Alkermes plc Reports Third Quarter 2024 Financial Results

October 24, 2024

—Third Quarter Revenues of $378.1 Million —

—Net Sales of Proprietary Products Increased Approximately 18% Year-Over-Year —

—GAAP Net Income from Continuing Operations of $92.8 Million and Diluted GAAP Earnings per Share from Continuing Operations of $0.56 —

—Company Reiterates 2024 Financial Expectations —

DUBLIN, Oct. 24, 2024 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today reported financial results for the third quarter of 2024.

"Our third quarter financial results reflect strong year-over-year growth of our portfolio of proprietary commercial products and position us well to meet our strategic, operational and financial priorities for the year. Looking ahead, we believe growing our proprietary commercial products and advancing our pipeline, particularly ALKS 2680, our novel, investigational, orexin 2 receptor agonist, and additional orexin development candidates, will serve as the key drivers of shareholder value. We plan to manage the business to deliver significant profitability and cash flow while investing in these strategic initiatives," said Richard Pops, Chief Executive Officer of Alkermes. "2025 has the potential to be a transformational year for Alkermes as we expect to complete the ongoing phase 2 studies in narcolepsy type 1 and narcolepsy type 2, and prepare for potential registrational studies for ALKS 2680. With the potential to transform the treatment of hypersomnolence disorders, and with broad potential applicability across other symptomatic domains, orexin 2 receptor agonists represent one of the most exciting new therapeutic categories in development and we believe a significant opportunity for Alkermes and our shareholders."

Key Financial Highlights

Revenues

(In millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Total Revenues	$ 378.1	$ 380.9	$ 1,127.6	$ 1,285.9*
Total Proprietary Net Sales	$ 273.0	$ 231.8	$ 775.8	$ 678.0
VIVITROL®	$ 113.7	$ 99.3	$ 323.2	$ 298.0
ARISTADA®i	$ 84.7	$ 81.8	$ 249.6	$ 244.3
LYBALVI®	$ 74.7	$ 50.7	$ 203.1	$ 135.7

Profitability

(In millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023*
GAAP Net Income From Continuing Operations	$ 92.8	$ 91.6	$ 226.4	$ 358.6
GAAP Net Loss From Discontinued Operations	*$ (0.4)*	*$ (43.8)*	*$ (5.8)*	*$ (115.6)*
GAAP Net Income	$ 92.4	$ 47.8	$ 220.6	$ 243.0
Non-GAAP Net Income From Continuing Operations	$ 121.4	$ 150.4	$ 321.0	$ 314.7
Non-GAAP Net Loss From Discontinued Operations	*$ (0.4)*	*$ (40.8)*	*$ (5.8)*	*$ (108.5)*
Non-GAAP Net Income	$ 121.0	$ 109.5	$ 315.2	$ 206.2
EBITDA From Continuing Operations	$ 112.3	$ 107.2	$ 282.4	$ 413.5
EBITDA From Discontinued Operations	*$ (0.5)*	*$ (44.6)*	*$ (6.9)*	*$ (121.9)*
EBITDA	$ 111.8	$ 62.7	$ 275.5	$ 291.5

*As a result of the successful resolution of the arbitration with Janssen Pharmaceutica N.V., the nine months ended September 30, 2023 included approximately $195.4 million of back royalties (and related interest) related to U.S. net sales of long-acting INVEGA® products that would ordinarily have been recognized in prior periods.

Revenue Highlights

LYBALVI

- Revenues for the quarter were $74.7 million.
- Revenues and total prescriptions for the quarter grew 47% and 37%, respectively, compared to the third quarter of 2023.

ARISTADA[i]

- Revenues for the quarter were $84.7 million.

VIVITROL

- Revenues for the quarter were $113.7 million.
- Revenues for the quarter grew 14% compared to the third quarter of 2023, driven by the alcohol dependence indication.

Manufacturing & Royalty Revenues

- Royalty revenues from INVEGA SUSTENNA®/XEPLION®, INVEGA TRINZA®/TREVICTA® and INVEGA HAFYERA®/BYANNLI® for the quarter were $58.4 million.
- VUMERITY® manufacturing and royalty revenues for the quarter were $32.6 million.

Key Operating Expenses

Please see Note 1 below for details regarding discontinued operations.

(In millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
R&D Expense – Continuing Operations	$ 59.9	$ 64.9	$ 187.2	$ 196.9
R&D Expense – Discontinued Operations	*$ 0.5*	*$ 32.3*	*$ 6.9*	*$ 94.7*
SG&A Expense – Continuing Operations	$ 150.4	$ 156.4	$ 498.2	$ 520.0
SG&A Expense – Discontinued Operations	*$ -*	*$ 13.1*	*$ -*	*$ 29.2*

Balance Sheet

At Sept. 30, 2024, the company recorded cash, cash equivalents and total investments of $927.8 million, compared to $962.5 million at June 30, 2024. The company's total debt outstanding as of Sept. 30, 2024 was $288.8 million.

Share Repurchase Program

During the third quarter of 2024, the company repurchased approximately 4.4 million of the company's ordinary shares under the share repurchase program authorized in February 2024, at a total purchase price of $115.6 million. As of Sept. 30, 2024, the company had $200 million (exclusive of any fees, commissions or other related expenses) remaining under the program.

Financial Expectations for 2024

Alkermes reiterates its financial expectations for 2024, as set forth in its press release dated Feb. 15, 2024.

Recent Events

- In October 2024, the company hosted an investor event to review its portfolio of orexin 2 receptor agonists and development strategy. The company presented data from its ALKS 2680 phase 1b study in patients with narcolepsy type 1 (NT1), narcolepsy type 2 (NT2) and idiopathic hypersomnia (IH), and discussed the study design for its ongoing phase 2 studies in NT1 and NT2. The company also announced its plans to initiate a phase 2 study in patients with IH in 2025.
- In September 2024, the company presented positive clinical data from its phase 1b study of ALKS 2680 in patients with NT2 and IH at the European Sleep Research Society's 27th Congress, Sleep Europe 2024.
- In August 2024, the company announced the initiation of its Vibrance-2 phase 2 study of ALKS 2680 in patients with NT2.
- In August 2024, the company published its latest Corporate Responsibility Report, which details how the company integrates environmental, social and governance considerations into its business. A copy of the report is available on the Responsibility section of Alkermes' website.

Notes and Explanations

1. The company determined that upon the separation of its oncology business, completed on Nov. 15, 2023, the oncology business met the criteria for discontinued operations in accordance with Financial Accounting Standards Board Accounting Standards Codification 205, *Discontinued Operations*. Accordingly, the accompanying selected financial information has been updated to present the results of the oncology business as discontinued operations for the three and nine months ended Sept. 30, 2023.

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 Thursday, Oct. 24, 2024, 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 global biopharmaceutical company that seeks to develop innovative medicines in the field of neuroscience. The company has a portfolio of proprietary commercial products for the treatment of alcohol dependence, opioid dependence, schizophrenia and bipolar I disorder, and a pipeline of clinical and preclinical candidates in development for neurological disorders, including narcolepsy and idiopathic hypersomnia. Headquartered in Ireland, Alkermes also has a corporate office and research and development center in Massachusetts and a manufacturing facility in

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 and EBITDA. 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 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; change in the fair value of contingent consideration; certain other one-time or non-cash items; and the income tax effect of these reconciling items. EBITDA represents earnings before interest, tax, depreciation and amortization; earnings include share-based compensation expense.

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 financial 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 and EBITDA 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 and EBITDA 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 drivers of shareholder value and profitability; and the company’s expectations regarding development plans, activities and timelines for, and the potential therapeutic and commercial value of, ALKS 2680 and the company’s other orexin portfolio candidates. 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: whether the company is able to achieve its financial expectations, including those related to profitability; the unfavorable outcome of arbitration or litigation, including so-called “Paragraph IV” litigation and other patent litigation which may lead to competition from generic drug manufacturers, 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; the U.S. Food and Drug Administration (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 or support revenue growth from such 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, 2023 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®, ARISTADA INITIO® and LYBALVI® are registered trademarks of Alkermes Pharma Ireland Limited, used by Alkermes, Inc. under license; BYANNLI®, INVEGA®, INVEGA HAFYERA®, INVEGA SUSTENNA®, INVEGA TRINZA®, TREVICTA® and XEPLION® are registered trademarks of Johnson & Johnson or its affiliated companies; and VUMERITY® is a registered trademark of Biogen MA Inc., used by Alkermes under license.

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

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, 2024	Three Months Ended September 30, 2023
Revenues:		
Product sales, net	$ 272,999	$ 231,822
Manufacturing and royalty revenues	105,144	149,113
Research and development revenue	—	3
Total Revenues	378,143	380,938
Expenses:		
Cost of goods manufactured and sold	63,099	61,498
Research and development	59,892	64,878
Selling, general and administrative	150,382	156,373
Amortization of acquired intangible assets	14	8,995
Total Expenses	273,387	291,744
Operating Income	104,756	89,194
Other Income, net:		
Interest income	10,916	9,370

Interest expense	(6,000)	(6,006)
Other income, net	558	149
Total Other Income, net	5,474	3,513
Income Before Income Taxes	110,230	92,707
Income Tax Provision	17,435	1,153
Net Income From Continuing Operations	92,795	91,554
Loss From Discontinued Operations — Net of Tax	(414)	(43,796)
Net Income — GAAP	$ 92,381	$ 47,758
GAAP Earnings (Loss) Per Ordinary Share - Basic:		
From continuing operations	$ 0.57	$ 0.55
From discontinued operations	$ (0.00)	$ (0.26)
From net income	$ 0.57	$ 0.29
GAAP Earnings (Loss) Per Ordinary Share - Diluted:		
From continuing operations	$ 0.56	$ 0.53
From discontinued operations	$ (0.00)	$ (0.25)
From net income	$ 0.55	$ 0.28
Weighted Average Number of Ordinary Shares Outstanding:		
Basic — GAAP and Non-GAAP	163,368	166,607
Diluted — GAAP and Non-GAAP	167,025	171,903

Condensed Consolidated Statements of Operations - GAAP (Continued) **(In thousands, except per share data)**	**Three Months Ended September 30, 2024**	**Three Months Ended September 30, 2023**
An itemized reconciliation between net income from continuing operations on a GAAP basis and EBITDA is as follows:		
Net Income from Continuing Operations	$ 92,795	$ 91,554
Adjustments:		
Depreciation expense	6,958	8,886
Amortization expense	14	8,995
Interest income	(10,916)	(9,370)
Interest expense	6,000	6,006
Income tax provision	17,435	1,153
EBITDA from Continuing Operations	112,286	107,224
EBITDA from Discontinued Operations	(481)	(44,567)
EBITDA	$ 111,805	$ 62,657
An itemized reconciliation between net income from continuing operations on a GAAP basis and non-GAAP net income is as follows:		
Net Income from Continuing Operations	$ 92,795	$ 91,554
Adjustments:		
Share-based compensation expense	22,533	21,733
Depreciation expense	6,958	8,886
Amortization expense	14	8,995
Non-cash net interest expense	114	115
Separation expense	206	9,640
Income tax effect related to reconciling items	(1,255)	3,511
Restructuring expense	—	5,938
Non-GAAP Net Income from Continuing Operations	121,365	150,372
Non-GAAP Net Loss from Discontinued Operations	(414)	(40,835)
Non-GAAP Net Income	$ 120,951	$ 109,537
Non-GAAP diluted earnings per ordinary share from continuing operations	$ 0.73	$ 0.87
Non-GAAP diluted loss per ordinary share from discontinued operations	$ (0.00)	$ (0.24)
Non-GAAP diluted earnings per ordinary share from net income	$ 0.72	$ 0.64

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, 2024**	**Nine Months Ended September 30, 2023**
Revenues:		
Product sales, net	$ 775,808	$ 678,026
Manufacturing and royalty revenues	351,835	607,888
Research and development revenue	3	16
Total Revenues	1,127,646	1,285,930

Expenses:		
Cost of goods manufactured and sold	183,215	182,911
Research and development	187,152	196,873
Selling, general and administrative	498,244	519,962
Amortization of acquired intangible assets	1,087	26,693
Total Expenses	869,698	926,439
Operating Income	257,948	359,491
Other Income, net:		
Interest income	31,050	21,105
Interest expense	(17,930)	(16,978)
Other income (expense), net	2,793	(415)
Total Other Income, net	15,913	3,712
Income Before Income Taxes	273,861	363,203
Income Tax Provision	47,460	4,598
Net Income From Continuing Operations	226,401	358,605
Loss From Discontinued Operations — Net of Tax	(5,834)	(115,627)
Net Income — GAAP	$ 220,567	$ 242,978
GAAP Earnings (Loss) Per Ordinary Share - Basic:		
From continuing operations	$ 1.36	$ 2.16
From discontinued operations	$ (0.04)	$ (0.70)
From net income	$ 1.32	$ 1.47
GAAP Earnings (Loss) Per Ordinary Share - Diluted:		
From continuing operations	$ 1.33	$ 2.10
From discontinued operations	$ (0.03)	$ (0.68)
From net income	$ 1.30	$ 1.42
Weighted Average Number of Ordinary Shares Outstanding:		
Basic — GAAP and Non-GAAP	166,546	165,686
Diluted — GAAP and Non-GAAP	170,196	170,747

Condensed Consolidated Statements of Operations - GAAP (Continued) **(In thousands, except per share data)**	**Nine Months Ended September 30, 2024**	**Nine Months Ended September 30, 2023**
An itemized reconciliation between net income from continuing operations on a GAAP basis and EBITDA is as follows:		
Net Income from Continuing Operations	$ 226,401	$ 358,605
Adjustments:		
Depreciation expense	20,599	27,696
Amortization expense	1,087	26,693
Interest income	(31,050)	(21,105)
Interest expense	17,930	16,978
Income tax provision	47,460	4,598
EBITDA from Continuing Operations	282,427	413,465
EBITDA from Discontinued Operations	(6,910)	(121,947)
EBITDA	$ 275,517	$ 291,518
An itemized reconciliation between net income from continuing operations on a GAAP basis and non-GAAP net income is as follows:		
Net Income from Continuing Operations	$ 226,401	$ 358,605
Adjustments:		
Share-based compensation expense	75,889	69,943
Depreciation expense	20,599	27,696
Amortization expense	1,087	26,693
Separation expense	1,446	19,280
Income tax effect related to reconciling items	(3,316)	3,332
Gain on sale of Athlone manufacturing facility	(1,462)	—
Restructuring expense	—	5,938
Final award in the Janssen arbitration (2022 back royalties and interest)	—	(197,092)
Non-cash net interest expense	342	346
Non-GAAP Net Income from Continuing Operations	320,986	314,741
Non-GAAP Net Loss from Discontinued Operations	(5,834)	(108,511)
Non-GAAP Net Income	$ 315,152	$ 206,230
Non-GAAP diluted earnings per ordinary share from continuing operations	$ 1.89	$ 1.84
Non-GAAP diluted loss per ordinary share from discontinued operations	$ (0.03)	$ (0.64)
Non-GAAP diluted earnings per ordinary share from net income	$ 1.85	$ 1.21

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Balance Sheets (In thousands)	**September 30, 2024**	**December 31, 2023**
Cash, cash equivalents and total investments	$ 927,784	$ 813,378
Receivables	367,211	332,477
Inventory	191,087	186,406
Contract assets	2,969	706
Prepaid expenses and other current assets	94,047	98,166
Property, plant and equipment, net	225,422	226,943
Intangible assets, net and goodwill	83,931	85,018
Assets held for sale	—	94,260
Deferred tax assets	159,960	195,888
Other assets	102,880	102,981
Total Assets	$ 2,155,291	$ 2,136,223
Long-term debt — current portion	$ 3,000	$ 3,000
Other current liabilities	450,705	512,678
Long-term debt	285,823	287,730
Liabilities from discontinued operations	—	4,542
Other long-term liabilities	123,658	125,587
Total shareholders' equity	1,292,105	1,202,686
Total Liabilities and Shareholders' Equity	$ 2,155,291	$ 2,136,223
Ordinary shares outstanding (in thousands)	161,776	166,980

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 quarter ended September 30, 2024, which the company intends to file in October 2024.

Alkermes plc and Subsidiaries
Amounts Included in Discontinued Operations

(In thousands)	**Three Months Ended March 31, 2024**	**Three Months Ended June 30, 2024**	**Three Months Ended September 30, 2024**	**Nine Months Ended September 30, 2024**
Cost of goods manufactured and sold	$ —	$ —	$ —	**$ —**
Research and development	2,516	3,913	481	**6,910**
Selling, general and administrative	—	—	—	**—**
Income tax benefit	(396)	(613)	(67)	**(1,076)**
Loss from discontinued operations, net of tax	**$ 2,120**	**$ 3,300**	**$ 414**	**$ 5,834**

(In thousands)	**Three Months Ended March 31, 2023**	**Three Months Ended June 30, 2023**	**Three Months Ended September 30, 2023**	**Nine Months Ended September 30, 2023**
Cost of goods manufactured and sold	$ 11	$ 11	$ 11	**$ 33**
Research and development	29,867	32,563	32,262	**94,692**
Selling, general and administrative	6,644	9,502	13,073	**29,219**
Income tax benefit	(6,727)	(40)	(1,550)	**(8,317)**
Loss from discontinued operations, net of tax	**$ 29,795**	**$ 42,036**	**$ 43,796**	**$ 115,627**

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