



Alkermes plc Reports Second Quarter 2016 Financial Results

July 28, 2016

—Second Quarter Revenues Increase 29% Year-Over-Year to \$195.2 Million; GAAP Loss per Share of \$0.31 and Non-GAAP Loss per Share of \$0.01 —

—Company Improves Financial Expectations for 2016 Driven by Strong VIVITROL® Performance —

—ARISTADA® Revenues Grow as Launch Progresses —

DUBLIN--(BUSINESS WIRE)--Jul. 28, 2016-- [Alkermes plc](#) (NASDAQ: ALKS) today reported financial results for the second quarter of 2016.

“Our second quarter results demonstrate the power of our business model to efficiently capture operating leverage as our topline grows. These results reflect the growth of VIVITROL® and launch of ARISTADA® as well as the continued strength of our royalty and manufacturing business. VIVITROL’s robust growth continued as we expand access and utilization in the large Medicaid patient population. We are also encouraged by our progress with the launch of ARISTADA, for which our second quarter results were slightly ahead of expectations,” commented James Frates, Chief Financial Officer of Alkermes. “Today we are improving our financial expectations for 2016 to reflect the accelerating growth in VIVITROL net sales. With our highly diversified portfolio and strong financial position, we have the resources to advance our innovative pipeline and invest in the ongoing launch of ARISTADA and growth of VIVITROL.”

“Our proprietary commercial products, VIVITROL and ARISTADA, represent important growth opportunities at a time when substance abuse and mental illness are significant public health priorities,” said Richard Pops, Chief Executive Officer of Alkermes. “Against this backdrop, we continue to make important advances for VIVITROL and are just beginning to see what its ultimate potential may be. The launch of ARISTADA in the rapidly growing, long-acting antipsychotic market continues to progress well, with reimbursement and access initiatives advancing across the country. We are also making headway on our late-stage pipeline of product candidates: the phase 3 studies for ALKS 3831 for schizophrenia and ALKS 8700 for multiple sclerosis will enroll throughout the remainder of 2016, and we expect to report topline data from the FORWARD-5 study of ALKS 5461 for major depressive disorder by year-end.”

Quarter Ended June 30, 2016 Highlights

- Total revenues for the quarter were \$195.2 million. This compared to \$151.4 million for the same period in the prior year.
- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was \$47.2 million, or a basic and diluted GAAP loss per share of \$0.31, for the quarter, which reflected increased investment in the company’s advancing late-stage pipeline and commercial infrastructure. This compared to GAAP net loss of \$46.1 million, or a basic and diluted GAAP loss per share of \$0.31, for the same period in the prior year.
- Non-GAAP net loss was \$1.6 million, or a non-GAAP basic and diluted loss per share of \$0.01, for the quarter. This compared to non-GAAP net loss of \$18.7 million, or a non-GAAP basic and diluted loss per share of \$0.13, for the same period in the prior year.

Quarter Ended June 30, 2016 Financial Results

Revenues

- Net sales of VIVITROL were \$47.2 million, compared to \$37.2 million for the same period in the prior year.
- Net sales of ARISTADA were \$10.3 million, up from \$5.5 million in the first quarter of 2016.
- Manufacturing and royalty revenues from RISPERDAL CONSTA®, INVEGA SUSTENNA®/XEPLION® and INVEGA TRINZA®/TREVICTA® were \$69.6 million, compared to \$60.8 million for the same period in the prior year.
- Manufacturing and royalty revenues from AMPYRA®/FAMPYRA®¹ were \$40.8 million, compared to \$26.9 million for the same period in the prior year, reflecting the timing of shipments.
- Royalty revenue from BYDUREON® was \$12.3 million, compared to \$11.1 million for the same period in the prior year.

Costs and Expenses

- Operating expenses were \$242.3 million, reflecting increased investment in the company’s development pipeline and the continued launch of ARISTADA. Operating expenses for the quarter ended June 30, 2015 were \$203.9 million.

Balance Sheet

At June 30, 2016, Alkermes had cash and total investments of \$677.7 million, compared to \$798.8 million at Dec. 31, 2015. At June 30, 2016, the company's total debt outstanding was \$347.0 million. Alkermes expects to pay down \$60.0 million of term loan upon maturity in September 2016. The remainder of the debt is due in September 2019.

Financial Expectations

Alkermes is updating its financial expectations for 2016 as a result of accelerating growth trends for VIVITROL, which are driving a \$10 million increase in expected revenues and a corresponding \$10 million improvement in GAAP net loss. This, in addition to certain changes to the calculation of non-GAAP measures, pursuant to guidelines issued by the Securities and Exchange Commission ("SEC"), results in a \$20 million improvement to non-GAAP net loss. The following outlines Alkermes' updated financial expectations for 2016.

- **Revenues:** The company now expects total revenues to range from \$710 million to \$760 million, up from the previous range of \$700 million to \$750 million.
 - The company now expects VIVITROL net sales to range from \$190 million to \$210 million, up from a previous range of \$180 million to \$200 million.
- **Cost of Goods Manufactured and Sold:** The company continues to expect cost of goods manufactured and sold to range from \$125 million to \$135 million.
- **Research and Development (R&D) Expenses:** The company continues to expect R&D expenses to range from \$370 million to \$400 million.
- **Selling, General and Administrative (SG&A) Expenses:** The company continues to expect SG&A expenses to range from \$360 million to \$390 million.
- **Amortization of Intangible Assets:** The company continues to expect amortization of intangible assets of approximately \$60 million.
- **Net Interest Expense:** The company continues to expect net interest expense of approximately \$10 million.
- **Net Income Tax Expense:** The company continues to expect net income tax expense to range from \$0 million to \$10 million.
- **GAAP Net Loss:** The company now expects GAAP net loss to range from \$215 million to \$245 million, or a basic and diluted loss per share of \$1.41 to \$1.61, based on weighted average basic and diluted share counts of approximately 152 million shares outstanding. This compares to previous expectations of GAAP net loss in the range of \$225 million to \$255 million, or a basic and diluted loss per share of approximately \$1.48 to \$1.68, based on weighted average basic and diluted share counts of approximately 152 million shares outstanding.
- **Non-GAAP Net Loss:** The company now expects non-GAAP net loss to range from \$5 million to \$35 million, or a basic and diluted loss per share of \$0.03 to \$0.23, based on weighted average basic and diluted share counts of approximately 152 million shares outstanding. This compares to previous expectations of non-GAAP net loss in the range of \$25 million to \$55 million, or a non-GAAP diluted loss per share of \$0.16 to \$0.36, based on weighted average diluted share counts of approximately 152 million shares outstanding.
- **Capital Expenditures:** The company continues to expect capital expenditures to be approximately \$45 million.

Conference Call

Alkermes will host a conference call at 8:30 a.m. EDT (1:30 p.m. BST) on Thursday, July 28, 2016, to discuss these financial results and provide an update on the company. 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. EDT (4:00 p.m. BST) on Thursday, July 28, 2016, through 5:00 p.m. EDT (10:00 p.m. BST) on Thursday, August 4, 2016, 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

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 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.

Following compliance and disclosure interpretations published by the SEC in May 2016, the company made certain changes to how it presents non-GAAP net income (loss). Non-GAAP net income (loss) in the three and six months ended June 30, 2016 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. Previously, non-GAAP net income (loss) excluded from GAAP results: the aforementioned items; an adjustment for deferred revenue recognized in the period; and an adjustment for non-cash tax expense, rather than the income tax effect of the reconciling items. The company revised its presentation for certain prior periods to reflect its current non-GAAP net income (loss) methodology. A reconciliation of the prior non-GAAP net income (loss) to the revised non-GAAP net income (loss) for such prior periods has been provided in the tables included in this press release. The company provides the following limited reconciling items under the previous methodology: deferred revenue of \$0.5 million and non-cash taxes of \$3.8 million for the quarterly period ended June 30, 2016; the company has provided this information for comparative purposes in connection with the transition to the new non-GAAP net income (loss) methodology, and will not provide this information on an ongoing basis.

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, better indicate underlying trends in ongoing operations. However, non-GAAP net income (loss) and non-GAAP 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 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; the therapeutic and commercial value of the company's products; and expectations concerning the timing and results of clinical development activities. 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: clinical development activities may not be completed on time or at all; the results of such 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 partners, may not be able to continue to successfully commercialize its 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 U.S. Food and Drug Administration 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 Annual Report on Form 10-K for the fiscal year ended Dec. 31, 2015, and in any other subsequent filings made by the company with the SEC and 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 they are made. The information contained in this press release is provided by the company as of the date hereof, and, except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking information contained in this press release.

VIVITROL[®] is a registered trademark of Alkermes, Inc.; ARISTADA[®] is a registered trademark 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.; BYDUREON[®] is a registered trademark of Amylin Pharmaceuticals, LLC.

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)

Condensed Consolidated Statements of Operations - GAAP (In thousands, except per share data)	Three Months Ended June 30, 2016	Three Months Ended June 30, 2015
Revenues:		
Manufacturing and royalty revenues	\$ 137,034	\$ 113,162
Product sales, net	57,519	37,172
Research and development revenues	612	1,036
Total Revenues	195,165	151,370
Expenses:		
Cost of goods manufactured and sold	33,998	30,418
Research and development	97,007	87,882

Selling, general and administrative	96,120	71,539
Amortization of acquired intangible assets	15,157	14,052
Total Expenses	242,282	203,891
Operating Loss	(47,117)	(52,521)
Other (Expense) Income, net:		
Interest income	994	795
Interest expense	(3,323)	(3,315)
Gain on Gainesville Transaction	-	9,911
Increase in the fair value of contingent consideration	2,200	1,500
Other (expense) income, net	(467)	585
Total Other (Expense) Income, net	(596)	9,476
Loss Before Income Taxes	(47,713)	(43,045)
Income Tax (Benefit) Provision	(520)	3,064
Net Loss — GAAP	\$ (47,193)	\$ (46,109)

Net Loss Per Share:

GAAP net loss per share — basic and diluted	\$ (0.31)	\$ (0.31)
Non-GAAP net loss per share — basic and diluted	\$ (0.01)	\$ (0.13)

Weighted Average Number of Ordinary Shares Outstanding:

Basic and diluted — GAAP and Non-GAAP	151,301	148,867
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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	\$ (47,193)	\$ (46,109)
Adjustments:		
Share-based compensation expense	26,631	21,877
Amortization expense	15,157	14,052
Depreciation expense	7,927	6,584
Income tax effect related to reconciling items	(2,051)	(2,531)
Non-cash net interest expense	231	235
Gain on warrants and equity method investments	(127)	(1,273)
Increase in the fair value of contingent consideration	(2,200)	(1,500)
Gain on Gainesville Transaction	-	(9,911)
Gain on sale of property, plant and equipment	-	(114)
Non-GAAP Net Loss	\$ (1,625)	\$ (18,690)

	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015
Condensed Consolidated Statements of Operations - GAAP		
(In thousands, except per share data)		
Revenues:		
Manufacturing and royalty revenues	\$ 243,194	\$ 241,906
Product sales, net	106,893	68,309
Research and development revenues	1,853	2,369
Total Revenues	351,940	312,584
Expenses:		
Cost of goods manufactured and sold	61,709	70,392
Research and development	198,079	158,160
Selling, general and administrative	185,840	134,589
Amortization of acquired intangible assets	30,313	29,272
Total Expenses	475,941	392,413
Operating Loss	(124,001)	(79,829)
Other (Expense) Income, net:		
Interest income	2,005	1,455
Interest expense	(6,618)	(6,603)
Gain on Gainesville Transaction	-	9,911
Increase in the fair value of contingent consideration	4,100	1,500
Other (expense) income, net	(218)	374

Total Other (Expense) Income, net	(731)	6,637
Loss Before Income Taxes	(124,732)	(73,192)
Income Tax (Benefit) Provision	(116)	3,574
Net Loss — GAAP	\$(124,616)	\$ (76,766)

Net Loss Per Share:

GAAP net loss per share — basic and diluted	\$ (0.82)	\$ (0.52)
Non-GAAP net loss per share — basic and diluted	\$ (0.13)	\$ (0.05)

Weighted Average Number of Ordinary Shares Outstanding:

Basic and diluted — GAAP and Non-GAAP	<u>151,063</u>	<u>148,480</u>
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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	\$(124,616)	\$ (76,766)
Adjustments:		
Share-based compensation expense	50,887	39,206
Amortization expense	30,313	29,272
Depreciation expense	15,475	13,850
Income tax effect related to reconciling items	1,289	140
Loss (gain) on warrants and equity method investments	743	(1,670)
Non-cash net interest expense	463	471
Upfront license option payment to Reset Therapeutics, Inc. charged to R&D expense	10,000	-
Increase in the fair value of contingent consideration	(4,100)	(1,500)
Gain on Gainesville Transaction	-	(9,911)
Gain on sale of property, plant and equipment	-	(114)
Non-GAAP Net Loss	\$ (19,546)	\$ (7,022)

Pursuant to compliance and disclosure interpretations published by the SEC in May 2016, the Company made certain changes to how it presents non-GAAP net income (loss). The Company no longer adjusts the deferred revenue recognized in the period and now reflects the tax effect of the reconciling items, as opposed to the non-cash taxes, as was previously the case. The Company revised its prior period presentation to reflect its current period presentation.

Condensed Consolidated Balance Sheets (In thousands)	June 30, 2016	December 31, 2015
Cash, cash equivalents and total investments	\$ 677,671	\$ 798,849
Receivables	185,008	155,487
Inventory	49,896	38,411
Prepaid expenses and other current assets	38,369	26,286
Property, plant and equipment, net	258,354	254,819
Intangible assets, net and goodwill	441,746	472,059
Other assets	134,242	109,833
Total Assets	\$1,785,286	\$ 1,855,744
Long-term debt — current portion	\$ 63,913	\$ 65,737
Other current liabilities	172,350	170,470
Long-term debt	283,120	284,207
Deferred revenue — long-term	6,943	7,975
Other long-term liabilities	15,434	13,080
Total shareholders' equity	1,243,526	1,314,275
Total Liabilities and Shareholders' Equity	\$1,785,286	\$ 1,855,744
Ordinary shares outstanding (in thousands)	151,503	150,701

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 and six months ended June 30, 2016, which the company intends to file in July 2016.

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

(In millions, except per share data)	Amount	Shares	Loss Per Share
Projected Net Loss — GAAP	\$ (230.0)	152	\$ (1.51)
Adjustments:			
Non-cash net interest expense	1.0		
Income taxes	5.0		
Depreciation expense	32.5		
Amortization expense	60.0		
Share-based compensation expense	101.5		
Upfront license option payment to Reset Therapeutics, Inc. charged to R&D expense	10.0		
Projected Non-GAAP Net Loss	<u>\$ (20.0)</u>	152	<u>\$ (0.13)</u>

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

Pursuant to compliance and disclosure interpretations published by the SEC in May 2016, the Company made certain changes to how it presents non-GAAP net loss. The Company no longer adjusts the deferred revenue recognized in the period and now reflects the tax effect of the reconciling items, as opposed to the non-cash taxes, as was previously the case. The revised guidance above includes the impact of these items, in addition to an adjustment related to the \$10 million license option payment to Reset Therapeutics, Inc. and an \$11 million reduction to share-based compensation expense.

Non-GAAP Reconciliation from Prior to Current Presentation

Pursuant to compliance and disclosure interpretations published by the SEC in May 2016, the Company made certain changes to how it presents non-GAAP net loss. The Company no longer adjusts the deferred revenue recognized in the period and now reflects the tax effect of the reconciling items, as opposed to the non-cash taxes, as was previously the case. The Company revised its prior period presentation to reflect its current period presentation. The following reconciliation shows the effect of this change in presentation of non-GAAP net income (loss) for each of the quarters in the year ended December 31, 2015, the year ended December 31, 2015 and the quarter ended March 31, 2016:

	Three Months Ended March 31, 2015	Three Months Ended June 30, 2015	Three Months Ended September 30, 2015	Three Months Ended December 31, 2015	Year Ended December 31, 2015	Three Months Ended March 31, 2016
Non-GAAP Net Income (Loss) — as previously reported	\$ 9,157	\$ (13,585)	\$ (26,174)	\$ (22,629)	\$ (53,231)	\$ (24,566)
Removal of the adjustment for deferred revenue	328	460	384	(542)	630	442
Removal of the adjustment for non-cash taxes	(488)	(3,034)	(677)	2,790	(1,409)	2,863
Adjustment for the income tax effect of other non-GAAP adjustments	2,671	(2,531)	(2,344)	(618)	(2,822)	3,340
Non-GAAP Net Income (Loss) — revised	<u>\$ 11,668</u>	<u>\$ (18,690)</u>	<u>\$ (28,811)</u>	<u>\$ (20,999)</u>	<u>\$ (56,832)</u>	<u>\$ (17,921)</u>
Net Increase (Decrease) From Previously Reported Non-GAAP Net Income (Loss)	<u>\$ 2,511</u>	<u>\$ (5,105)</u>	<u>\$ (2,637)</u>	<u>\$ 1,630</u>	<u>\$ (3,601)</u>	<u>\$ 6,645</u>



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Source: Alkermes plc

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