Alkermes plc Reports Third Quarter 2021 Financial Results

October 27, 2021

-- Third Quarter Revenues of $294.1 Million Reflect 11% Growth Year-Over-Year --
-- Diluted GAAP Loss per Share of $0.18 and Diluted Non-GAAP Earnings per Share of $0.14 --
-- Company Reiterates Financial Expectations for 2021 --

DUBLIN, Oct. 27, 2021 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today reported financial results for the third quarter of 2021.

"We have made significant strides across our commercial and development portfolios over the course of 2021. With the recent commercial launch of LYBALVI®, we have expanded our psychiatry franchise and added an important new growth opportunity that leverages our experience and capabilities in the antipsychotic market. Within our development pipeline, we initiated clinical studies designed to support potential registration of nemvaleukin in mucosal melanoma and platinum-resistant ovarian cancer. We also initiated a phase 1 study of ALKS 1140 and advanced our preclinical orexin 2 receptor agonist program. Each of these important achievements demonstrates the continued execution of our strategy to advance differentiated medicines in neuroscience and oncology," said Richard Pops, Chief Executive Officer of Alkermes. "As we look ahead, we believe we are well-positioned to deliver long-term growth and value creation, driven by our diversified commercial business, our advancing development pipeline and our focus on profitability."

Quarter Ended Sept. 30, 2021 Financial Results

Revenues

- Total revenues for the quarter were $294.1 million. This compared to $265.0 million for the same period in the prior year.

- Net sales of proprietary products for the quarter were $157.7 million, compared to $142.7 million for the same period in the prior year.

- Net sales of VIVITROL® were $88.8 million, compared to $80.3 million for the same period in the prior year, representing an increase of approximately 11%.
- Net sales of ARISTADA®i were $68.9 million, compared to $62.4 million for the same period in the prior year, representing an increase of approximately 10%.

- Manufacturing and royalty revenues for the quarter were $136.3 million, compared to $120.4 million for the same period in the prior year.

- Manufacturing and royalty revenues from INVEGA SUSTENNA®/XEPLION®, INVEGA TRINZA®/TREVICTA®, and RISPERDAL CONSTA® were $90.3 million, compared to $87.9 million for the same period in the prior year.
- Manufacturing and royalty revenues from VUMERITY® were $26.7 million, compared to $2.7 million for the same period in the prior year.

Costs and Expenses

- Total operating expenses for the quarter were $313.8 million, compared to $275.7 million for the same period in the prior year.

- Cost of Goods Manufactured and Sold were $49.6 million, compared to $43.1 million for the same period in the prior year.
- Research and Development (R&D) expenses were $118.4 million, compared to $95.0 million for the same period in the prior year. R&D expenses for the third quarter included accrual of a $25.0 million development milestone to be paid to the former shareholders of Rodin Therapeutics, Inc. related to ALKS 1140, the first clinical candidate to emerge from the histone deacetylase (HDAC) inhibitor platform acquired by Alkermes in 2019. Excluding this milestone, R&D expenses for the quarter were $93.4 million.
- Selling, General and Administrative (SG&A) expenses were $136.2 million, compared to $127.7 million for the same period in the prior year, primarily reflecting increased investment to support the launch of LYBALVI.

Profitability

- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was $29.0 million for the quarter, or a basic and diluted GAAP loss per share of $0.18, and included the $25.0 million development milestone related to ALKS 1140. This compared to GAAP net loss of $0.1 million, or a basic and diluted GAAP loss per share of $0.00, for the same period in the prior year.

- Non-GAAP net income was $23.6 million for the quarter, or a non-GAAP basic earnings per share of $0.15 and a non-GAAP diluted earnings per share of $0.14, and included the $25.0 million development milestone related to ALKS 1140. This compared to non-GAAP net income of $41.5 million, or a non-GAAP basic and diluted earnings per share of $0.26 for the same period in the prior year.

Balance Sheet

- At Sept. 30, 2021, the company recorded cash, cash equivalents and total investments of $748.2 million, compared to $669.4 million at June 30, 2021, driven primarily by the company's operating results and changes in working capital. The company's total debt outstanding as of Sept. 30, 2021 was $296.4 million.

Financial Expectations for 2021

Alkermes reiterates its financial expectations for 2021 set forth in its press release dated July 28, 2021. These financial expectations assume improvement in patient access to treatment providers and further normalization of the treatment system in the fourth quarter of 2021. If patient access does not improve or the treatment system does not normalize as anticipated, or if new COVID-19-related disruptions emerge, the company's ability to meet these expectations could be negatively impacted.

"We are pleased to report another strong quarter that reflects our continued focus on commercial execution, with solid year-over-year growth for VIVITROL and ARISTADA, and on driving operational efficiencies," commented Iain Brown, Chief Financial Officer of Alkermes. "As we look ahead, we believe that we are in a strong financial position to successfully launch LYBALVI and invest in our pipeline of development candidates as we seek to drive long-term value creation and profitability."

Recent Events:

Psychiatry

- In October 2021, the company announced the commercial availability of LYBALVI (olanzapine and samidorphan) in the U.S. for the treatment of adults with schizophrenia, and for the treatment of adults with bipolar I disorder, as a maintenance monotherapy or for the acute treatment of manic or mixed episodes as monotherapy or an adjunct to lithium or valproate[ii]. LYBALVI is a once-daily, oral atypical antipsychotic composed of olanzapine, an established antipsychotic agent, co-formulated with samidorphan, a new chemical entity, in a single bilayer tablet.

Oncology

- In August 2021, the U.S. Food and Drug Administration (FDA) granted Fast Track designation to nemvaleukin alfa (nemvaleukin) for the treatment of mucosal melanoma. This followed the FDA's grant of Orphan Drug designation to nemvaleukin for the treatment of mucosal melanoma and the recent initiation of ARTISTRY-6, a global phase 2 trial evaluating the anti-tumor activity, safety and tolerability of nemvaleukin monotherapy in patients with melanoma who have been previously treated with anti-PD-(L)1 therapy.
- In October 2021, the FDA granted Fast Track designation to nemvaleukin in combination with pembrolizumab for the treatment of platinum-resistant ovarian cancer.
- In October 2021, the company announced the initiation of ARTISTRY-7, a global phase 3 trial evaluating the anti-tumor activity and safety of intravenously administered (IV) nemvaleukin in combination with pembrolizumab compared to investigator's choice chemotherapy in patients with platinum-resistant ovarian cancer.

Neuroscience

- In October 2021, the company initiated a phase 1, first-in-human study evaluating the safety and tolerability of ALKS 1140 in healthy subjects. ALKS 1140 is a novel, investigational CoREST-selective (co-repressor of repressor element-1 silencing transcription factor) HDAC inhibitor candidate for the treatment of neurodegenerative and neurodevelopmental disorders. ALKS 1140 is designed to increase functional synaptic connections and synaptic integrity in the brain.

Conference Call

Alkermes will host a conference call and webcast presentation with accompanying slides at 8:00 a.m. ET (1:00 p.m. BST) on Wednesday, Oct. 27, 2021, to discuss these financial results and provide an update on the company. The webcast may be accessed on the Investors section of Alkermes' website at www.alkermes.com. The conference call may be accessed by dialing +1 877 407 2988 for U.S. callers and +1 201 389 0923 for international callers. In addition, a replay of the conference call may be accessed by visiting Alkermes' website.

About Alkermes plc

Alkermes plc is a fully-integrated, global biopharmaceutical company developing innovative medicines in the fields of neuroscience and oncology. The company has a portfolio of proprietary commercial products focused on addiction, schizophrenia and bipolar I disorder, and a pipeline of product candidates in development for neurodegenerative disorders and cancer. Headquartered in Dublin, Ireland, Alkermes 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 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 certain 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 the company's liquidity.

A reconciliation of GAAP to non-GAAP financial measures has been provided in the tables included in this press release.

Note Regarding Forward-Looking Statements

Certain statements set forth in this press release constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: the company's expectations concerning its future financial and operating performance, business plans or prospects, including its ability to deliver, and the expected drivers of, growth and value creation; the company's expectations of improvement in patient access to treatment providers and further normalization of the treatment system; the potential therapeutic and commercial value of the company's marketed and development products; the company's expectations concerning its future development activities, including further investment in and advancement of the company's neuroscience and oncology development pipeline; and the company's expectations concerning its commercial activities, including its ability to successfully launch LYBALVI and to leverage its commercial experience and capabilities in the antipsychotic market. The company cautions that forward-looking statements are inherently uncertain. 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 company may not be able to achieve its targeted financial and profitability metrics in a timely manner or at all; unexpected costs or delays in the commercial launch of LYBALVI; whether LYBALVI will be commercialized successfully; whether third-party payers will cover or reimburse LYBALVI for the treatment of adults with schizophrenia or the treatment of adults with bipolar I disorder; the impacts of the ongoing COVID-19 pandemic and continued efforts to mitigate its spread on the company's business, results of operations or financial condition, including impacts on healthcare systems and patient and healthcare provider access to the company's commercial products and impacts on the regulatory agencies with which the company interacts in the development, review, approval and commercialization of its medicines; the unfavorable outcome of litigation, including so-called "Paragraph IV" litigation and other patent litigation, or other disputes related to the company's products or products using the company's proprietary technologies; clinical development activities may not be completed on time or at all; the results of the company's development activities may not be positive, or predictive of final results from such activities, results of future development activities or real-world results; data from clinical trials may be interpreted by the FDA in different ways than the company interprets it; the FDA may not agree with the company's regulatory approval strategies or components of its filings, including its clinical trial designs, conduct and methodologies and the adequacy of the data and other information included in its submissions to support the FDA's requirements for approval; regulatory submissions may not occur or be submitted in a timely manner; the FDA or regulatory authorities outside the U.S. may make adverse decisions regarding the company's products; 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 government payers; 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 year ended Dec. 31, 2020 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.

(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, 2021**	**Three Months Ended September 30, 2020**
Revenues:		
Product sales, net	$ 157,737	$ 142,658
Manufacturing and royalty revenues	136,294	120,351
Research and development revenue	110	953
License revenue	—	1,050
Total Revenues	294,141	265,012
Expenses:		
Cost of goods manufactured and sold	49,561	43,129
Research and development	118,411	94,980
Selling, general and administrative	136,213	127,653
Amortization of acquired intangible assets	9,615	9,917
Total Expenses	313,800	275,679
Operating Loss	(19,659)	(10,667)
Other (Expense) Income, net:		
Interest income	468	1,376
Interest expense	(2,437)	(1,811)
Change in the fair value of contingent consideration	(5,195)	3,926
Other income, net	288	9,368

Total Other (Expense) Income, net		(6,876)		12,859
(Loss) Income Before Income Taxes		(26,535)		2,192
Provision for Income Taxes		2,453		2,326
Net Loss — GAAP	$	(28,988)	$	(134)
(Loss) Earnings Per Share:				
GAAP loss per share — basic and diluted	$	(0.18)	$	(0.00)
Non-GAAP earnings per share — basic	$	0.15	$	0.26
Non-GAAP earnings per share — diluted	$	0.14	$	0.26
Weighted Average Number of Ordinary Shares Outstanding:				
Basic and diluted — GAAP		161,456		159,062
Basic — Non-GAAP		161,456		159,062
Diluted — Non-GAAP		166,758		160,335

An itemized reconciliation between net loss on a GAAP basis and non-GAAP net income is as follows:

Net Loss — GAAP	$	(28,988)	$	(134)
Adjustments:				
Share-based compensation expense		25,600		22,618
Depreciation expense		9,775		10,663
Amortization expense		9,615		9,917
Income tax effect related to reconciling items		2,243		2,174
Non-cash net interest expense		117		166
Change in the fair value of contingent consideration		5,195		(3,926)
Non-GAAP Net Income	$	23,557	$	41,478

Condensed Consolidated Statements of Operations - GAAP **(In thousands, except per share data)**		**Nine Months Ended September 30, 2021**		**Nine Months Ended September 30, 2020**
Revenues:				
Product sales, net	$	448,508	$	402,799
Manufacturing and royalty revenues		398,435		353,107
License revenue		1,500		1,050
Research and development revenue		845		1,805
Total Revenues		849,288		758,761
Expenses:				
Cost of goods manufactured and sold		143,705		135,394
Research and development		308,152		282,481
Selling, general and administrative		400,569		393,049
Amortization of acquired intangible assets		28,532		29,535
Total Expenses		880,958		840,459
Operating Loss		(31,670)		(81,698)
Other (Expense) Income, net:				
Interest income		1,955		5,924
Interest expense		(8,814)		(6,790)
Change in the fair value of contingent consideration		(677)		16,626
Other (expense) income, net		(327)		11,047
Total Other (Expense) Income, net		(7,863)		26,807
Loss Before Income Taxes		(39,533)		(54,891)
Provision for Income Taxes		9,509		13,328
Net Loss — GAAP	$	(49,042)	$	(68,219)
(Loss) Earnings Per Share:				
GAAP loss per share — basic and diluted	$	(0.31)	$	(0.43)
Non-GAAP earnings per share — basic	$	0.56	$	0.33
Non-GAAP earnings per share — diluted	$	0.55	$	0.33
Weighted Average Number of Ordinary Shares Outstanding:				
Basic and diluted — GAAP		160,642		158,685
Basic — Non-GAAP		160,642		158,685
Diluted — Non-GAAP		164,077		159,467

An itemized reconciliation between net loss on a GAAP basis and non-GAAP net income is as follows:

Net Loss — GAAP	$	(49,042)	$	(68,219)
Adjustments:				
Share-based compensation expense		68,603		65,277
Depreciation expense		28,978		31,991

Amortization expense	28,532	29,535
Income tax effect related to reconciling items	10,349	8,971
Non-cash net interest expense	352	500
Debt refinancing charge	2,109	—
Change in the fair value of contingent consideration	677	(16,626)
Acquisition of IPR&D	—	674
Non-GAAP Net Income	$ 90,558	$ 52,103

Condensed Consolidated Balance Sheets (In thousands)	**September 30, 2021**	**December 31, 2020**
Cash, cash equivalents and total investments	$ 748,155	$ 659,807
Receivables	289,160	275,143
Inventory	138,696	125,738
Contract assets	3,509	14,401
Prepaid expenses and other current assets	61,341	60,662
Property, plant and equipment, net	340,594	350,003
Intangible assets, net and goodwill	176,532	204,064
Other assets	237,445	259,912
Total Assets	$ 1,995,432	$ 1,949,730
Long-term debt — current portion	$ 3,000	$ 2,843
Other current liabilities	449,984	435,415
Long-term debt	293,437	272,118
Contract liabilities — long-term	12,864	16,397
Other long-term liabilities	139,979	155,975
Total shareholders' equity	1,096,168	1,066,982
Total Liabilities and Shareholders' Equity	$ 1,995,432	$ 1,949,730
Ordinary shares outstanding (in thousands)	161,686	159,161

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 nine months ended September 30, 2021, which the company intends to file in October 2021.

[i] The term "ARISTADA" as used in this press release refers to ARISTADA and ARISTADA INITIO®, unless the context indicates otherwise.

[ii] Full prescribing information, including boxed warning, for LYBALVI may be found at www.lybalvi.com/lybalvi-prescribing-information.pdf

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