Alkermes plc Reports Second Quarter 2022 Financial Results

July 27, 2022

— Second Quarter Revenues of $276.2 Million Reflect Strong Growth in Proprietary Net Sales —

— GAAP Loss per Share of $0.18 and Non-GAAP Earnings per Share of $0.06 —

— Raises Financial Expectations for Full-Year 2022 —

DUBLIN, July 27, 2022 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today reported financial results for the second quarter of 2022 and provided updated financial expectations for full-year 2022.

"In the second quarter, Alkermes continued to execute successfully across the business. VIVITROL® and ARISTADA® both grew year-over-year and sequentially, and LYBALVI® continued on a strong launch trajectory," commented Iain Brown, Chief Financial Officer of Alkermes. "Today, we are pleased to be raising our financial expectations for full-year 2022, primarily due to LYBALVI's launch performance and updated assumptions related to continued royalty revenues on sales of long-acting INVEGA® products outside of the U.S. We believe that we are well positioned to continue to make meaningful progress against our strategic priorities and to drive shareholder value."

Quarter Ended June 30, 2022 Financial Results

Revenues

- Total revenues for the quarter were $276.2 million, compared to $303.7 million for the same period in the prior year.

- Net sales of proprietary products for the quarter were $190.8 million, compared to $160.8 million for the same period in the prior year.

- Net sales of VIVITROL were $96.1 million, compared to $88.4 million for the same period in the prior year, representing an increase of approximately 9%.
- Net sales of ARISTADA[i] were $74.6 million, compared to $72.4 million for the same period in the prior year, representing an increase of approximately 3%.
- Net sales of LYBALVI were $20.1 million, following its commercial launch in October 2021.

- Manufacturing and royalty revenues for the quarter were $85.3 million, compared to $142.3 million for the same period in the prior year.

- Royalty revenues from INVEGA SUSTENNA®/XEPLION®, INVEGA TRINZA®/TREVICTA® and INVEGA HAFYERA®/BYANNLI® (the long-acting INVEGA products) were $26.6 million, compared to $81.1 million for the same period in the prior year. This decrease was driven primarily by Janssen Pharmaceutica N.V.'s (Janssen) partial termination of the license agreement related to sales of the long-acting INVEGA products in the United States (U.S.).
- Manufacturing and royalty revenues from VUMERITY® were $26.2 million, compared to $20.3 million for the same period in the prior year.

Costs and Expenses

- Total operating expenses for the quarter were $310.7 million, compared to $299.3 million for the same period in the prior year, primarily reflecting increased investment to support the commercial launch of LYBALVI.

- Cost of Goods Manufactured and Sold were $58.4 million, compared to $53.1 million for the same period in the prior year.
- Research and Development (R&D) expenses were $92.9 million, compared to $97.5 million for the same period in the prior year.
- Selling, General and Administrative (SG&A) expenses were $150.4 million, compared to $139.2 million for the same period in the prior year.

Profitability

- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was $30.1 million for the quarter, or a basic and diluted GAAP loss per share of $0.18. This compared to GAAP net income of $2.4 million, or a basic and diluted GAAP earnings per share of $0.01, for the same period in the prior year.

- Non-GAAP net income was $10.5 million for the quarter, or a non-GAAP basic and diluted earnings per share of $0.06. This compared to non-GAAP net income of $49.2 million for the quarter, or a non-GAAP basic earnings per share of $0.31 and a diluted earnings per share of $0.30, for the same period in the prior year.

Balance Sheet

- At June 30, 2022, the company recorded cash, cash equivalents and total investments of $760.0 million, compared to $758.7 million at March 31, 2022. The company's total debt outstanding as of June 30, 2022 was $294.5 million.

"Our second quarter results reflect revenue growth from our proprietary commercial portfolio, highlighted by our continued progress in the launch of LYBALVI, a new oral treatment for schizophrenia and bipolar I disorder," said Richard Pops, Chief Executive Officer of Alkermes. "At the same time, we continued to make progress in our development pipeline, highlighted by the presentation of nemvaleukin ARTISTRY-1 data at the 2022 ASCO annual meeting. As we strive to make a meaningful impact on the lives of patients and families, we will continue to focus on execution against our strategic priorities and our commitment to deliver value for our shareholders."

Financial Expectations for 2022

The following updated financial expectations for 2022 primarily reflect LYBALVI's launch performance to date and the company's current assumption that it will continue to receive royalty payments related to sales of the long-acting INVEGA products outside the U.S. through at least October 2022. All line items are according to GAAP, except as otherwise noted.

In millions (except per share amounts)	**Current 2022 Expectation** (Provided 7/27/22)	**Prior 2022 Expectation** (Provided 2/16/22)
Total Revenue	$1,050 – $1,120	$1,000 – $1,090
VIVITROL Net Sales	$365 – $385	$355 – $385
ARISTADA Net Sales	$295 – $315	$290 – $320
LYBALVI Net Sales	$75 – $90	$55 – $75
INVEGA Franchise Royalties*	$95 – $100	$45 – $50
Other revenues	$220 – $230	$255 - $260
Cost of Goods Sold	$215 – $225	$215 – $225
R&D Expenses	$380 – $400	$385 – $415
SG&A Expenses	$575 – $605	$575 – $605
Amortization of Intangible Assets	~$35	~$35
Interest Expense, Net	$5 – $10	$5 – $10
Other Expense, Net	~$15	$0
Income Tax Benefit	$10 – $15	$10 – $15
GAAP Net Loss	($145) – ($175)	($180) – ($210)
GAAP Net Loss per Share+	($0.88) – ($1.07)	($1.10) – ($1.29)
Non-GAAP Net Income (Loss)	$15 – $45	($30) – $0
Non-GAAP Earnings (Loss) Per Share+	$0.09 – $0.27	($0.18) – $0.00
Capital Expenditures	$35 – $40	$35 – $40

*Reflects royalties related to sales of INVEGA SUSTENNA/INVEGA TRINZA/INVEGA HAFYERA in the U.S. through January 2022 and royalties related to sales of XEPLION/TREVICTA/BYANNLI through October 2022.

+ Current 2022 per share expectations are calculated based on a weighted average basic share count of approximately 164.0 million shares outstanding and a weighted average diluted share count of approximately 169.0 million shares outstanding.

Recent Events:

Oncology

- In June 2022, the company presented data from its phase 1/2 ARTISTRY-1 clinical trial for nemvaleukin alfa (nemvaleukin), the company's novel, investigational, engineered interleukin-2 (IL-2) variant immunotherapy, at the American Society of Clinical Oncology (ASCO) Annual Meeting. Trial-in-progress posters from the ongoing ARTISTRY-3 trial and the potential registration-enabling ARTISTRY-6 and ARTISTRY-7 trials were also presented at the ASCO meeting.

Psychiatry

- In May 2022, the company presented research related to its psychiatry portfolio at four scientific conferences. The meetings included: American Telemedicine Association (ATA) Annual Conference, International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Annual Meeting, American Psychiatric Association (APA) Annual Meeting, and American Society of Clinical Psychopharmacology (ASCP) Annual Conference.

Other

- In May 2022, the company announced a series of actions as part of its ongoing commitment to strong corporate governance and regular board refreshment, including the appointment to the company's Board of Directors (the Board) of Christopher I. Wright, M.D., Ph.D., a new, independent director with neuroscience and drug development expertise and the seventh independent director to join the Board in the last three years; the appointment of Nancy J. Wysenski as Lead Independent Director of the Board; and the retirement from the Board of two longer-serving directors, David W. Anstice AO and Wendy L. Dixon, Ph.D.

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, July 27, 2022, 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 will be available from 11:00 a.m. ET (4:00 p.m. BST) on Wednesday, July 27, 2022, through Wednesday, August 3, 2022, and may be accessed by visiting Alkermes' website or by dialing +1 877 660 6853 for U.S. callers and +1 201 612 7415 for international callers. The replay conference ID is 13731319.

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 alcohol dependence, opioid dependence, 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; 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.

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 (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 assumptions regarding royalty payments on sales of the long-acting INVEGA products outside the U.S., its commitment and plans to drive shareholder value, and its ability to execute on its strategic priorities; and the potential therapeutic and commercial value of the company's products. 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's efforts to manage its cost structure may not yield the intended results; the company may not be able to achieve long-term profitability or its profitability targets in a timely manner or at all; the impacts of the ongoing COVID-19 pandemic on the company's business, results of operations or financial condition, including impacts on healthcare systems and on patient and healthcare provider access to the company's marketed products; the unfavorable outcome of arbitration or 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, including the arbitration proceedings with Janssen; 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) may not agree with the company's regulatory approval strategies or components of the company's marketing applications; 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, 2021 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)

[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 June 30, 2022**	**Three Months Ended June 30, 2021**
Revenues:		
Product sales, net	$ 190,787	$ 160,808
Manufacturing and royalty revenues	85,326	142,294
Research and development revenue	106	615
Total Revenues	276,219	303,717
Expenses:		
Cost of goods manufactured and sold	58,360	53,124
Research and development	92,873	97,473
Selling, general and administrative	150,377	139,188
Amortization of acquired intangible assets	9,066	9,511
Total Expenses	310,676	299,296
Operating (Loss) Income	(34,457)	4,421
Other Income, net:		
Interest income	896	623
Interest expense	(2,369)	(2,407)
Change in the fair value of contingent consideration	870	3,240
Other income (expense), net	1,810	(222)
Total Other Income, net	1,207	1,234
(Loss) Income Before Income Taxes	(33,250)	5,655
(Benefit) Provision for Income Taxes	(3,114)	3,291
Net (Loss) Income — GAAP	$ (30,136)	$ 2,364
(Loss) Earnings Per Share:		
GAAP (loss) earnings per share — basic and diluted	$ (0.18)	$ 0.01
Non-GAAP earnings per share — basic	$ 0.06	$ 0.31
Non-GAAP earnings per share — diluted	$ 0.06	$ 0.30
Weighted Average Number of Ordinary Shares Outstanding:		
Basic — GAAP	163,839	160,817
Diluted — GAAP	163,839	163,937
Basic — Non-GAAP	163,839	160,817
Diluted — Non-GAAP	168,706	163,937
An itemized reconciliation between net (loss) income on a GAAP basis and non-GAAP net income is as follows:		
Net (Loss) Income — GAAP	$ (30,136)	$ 2,364
Adjustments:		
Share-based compensation expense	23,377	27,552
Depreciation expense	10,326	8,966
Amortization expense	9,066	9,511
Income tax effect related to reconciling items	(1,383)	3,927
Non-cash net interest expense	117	117
Change in the fair value of contingent consideration	(870)	(3,240)
Non-GAAP Net Income	$ 10,497	$ 49,197

Condensed Consolidated Statements of Operations - GAAP **(In thousands, except per share data)**	**Six Months Ended June 30, 2022**	**Six Months Ended June 30, 2021**
Revenues:		
Product sales, net	$ 362,055	$ 290,771
Manufacturing and royalty revenues	190,496	262,141
License revenue	2,000	1,500
Research and development revenue	213	735
Total Revenues	554,764	555,147
Expenses:		
Cost of goods manufactured and sold	113,519	94,144
Research and development	188,826	189,741
Selling, general and administrative	295,429	264,356
Amortization of acquired intangible assets	18,032	18,917
Total Expenses	615,806	567,158
Operating Loss	(61,042)	(12,011)
Other Expense, net:		
Interest income	1,469	1,487

Interest expense		(4,719)		(6,377)
Change in the fair value of contingent consideration		(18,197)		4,518
Other income (expense), net		4,241		(615)
Total Other Expense, net		(17,206)		(987)
Loss Before Income Taxes		(78,248)		(12,998)
(Benefit) Provision for Income Taxes		(12,209)		7,056
Net Loss — GAAP	$	(66,039)	$	(20,054)
(Loss) Earnings Per Share:				
GAAP loss per share — basic and diluted	$	(0.40)	$	(0.13)
Non-GAAP earnings per share — basic	$	0.18	$	0.42
Non-GAAP earnings per share — diluted	$	0.18	$	0.41
Weighted Average Number of Ordinary Shares Outstanding:				
Basic and diluted — GAAP		163,165		160,229
Basic — Non-GAAP		163,165		160,229
Diluted — Non-GAAP		167,372		163,174

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

Net Loss — GAAP	$	(66,039)	$	(20,054)
Adjustments:				
Share-based compensation expense		41,720		43,003
Depreciation expense		20,557		19,203
Amortization expense		18,032		18,917
Income tax effect related to reconciling items		(2,576)		8,106
Non-cash net interest expense		234		235
Change in the fair value of contingent consideration		18,197		(4,518)
Debt refinancing charge		—		2,109
Non-GAAP Net Income	$	30,125	$	67,001

Condensed Consolidated Balance Sheets (In thousands)	**June 30, 2022**		**December 31, 2021**	
Cash, cash equivalents and total investments	$	759,977	$	765,741
Receivables		245,840		313,193
Inventory		155,608		150,335
Contract assets		16,486		13,363
Prepaid expenses and other current assets		47,090		48,967
Property, plant and equipment, net		337,146		341,054
Intangible assets, net and goodwill		148,884		166,916
Other assets		246,386		224,915
Total Assets	$	1,957,417	$	2,024,484
Long-term debt — current portion	$	3,000	$	3,000
Other current liabilities		435,518		468,286
Long-term debt		291,537		292,804
Contract liabilities — long-term				
Other long-term liabilities		145,038		147,810
Total shareholders' equity		1,082,324		1,112,584
Total Liabilities and Shareholders' Equity	$	1,957,417	$	2,024,484
Ordinary shares outstanding (in thousands)		164,233		161,937

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, 2022, which the company intends to file in July 2022.

2022 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**
Projected Net Loss — GAAP	$	(160.0)	164
Adjustments:			
Share-based compensation expense		93.0	
Depreciation expense		40.0	
Amortization expense		35.0	

Change in the fair value of contingent consideration		18.0	
Income tax effect related to reconciling items		3.0	
Other expense, net		-	
Non-cash net interest expense		1.0	
Projected Net Income — Non-GAAP	$	30.0	169

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

Alkermes Contacts:
For Investors: Sandy Coombs +1 781 609 6377
For Media: Katie Joyce +1 781 249 8927

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