



Alkermes Plc Reports First Quarter 2020 Financial Results and Provides COVID-19 Related Business Update

April 29, 2020

- **First Quarter Revenues of \$246.2 Million, Primarily Driven by 30% Year-Over-Year Growth of Proprietary Product Net Sales --**
- **Company Reports Diluted GAAP Net Loss per Share of \$0.24 and Diluted Non-GAAP Earnings per Share of \$0.01 --**
- **Company Withdraws Previously Provided 2020 Financial Expectations Due to COVID-19 Uncertainties --**

DUBLIN, April 29, 2020 /PRNewswire/ -- [Alkermes plc](#) (Nasdaq: ALKS) today reported financial results for the first quarter of 2020, and provided commentary related to the impact of the COVID-19 pandemic on the business.

"In the face of the COVID-19 pandemic, Alkermes has adapted our business practices so that we can both continue to operate safely and meet our public health responsibilities. People living with serious mental illness and addiction have an ongoing need for their medicines and care, yet many are facing challenges in accessing their caregivers and the healthcare system," said Richard Pops, Chief Executive Officer of Alkermes. "We immediately mobilized to change the way we do business to protect the health and wellbeing of our employees and maintain business continuity, including preserving our ability to provide uninterrupted supply of the medicines we manufacture. I am grateful and proud of the resiliency and adaptability demonstrated by employees across the company. In the next stage of our response, we are focusing on how we can learn from the challenges posed by this pandemic and be creative in developing new best practices that have the potential to have a lasting positive impact on our business."

"We entered 2020 with clear operational objectives: drive the growth of VIVITROL[®] and ARISTADA[®]; prepare for the potential approval and launch of ALKS 3831; and advance our research and development portfolio, including the clinical development program for ALKS 4230 in oncology. We have made progress against all these objectives and our first quarter results reflect solid commercial execution for our proprietary products," continued Mr. Pops. "We will continue to adapt as needed in this dynamic environment to advance these key priorities. ALKS 4230 and ALKS 3831 represent the next major potential value drivers for the business. The potential of ALKS 4230 continues to be supported by the accumulating clinical data across our studies of both intravenous and subcutaneous administration in monotherapy and combination settings. We look forward to sharing data at a medical meeting later this year. For ALKS 3831, we will be finalizing our commercial launch planning as we approach the November 2020 PDUFA date. ALKS 3831 offers an important opportunity to drive operating leverage and efficiencies related to our existing psychiatry commercial infrastructure and drive long-term profitability."

Quarter Ended March 31, 2020 Financial Highlights

- Total revenues for the quarter were \$246.2 million. This compared to \$223.1 million for the same period in the prior year.
- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was \$38.7 million for the quarter, or a basic and diluted GAAP net loss per share of \$0.24. This compared to GAAP net loss of \$96.4 million, or a basic and diluted GAAP net loss per share of \$0.62, for the same period in the prior year.
- Non-GAAP net income was \$1.7 million for the quarter, or a non-GAAP basic and diluted earnings per share of \$0.01. This compared to non-GAAP net loss of \$26.0 million, or a non-GAAP basic and diluted net loss per share of \$0.17, for the same period in the prior year.

Quarter Ended March 31, 2020 Financial Results

Revenues

- Net sales of proprietary products were \$129.7 million, compared to \$99.5 million for the same period in the prior year.
 - Net sales of VIVITROL were \$78.8 million, compared to \$69.2 million for the same period in the prior year, representing an increase of approximately 14%.
 - Net sales of ARISTADA¹ were \$51.0 million, compared to \$30.3 million for the same period in the prior year, representing an increase of approximately 68%.
- Manufacturing and royalty revenues were \$116.3 million, compared to \$108.9 million for the same period in the prior year.
 - Manufacturing and royalty revenues from RISPERDAL CONSTA[®], INVEGA SUSTENNA[®]/XEPLION[®] and INVEGA TRINZA[®]/TREVICTA[®] were \$82.2 million, compared to \$75.6 million for the same period in the prior year.

Costs and Expenses

- Total operating expenses were \$283.6 million, compared to \$299.1 million for the same period in the prior year.
 - Research and Development (R&D) expenses were \$93.3 million, compared to \$102.6 million for the same period in the prior year.
 - Selling, General and Administrative (SG&A) expenses were \$133.4 million, compared to \$141.2 million for the same period in the prior year.

Balance Sheet

- At March 31, 2020, Alkermes recorded cash, cash equivalents and total investments of \$549.7 million, compared to \$614.4 million at Dec. 31, 2019. Cash on hand at March 31, 2020 significantly exceeded the company's total debt outstanding of \$276.6 million under its term loan, which matures in March 2023.

"Our first quarter results were slightly ahead of expectations, reflecting 30% year-over-year growth in net sales of our proprietary products, and continued focus on advancing our pipeline of novel oncology and neuroscience candidates," commented James Frates, Chief Financial Officer of Alkermes. "Due to the uncertain duration and extent of COVID-19 disruptions to the healthcare system, including patient access to treatment, we cannot reliably estimate the future impact that COVID-19 may have on our business and are withdrawing our 2020 financial expectations at this time. We remain focused on driving the growth of VIVITROL and ARISTADA, advancing our research and development activities, and maintaining disciplined expense management. We believe Alkermes is financially well-positioned, with sufficient capital and liquidity to weather the impacts of this pandemic. We will continue to take proactive steps to help ensure business continuity and advance our business objectives."

Financial Expectations for 2020

Due to uncertainties regarding the impact of the COVID-19 pandemic on Alkermes' operating and financial results, Alkermes withdraws the financial expectations for 2020 set forth in its press release dated Feb. 13, 2020. The company expects that the extent of the impact of COVID-19 on its business will be driven primarily by the severity and duration of the pandemic. While the company has adopted practices to mitigate the impact of COVID-19 disruptions, at this time, it is unable to reasonably estimate the impact of the pandemic on future results.

COVID-19 Update

Protection of Employee Well-Being

- The company has instituted a global remote work policy that will continue until further notice for those employees who can work remotely, including field-based employees. For those manufacturing and lab-based employees who work on critical research and manufacturing tasks, the company has instituted additional equipment, sanitization and physical distancing practices to help protect their health and safety as they continue to advance important research and deliver medicines for patients.

Manufacturing & Supply

- At this time, the company continues to operate its manufacturing facilities in Wilmington, Ohio and Athlone, Ireland and does not anticipate any interruptions in its ability to supply commercial product to the patients that rely on VIVITROL, ARISTADA and the third-party products it manufactures, and investigational product for ongoing clinical trials. Together with its critical supply chain vendors, the company is working to continually assess and mitigate the potential impact of COVID-19 on Alkermes' manufacturing operations.

Supporting Patients & Healthcare Providers

- The company has taken action to support people living with schizophrenia, opioid dependence and alcohol dependence and help assure that they have access to the information, resources and medicines that may assist in their treatment. To support these efforts, the company is:
 - identifying new healthcare providers who are currently available to administer injections of its medicines, including appropriate retail pharmacies and clinics;
 - updating the provider locators on VIVITROL.com and ARISTADA.com with information on these healthcare providers and injection sites; and
 - working closely with healthcare providers, including pharmacies, and payers to help navigate new challenges that may arise for patients in accessing their prescribed medications.
- For the safety of employees and in consideration of national and local guidelines, in mid-March the company suspended all in-person meetings and interactions with the healthcare community for field-based sales personnel. The company remains dedicated to supporting the needs of healthcare providers and patients through virtual interactions.

Research and Development

- **Clinical trials:** The company has been in frequent communication with investigators regarding the impact of the current environment on the conduct of its ongoing clinical trials and is focused on supporting treatment continuity and ensuring patient safety. While COVID-19 has impacted timelines of certain clinical trials, ongoing studies are continuing with the appropriate precautions, managed in consultation with investigators and academic institutions.
- **Regulatory:** At this time, the company continues its regulatory activities relating to ALKS 3831, including preparation for an Advisory Committee meeting in advance of the November 2020 Prescription Drug User Fee Act ("PDUFA") target action date for ALKS 3831.

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, April 29, 2020, 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, April 29, 2020, through Wednesday, May 6, 2020, 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 13701480.

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 and schizophrenia, and a pipeline of product candidates in development for schizophrenia, bipolar I disorder, 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 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 our 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 resilience of the company's business model and its ability to weather the financial impacts of the COVID-19 pandemic and the company's potential to drive long-term profitability and continued revenue growth from its commercial products and royalty streams; the potential therapeutic and commercial value of the company's marketed and development products; the company's expectations regarding the impact of COVID-19 on its business; the company's expectations regarding its ability to adapt its business to the evolving COVID-19 pandemic, mitigate its impacts on the business and maintain business continuity, including its ability to protect the safety and well-being of its employees, to continue to operate its manufacturing facilities and support uninterrupted supply of its medicines and healthcare provider access to such medicines, to continue its ongoing clinical trials and other development activities, and to otherwise advance its business objectives; expectations concerning future regulatory activities including the U.S. Food and Drug Administration's ("FDA") target PDUFA action date for, and potential approval of, the NDA for ALKS 3831 and preparations for interactions with the FDA in advance thereof; expectations concerning future development activities, including accumulating data in the ALKS 4230 clinical development program in support of its potential and plans to present such data at a medical meeting; and expectations concerning the company's commercial activities, including preparations for the potential launch of ALKS 3831. 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 impacts of the COVID-19 pandemic and efforts to mitigate its spread on the company's business, results of operations or financial condition, including impacts on the vendors or distribution channels in its supply chain, impacts on its ability to continue to manufacture its products, impacts on its ability to continue its discovery activities, impacts on the conduct of its clinical trials, including with respect to enrollment rates, availability of investigators and clinical trial sites or monitoring of data, impacts on healthcare systems that serve people living with opioid dependence, alcohol dependence and schizophrenia and on patient and healthcare provider access to the company's medicines, impacts on the regulatory agencies with which the company interacts in the development, review, approval and commercialization of its medicines, impacts on reimbursement for its products, including its Medicaid rebate liability, and for services related to the use of its products, and impacts on the U.S., Irish and/or global economies more broadly; the unfavorable outcome of litigation, including so-called "Paragraph IV" litigation and other patent litigation, related to any of the company's products or products using the company's proprietary technologies, which may lead to competition from generic drug manufacturers; 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 regulatory filings, including the company's clinical trial designs, conduct and methodologies and the adequacy of the data included in its filings to support the FDA's requirements for approval of the proposed indications; clinical development activities may not be completed on time or at all; the results of the company's clinical development activities may not be positive, or predictive of real-world results or of results in subsequent clinical trials; regulatory submissions may not occur or be submitted in a timely manner; 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 governmental payers; the FDA or regulatory authorities outside the U.S. may make adverse decisions regarding the company's products; 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 most recent Annual Report on Form 10-K 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® and ARISTADA INITIO® are registered trademarks of Alkermes Pharma Ireland

Limited; and RISPERDAL CONSTA[®], INVEGA SUSTENNA[®], XEPLION[®], INVEGA TRINZA[®] and TREVICTA[®] are registered trademarks of Johnson & Johnson

(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 March 31, 2020	Three Months Ended March 31, 2019
Revenues:		
Product sales, net	\$ 129,726	\$ 99,481
Manufacturing and royalty revenues	116,251	108,915
Research and development revenue	243	14,706
Total Revenues	<u>246,220</u>	<u>223,102</u>
Expenses:		
Cost of goods manufactured and sold	47,211	45,361
Research and development	93,279	102,570
Selling, general and administrative	133,372	141,220
Amortization of acquired intangible assets	9,728	9,952
Total Expenses	<u>283,590</u>	<u>299,103</u>
Operating Loss	<u>(37,370)</u>	<u>(76,001)</u>
Other Income (Expense), net:		
Interest income	2,760	3,570
Interest expense	(2,857)	(3,500)
Change in the fair value of contingent consideration	6,800	(22,600)
Other expense, net	(658)	(1,721)
Total Other Income (Expense), net	<u>6,045</u>	<u>(24,251)</u>
Loss Before Income Taxes	<u>(31,325)</u>	<u>(100,252)</u>
Income Tax Provision (Benefit)	<u>7,329</u>	<u>(3,854)</u>
Net Loss — GAAP	<u>\$ (38,654)</u>	<u>\$ (96,398)</u>
(Loss) Earnings Per Share:		
GAAP loss per share — basic and diluted	<u>\$ (0.24)</u>	<u>\$ (0.62)</u>
Non-GAAP earnings (loss) per share — basic and diluted	<u>\$ 0.01</u>	<u>\$ (0.17)</u>
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and diluted — GAAP and Non-GAAP	<u>158,095</u>	<u>156,336</u>
Basic — Non-GAAP	<u>158,095</u>	<u>156,336</u>
Diluted — Non-GAAP	<u>159,038</u>	<u>156,336</u>
An itemized reconciliation between net loss on a GAAP basis and non-GAAP net income (loss) is as follows:		
Net Loss — GAAP	\$ (38,654)	\$ (96,398)
Adjustments:		
Share-based compensation expense	19,812	24,616
Depreciation expense	10,881	9,690
Amortization expense	9,728	9,952
Income tax effect related to reconciling items	5,920	2,972
Non-cash net interest expense	167	169
Change in the fair value of warrants and equity method investments	—	433
Acquisition of IPR&D	674	—
Change in the fair value of contingent consideration	(6,800)	22,600
Non-GAAP Net Income (Loss)	<u>\$ 1,728</u>	<u>\$ (25,966)</u>

Condensed Consolidated Balance Sheets (In thousands)	March 31, 2020	December 31, 2019
Cash, cash equivalents and total investments	\$ 549,738	\$ 614,370
Receivables	246,716	257,086
Contract assets	14,199	8,386
Inventory	109,314	101,803
Prepaid expenses and other current assets	46,361	59,716
Property, plant and equipment, net	362,539	362,168

Intangible assets, net and goodwill	233,788	243,516
Other assets	263,291	158,358
Total Assets	\$ 1,825,946	\$ 1,805,403
Long-term debt — current portion	\$ 2,843	\$ 2,843
Other current liabilities	337,006	388,269
Long-term debt	273,751	274,295
Contract liabilities — long-term	21,156	22,068
Other long-term liabilities	128,172	32,486
Total shareholders' equity	1,063,018	1,085,442
Total Liabilities and Shareholders' Equity	\$ 1,825,946	\$ 1,805,403
Ordinary shares outstanding (in thousands)	158,685	157,779

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 months ended March 31, 2020, which the company intends to file in April 2020.

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