Alkermes plc Reports Second Quarter 2021 Financial Results

July 28, 2021

-- Second Quarter Revenues of $303.7 Million Reflect 23% Growth Year-Over-Year --
-- Diluted GAAP Earnings per Share of $0.01 and Diluted Non-GAAP Earnings per Share of $0.30, Driven by Operational Execution --
-- Company Updates Full-Year 2021 Financial Expectations Based on Strong First Half Performance --

DUBLIN, July 28, 2021 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today reported financial results for the second quarter of 2021 and provided updated financial expectations for full-year 2021.

"Alkermes' strong performance in the second quarter was driven by commercial execution and our focus on profitability. VIVITROL® and ARISTADA® demonstrated robust sequential and year-over-year growth and VUMERITY® continued on an encouraging launch trajectory," commented Iain Brown, Chief Financial Officer of Alkermes. "Today, we are raising our financial expectations for full-year 2021 to reflect this performance and anticipated continued strength in the business. We believe that we are in a sound financial position to execute on our business strategy and efficiently invest in our future potential growth drivers."

Quarter Ended June 30, 2021 Financial Results

Revenues

- Total revenues for the quarter were $303.7 million. This compared to $247.5 million for the same period in the prior year.
- Net sales of proprietary products for the quarter were $160.8 million, compared to $130.4 million for the same period in the prior year.
  - Net sales of VIVITROL were $88.4 million, compared to $71.6 million for the same period in the prior year, representing an increase of approximately 23%.
  - Net sales of ARISTADA[i] were $72.4 million, compared to $58.8 million for the same period in the prior year, representing an increase of approximately 23%.
- Manufacturing and royalty revenues for the quarter were $142.3 million, compared to $116.5 million for the same period in the prior year.
  - Manufacturing and royalty revenues from RISPERDAL CONSTA®, INVEGA SUSTENNA®/XEPLION® and INVEGA TRINZA®/TREVICTA® were $95.5 million, compared to $83.1 million for the same period in the prior year.
  - Manufacturing and royalty revenues from VUMERITY® were $20.3 million, compared to $2.6 million for the same period in the prior year.

Costs and Expenses

- Total operating expenses for the quarter were $299.3 million, compared to $281.2 million for the same period in the prior year.
  - Cost of Goods Manufactured and Sold were $53.1 million, compared to $45.1 million for the same period in the prior year.
  - Research and Development (R&D) expenses were $97.5 million, compared to $94.2 million for the same period in the prior year.
  - Selling, General and Administrative (SG&A) expenses were $139.2 million, compared to $132.0 million for the same period in the prior year.

Profitability

- Net income according to generally accepted accounting principles in the U.S. (GAAP) was $2.4 million for the quarter, or a basic and diluted GAAP earnings per share of $0.01. This compared to GAAP net loss of $29.4 million, or a basic and diluted GAAP loss per share of $0.19, for the same period in the prior year.
- Non-GAAP net income was $49.2 million for the quarter, or a non-GAAP basic earnings per share of $0.31 and a non-GAAP diluted earnings per share of $0.30. This compared to non-GAAP net income of $8.9 million, or a non-GAAP basic and diluted earnings per share of $0.06 for the same period in the prior year.

Balance Sheet

- At June 30, 2021, the company recorded cash, cash equivalents and total investments of $669.4 million, compared to

$627.4 million at March 31, 2021, driven primarily by the company's operating results and changes in working capital. The company's total debt outstanding as of June 30, 2021 was $297.1 million.

Financial Expectations for 2021

The following financial expectations for 2021 are based on recent trends and assume continued improvement in patient access to treatment providers and to the company's commercial products in the second half of the year. If patient access does not improve as anticipated, or if new COVID-19-related disruptions emerge, the company's ability to meet these expectations could be negatively impacted. All line items are according to GAAP, except as otherwise noted.

In millions (except per share amounts)	**Current 2021 Expectation** (Provided 7/28/21)	**Prior 2021 Expectation** (Provided 2/11/21)
Total Revenue	$1,145 – $1,185	$1,100 – $1,170
VIVITROL Net Sales	$330 – $345	$315 – $345
ARISTADA Net Sales	$275 – $290	$260 – $290
LYBALVI® Net Sales	<$10	<$10
Cost of Goods Sold	$195 – $205	$190 – $200
R&D Expenses	$400 – $430*	$400 – $430*
SG&A Expenses	$560 – $590	$570 – $600
Amortization of Intangible Assets	~$40	~$40
Other Expense, Net	$0 – $5	$0
Income Tax Expense	$5 – $10	$0 – $10
GAAP Net Loss	($60) – ($90)	($85) – ($125)
GAAP Net Loss per Share+	($0.37) – ($0.56)	($0.53) – ($0.78)
Non-GAAP Net Income	$85 – $115	$60 – $100
Non-GAAP Diluted EPS+	$0.52 – $0.70	$0.37 – $0.62
Capital Expenditures	~$35	~$40

*R&D expense expectations for 2021 include an anticipated $25 million milestone payment in the third quarter to the former shareholders of Rodin Therapeutics, Inc. related to the expected submission of an investigational new drug application, or equivalent, for ALKS 1140, the first clinical candidate to emerge from the histone deacetylase (HDAC) inhibitor platform acquired by the company in late 2019.

+ The current 2021 per share expectations are calculated based on a weighted average basic share count of approximately 161 million shares outstanding and a weighted average diluted share count of approximately 164 million shares outstanding, as compared to prior expectations of approximately 160 million and 161 million, respectively.

"Our achievements in the second quarter demonstrated continued execution against our strategic priorities. Our strong commercial performance, the FDA approval of LYBALVI and the accumulating data and operational progress in our nemvaleukin immuno-oncology program represent important milestones for the company and provide a meaningful platform to drive future growth," said Richard Pops, Chief Executive Officer of Alkermes. "Guided by our intense focus on value creation, our objectives for the remainder of 2021 are clear: successfully launch LYBALVI; drive the growth of VIVITROL and ARISTADA; advance the clinical development program for nemvaleukin; and invest in our emerging neuroscience and oncology pipeline assets."

Recent Events:

Psychiatry

- In June 2021, the company announced FDA approval of LYBALVI (olanzapine and samidorphan) 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.

Nemvaleukin alfa ("nemvaleukin")

- In June 2021, the company presented updated data from the ARTISTRY clinical development program for nemvaleukin, the company's novel, investigational engineered interleukin-2 (IL-2) variant immunotherapy, at the American Society of Clinical Oncology (ASCO) Annual Meeting. In conjunction with the data presentation at ASCO, the company hosted an investor webcast with ARTISTRY clinical program investigators Valentina Boni, M.D., Ph.D., Medical Oncologist and Principal Investigator at START Madrid at Centro Integral Oncológico Clara Campal and Omid Hamid, M.D., Chief of Research and Immunotherapy at The Angeles Clinic and Research Institute.

Corporate

- In May 2021, the company announced the appointment of Emily Peterson Alva to the company's Board of Directors (the Board). Ms. Alva is an experienced public company board member and a financial, strategic and business advisor to growth companies. Ms. Alva is the fifth new, independent director to join the Board in the past two years.
- In July 2021, the company awarded grants from its Alkermes Inspiration Grants® program to 11 nonprofit organizations

working to address the needs of people living with addiction, serious mental illness or cancer.

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 28, 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 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 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 future financial and operating performance, business plans or prospects, including the expected drivers of future growth and value creation; expectations of continued improvement in patient access to healthcare providers and to the company's commercial products; the potential therapeutic and commercial value of the company's marketed and development products; expectations concerning the company's future development activities, including plans for submission of an investigational new drug application or equivalent for ALKS 1140, advancement of the clinical development program for nemvaleukin and further investment in the company's neuroscience and oncology development pipeline; and expectations concerning the company's commercial activities, including the anticipated launch of LYBALVI. 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; 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 our products or products using our 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 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 the adequacy of the data and other information included in our 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 June 30, 2021**	**Three Months Ended June 30, 2020**
Revenues:		
Product sales, net	$ 160,808	$ 130,415
Manufacturing and royalty revenues	142,294	116,505
Research and development revenue	615	609
Total Revenues	303,717	247,529
Expenses:		
Cost of goods manufactured and sold	53,124	45,053
Research and development	97,473	94,222
Selling, general and administrative	139,188	132,025
Amortization of acquired intangible assets	9,511	9,890
Total Expenses	299,296	281,190
Operating Income (Loss)	4,421	(33,661)
Other Income, net:		
Interest income	623	1,788
Interest expense	(2,407)	(2,122)
Change in the fair value of contingent consideration	3,240	5,900
Other (expense) income, net	(222)	2,337
Total Other Income, net	1,234	7,903
Income (Loss) Before Income Taxes	5,655	(25,758)
Provision for Income Taxes	3,291	3,673
Net Income (Loss) — GAAP	$ 2,364	$ (29,431)
Earnings (Loss) Per Share:		
GAAP earnings (loss) per share — basic and diluted	$ 0.01	$ (0.19)
Non-GAAP earnings per share — basic	$ 0.31	$ 0.06
Non-GAAP earnings per share — diluted	$ 0.30	$ 0.06
Weighted Average Number of Ordinary Shares Outstanding:		
Basic — GAAP	160,817	158,895
Diluted — GAAP	163,937	158,895
Basic — Non-GAAP	160,817	158,895
Diluted — Non-GAAP	163,937	159,275
An itemized reconciliation between net income (loss) on a GAAP basis and non-GAAP net income is as follows:		
Net Income (Loss) — GAAP	$ 2,364	$ (29,431)
Adjustments:		
Share-based compensation expense	27,552	22,846
Depreciation expense	8,966	10,447
Amortization expense	9,511	9,890
Income tax effect related to reconciling items	3,927	877
Non-cash net interest expense	117	167
Change in the fair value of contingent consideration	(3,240)	(5,900)
Non-GAAP Net Income	$ 49,197	$ 8,896

Condensed Consolidated Statements of Operations - GAAP **(In thousands, except per share data)**	**Six Months Ended June 30, 2021**	**Six Months Ended June 30, 2020**
Revenues:		
Product sales, net	$ 290,771	$ 260,141
Manufacturing and royalty revenues	262,141	232,756
License revenue	1,500	—
Research and development revenue	735	852
Total Revenues	555,147	493,749
Expenses:		
Cost of goods manufactured and sold	94,144	92,264
Research and development	189,741	187,501
Selling, general and administrative	264,356	265,397
Amortization of acquired intangible assets	18,917	19,618
Total Expenses	567,158	564,780
Operating Loss	(12,011)	(71,031)
Other (Expense) Income, net:		
Interest income	1,487	4,548

Interest expense		(6,377)		(4,979)
Change in the fair value of contingent consideration		4,518		12,700
Other (expense) income, net		(615)		1,679
Total Other (Expense) Income, net		(987)		13,948
Loss Before Income Taxes		(12,998)		(57,083)
Provision for Income Taxes		7,056		11,002
Net Loss — GAAP	$	(20,054)	$	(68,085)
(Loss) Earnings Per Share:				
GAAP loss per share — basic and diluted	$	(0.13)	$	(0.43)
Non-GAAP earnings per share — basic	$	0.42	$	0.07
Non-GAAP earnings per share — diluted	$	0.41	$	0.07
Weighted Average Number of Ordinary Shares Outstanding:				
Basic and diluted — GAAP		160,229		158,495
Basic — Non-GAAP		160,229		158,495
Diluted — Non-GAAP		163,174		159,151

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

Net Loss — GAAP	$	(20,054)	$	(68,085)
Adjustments:				
Share-based compensation expense		43,003		42,659
Depreciation expense		19,203		21,328
Amortization expense		18,917		19,618
Income tax effect related to reconciling items		8,106		6,797
Non-cash net interest expense		235		334
Debt refinancing charge		2,109		—
Change in the fair value of contingent consideration		(4,518)		(12,700)
Acquisition of IPR&D		—		674
Non-GAAP Net Income	$	67,001	$	10,625

Condensed Consolidated Balance Sheets (In thousands)	**June 30, 2021**		**December 31, 2020**	
Cash, cash equivalents and total investments	$	669,377	$	659,807
Receivables		297,357		275,143
Contract assets		8,793		14,401
Inventory		136,077		125,738
Prepaid expenses and other current assets		57,186		60,662
Property, plant and equipment, net		343,949		350,003
Intangible assets, net and goodwill		186,147		204,064
Other assets		238,683		259,912
Total Assets	$	1,937,569	$	1,949,730
Long-term debt — current portion	$	3,000	$	2,843
Other current liabilities		380,442		435,415
Long-term debt		294,070		272,118
Contract liabilities — long-term		14,167		16,397
Other long-term liabilities		147,988		155,975
Total shareholders' equity		1,097,902		1,066,982
Total Liabilities and Shareholders' Equity	$	1,937,569	$	1,949,730
Ordinary shares outstanding (in thousands)		161,296		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 six months ended June 30, 2021, which the company intends to file in July 2021.

2021 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	$	(75.0)	161	$ (0.47)
Adjustments:				

Share-based compensation expense	90.0			
Depreciation expense	42.0			
Amortization expense	40.0			
Income tax effect related to reconciling items	5.0			
Other (expense) income, net	2.0			
Non-cash net interest expense	1.0			
Change in the fair value of contingent consideration	(5.0)			
Projected Net Income — Non-GAAP	$ 100.0	164	$	0.61

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

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[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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