Alkermes Plc Reports Third Quarter 2018 Financial Results

October 23, 2018

-- 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, Oct. 23, 2018 /PRNewswire/ -- 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®[1], 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%.
- 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®[2] 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. 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.

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, 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. 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.

[1] 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.

[2] 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**	**Three Months Ended September 30, 2017**
Revenues:		
Manufacturing and royalty revenues	$ 116,411	$ 122,677
Product sales, net	116,035	93,681
Research and development revenue	16,274	1,027
Total Revenues	248,720	217,385
Expenses:		
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
Total Expenses	285,878	255,741
Operating Loss	(37,158)	(38,356)
Other Income, net:		
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)
Total Other Income, net	3,325	2,566
Loss Before Income Taxes	(33,833)	(35,790)
Income Tax Provision	611	486
Net Loss — GAAP	$ (34,444)	$ (36,276)
Net (Loss) Earnings Per Share:		
GAAP net loss per share — basic and diluted	$ (0.22)	$ (0.24)
Non-GAAP earnings per share — basic and diluted	$ 0.07	$ 0.03
Weighted Average Number of Ordinary Shares Outstanding:		
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:		
Net Loss — GAAP	$ (34,444)	$ (36,276)
Adjustments:		
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
Non-GAAP Net Income	$ 11,626	$ 4,164

Condensed Consolidated Statements of Operations - GAAP (In thousands, except per share data)	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Revenues:		
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	—
Total Revenues	778,512	628,004
Expenses:		
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
Total Expenses	877,660	781,739
Operating Loss	(99,148)	(153,735)
Other Expense, net:		
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)
Total Other Expense, net	(26,128)	(325)
Loss Before Income Taxes	(125,276)	(154,060)
Income Tax Provision (Benefit)	4,322	(5,904)
Net Loss — GAAP	$ (129,598)	$ (148,156)
Net (Loss) Earnings Per Share:		
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)
Weighted Average Number of Ordinary Shares Outstanding:		
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:		
Net Loss — GAAP	$ (129,598)	$ (148,156)
Adjustments:		
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	—
Non-GAAP Net Income (Loss)	$ 42,995	$ (22,501)

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
Total Assets	$ 1,760,710	$ 1,797,227
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
Total Liabilities and Shareholders' Equity	$ 1,760,710	$ 1,797,227
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.

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:

(In millions, except per share data)		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.

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