</u>
Projected Net Loss — GAAP	\$ (225.0)	155	\$ (1.45)
Adjustments:			
Non-cash net interest expense	1.0		
Income tax effect related to reconciling items	(3.5)		
Depreciation expense	42.5		
Amortization expense	65.0		
Share-based compensation expense	120.0		
Other (including debt refinancing & restructuring charges)	5.0		
Projected Net Income — Non-GAAP	<u>\$ 5.0</u>	161	<u>\$ 0.03</u>

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

Alkermes Contacts:

For Investors: Sandy Coombs +1 781 609 6377
Eva Stroynowski +1 781 609 6823
For Media: Jennifer Snyder +1 781 609 6166



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