Alkermes plc Reports First Quarter 2024 Financial Results

May 1, 2024

— First Quarter Revenues of $350.4 Million —

— GAAP Net Income from Continuing Operations of $38.9 Million and Diluted GAAP Earnings per Share from Continuing Operations of $0.23 —

— Company Reiterates 2024 Financial Expectations —

DUBLIN, May 1, 2024 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today reported financial results for the first quarter of 2024.

"The first quarter of 2024 marks our first full quarter as a profitable, pure-play neuroscience company. During the quarter, we continued to advance our strategic priorities across the business, highlighted by solid underlying prescription growth for LYBALVI® and advancement of ALKS 2680, our novel, investigational, oral orexin 2 receptor (OX2R) agonist in development as a once-daily treatment for narcolepsy," said Richard Pops, Chief Executive Officer of Alkermes. "For ALKS 2680, we recently initiated our Vibrance-1 phase 2 study in narcolepsy type 1 and announced positive topline phase 1b results in narcolepsy type 2. With these new data now in hand, we plan to initiate a phase 2 study in narcolepsy type 2 in the second half of 2024. In an area where there remains significant unmet patient need, orexin 2 biology represents an important new potential approach to treating disorders characterized by excessive daytime sleepiness. ALKS 2680 is the first candidate from our orexin portfolio to advance in the clinic and we plan to share details regarding our other orexin development programs later this year."

Key Financial Highlights

Revenues

(In millions)	Three Months Ended March 31,	
	2024	**2023**
Total Revenues	$ 350.4	$ 287.6
Total Proprietary Net Sales	$ 233.5	$ 214.7
VIVITROL®	$ 97.7	$ 96.7
ARISTADA®[i]	$ 78.9	$ 80.1
LYBALVI®	$ 57.0	$ 38.0

Profitability

(In millions)	Three Months Ended March 31,	
	2024	**2023**
GAAP Net Income (Loss) From Continuing Operations	$ 38.9	$ (12.1)
GAAP Net Loss From Discontinued Operations	*$ (2.1)*	*$ (29.8)*
GAAP Net Income (Loss)	$ 36.8	$ (41.8)
Non-GAAP Net Income From Continuing Operations	$ 76.2	$ 30.1
Non-GAAP Net Loss From Discontinued Operations	*$ (2.1)*	*$ (27.6)*
Non-GAAP Net Income	$ 74.1	$ 2.4
EBITDA From Continuing Operations	$ 51.5	$ 7.2
EBITDA From Discontinued Operations	*$ (2.5)*	*$ (36.0)*
EBITDA	$ 49.0	$ (28.8)

Revenue Highlights

LYBALVI

- Revenues for the quarter were $57.0 million.
- Revenues and total prescriptions for the quarter grew 50% and 56%, respectively, compared to the first quarter of 2023.
- Inventory in the channel decreased by approximately $2.3 million during the quarter.

ARISTADA[i]

- Revenues for the quarter were $78.9 million.
- Inventory in the channel decreased by approximately $3.6 million during the quarter.

VIVITROL

- Revenues for the quarter were $97.7 million.
- Inventory in the channel decreased by approximately $4.3 million during the quarter.

Manufacturing & Royalty Revenues

- Royalty revenues from INVEGA SUSTENNA®/XEPLION®, INVEGA TRINZA®/TREVICTA® and INVEGA HAFYERA®/BYANNLI® for the quarter were $62.7 million.
- VUMERITY® manufacturing and royalty revenues for the quarter were $31.3 million.

Key Operating Expenses

Please see Note 1 below for details regarding discontinued operations.

(In millions)	Three Months Ended March 31,	
	2024	**2023**
R&D Expense – Continuing Operations	$ 67.6	$ 63.8
R&D Expense – Discontinued Operations	*$ 2.5*	*$ 29.9*
SG&A Expense – Continuing Operations	$ 179.7	$ 167.8
SG&A Expense – Discontinued Operations	*$ -*	*$ 6.6*

- Year-over-year increase in R&D expense related to continuing operations was driven primarily by investment in the ALKS 2680 development program and approximately $3.2 million of non-recurring share-based compensation expenses.
- Year-over-year increase in SG&A expense related to continuing operations was driven primarily by investment in the LYBALVI direct-to-consumer advertising campaign and approximately $6.2 million of non-recurring share-based compensation expenses.

Balance Sheet

At March 31, 2024, the company recorded cash, cash equivalents and total investments of $807.8 million, compared to $813.4 million at Dec. 31, 2023. The company's total debt outstanding as of March 31, 2024 was $290.1 million.

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 March 2024, the company announced the appointment of new independent director Nancy S. Lurker to the company's board of directors.
- In April 2024, the company presented data from its long-term safety study of LYBALVI (olanzapine and samidorphan) at the 2024 Congress of the Schizophrenia International Research Society (SIRS).
- In April 2024, the company announced positive topline results from the narcolepsy type 2 and idiopathic hypersomnia cohorts in its phase 1b study of ALKS 2680, the company's novel, investigational orexin 2 receptor (OX2R) agonist in development as a once-daily treatment for narcolepsy.
- In April 2024, the company announced initiation of the Vibrance-1 phase 2 study of ALKS 2680 in patients with narcolepsy type 1.

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 months ended March 31, 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 Wednesday, May 1, 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. 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; the company's expectations regarding advancement of its development pipeline, including plans and expected timelines for the ALKS 2680 clinical development program; and the therapeutic and commercial potential of ALKS 2680 and the company's other development programs. 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 sustain 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 not agree with the company's regulatory approval strategies; 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 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.

[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 March 31, 2024	Three Months Ended March 31, 2023
Revenues:		
Product sales, net	$ 233,536	$ 214,727
Manufacturing and royalty revenues	116,833	72,862
Research and development revenue	3	6
Total Revenues	350,372	287,595
Expenses:		

Cost of goods manufactured and sold	58,644	58,164
Research and development	67,611	63,770
Selling, general and administrative	179,749	167,833
Amortization of acquired intangible assets	1,059	8,800
Total Expenses	307,063	298,567
Operating Income (Loss)	43,309	(10,972)
Other Income (Expense), net:		
Interest income	9,399	4,966
Interest expense	(5,978)	(5,288)
Other income (expense), net	182	(39)
Total Other Income (Expense), net	3,603	(361)
Income (Loss) Before Income Taxes	46,912	(11,333)
Income Tax Provision	7,964	717
Net Income (Loss) From Continuing Operations	38,948	(12,050)
Loss from Discontinued Operations — Net of Tax	(2,120)	(29,795)
Net Income (Loss) — GAAP	$ 36,828	$ (41,845)
GAAP Earnings (Loss) Per Share - Basic:		
From continuing operations	$ 0.23	$ (0.07)
From discontinued operations	(0.01)	(0.18)
Earnings (loss) per share	$ 0.22	$ (0.25)
GAAP Earnings (Loss) Per Share - Diluted:		
From continuing operations	$ 0.23	$ (0.07)
From discontinued operations	(0.01)	(0.18)
Earnings (loss) per share	$ 0.21	$ (0.25)
Weighted Average Number of Ordinary Shares Outstanding:		
Basic — GAAP	167,984	165,085
Diluted — GAAP	172,981	165,085
Diluted — Non-GAAP	172,981	170,270

Condensed Consolidated Statements of Operations - GAAP (Continued) **(In thousands, except per share data)**	**Three Months Ended March 31, 2024**	**Three Months Ended March 31, 2023**
An itemized reconciliation between net income (loss) from continuing operations on a GAAP basis and EBITDA is as follows:		
Net Income (Loss) from Continuing Operations	$ 38,948	$ (12,050)
Adjustments:		
Depreciation expense	6,997	9,384
Amortization expense	1,059	8,800
Interest income	(9,399)	(4,966)
Interest expense	5,978	5,288
Income tax provision	7,964	717
EBITDA from Continuing Operations	51,547	7,173
EBITDA from Discontinued Operations	(2,516)	(35,992)
EBITDA	$ 49,031	$ (28,819)
An itemized reconciliation between net income (loss) from continuing operations on a GAAP basis and non-GAAP net income is as follows:		
Net Income (Loss) from Continuing Operations	$ 38,948	$ (12,050)
Adjustments:		
Share-based compensation expense	32,755	21,023
Depreciation expense	6,997	9,384
Amortization expense	1,059	8,800
Non-cash net interest expense	114	116
Separation expense	427	3,783
Income tax effect related to reconciling items	(4,121)	(995)
Non-GAAP Net Income from Continuing Operations	76,179	30,061
Non-GAAP Net Loss from Discontinued Operations	(2,120)	(27,645)

Non-GAAP Net Income	$	74,059	$	2,416
Non-GAAP diluted earnings per share from continuing operations	$	0.44	$	0.18
Non-GAAP diluted loss per share from discontinued operations		(0.01)		(0.16)
Non-GAAP diluted earnings per share	$	0.43	$	0.01

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Balance Sheets (In thousands)	**March 31, 2024**		**December 31, 2023**	
Cash, cash equivalents and total investments	$	807,830	$	813,378
Receivables		315,848		332,477
Inventory		198,369		186,406
Contract assets		1,229		706
Prepaid expenses and other current assets		111,539		98,166
Property, plant and equipment, net		224,590		226,943
Intangible assets, net and goodwill		83,959		85,018
Assets held for sale		96,792		94,260
Deferred tax assets		182,536		195,888
Other assets		101,204		102,981
Total Assets	$	2,123,896	$	2,136,223
Long-term debt — current portion	$	3,000	$	3,000
Other current liabilities		455,977		512,678
Long-term debt		287,095		287,730
Liabilities from discontinued operations		—		4,542
Other long-term liabilities		123,061		125,587
Total shareholders' equity		1,254,763		1,202,686
Total Liabilities and Shareholders' Equity	$	2,123,896	$	2,136,223
Ordinary shares outstanding (in thousands)		169,185		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 March 31, 2024, which the company intends to file in May 2024.

Alkermes plc and Subsidiaries
Amounts included in Discontinued Operations

(In thousands)	**Three Months Ended March 31, 2024**
Cost of goods manufactured and sold	$ -
Research and development	2,516
Selling, general and administrative	
Income tax benefit	(396)
Loss from discontinued operations, net of tax	**$ 2,120**

(In thousands)	**Three Months Ended March 31, 2023**
Cost of goods manufactured and sold	$ 11
Research and development	29,867
Selling, general and administrative	6,644
Income tax benefit	(6,727)
Loss from discontinued operations, net of tax	**$ 29,795**

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