



Alkermes Announces Receipt of Notices of Partial Termination From Janssen Pharmaceutica

November 8, 2021

-- Investor Conference Call Scheduled for Today at 5:00 p.m. ET

DUBLIN, Nov. 8, 2021 /PRNewswire/ -- [Alkermes plc](#) (Nasdaq: ALKS) today announced that it received notices of partial termination (the "Notices") in respect of two license agreements with Janssen Pharmaceutica N.V. ("Janssen"), a subsidiary of Johnson & Johnson and, under these agreements, a licensee and recipient of Alkermes' nanoparticulate formulation technology, known as NanoCrystal[®] technology. The terminations impact know-how royalties related to sales of long-acting paliperidone products, such as INVEGA SUSTENNA[®] and INVEGA TRINZA[®], and other products in the United States. Pursuant to the agreements, the partial termination is to become effective three months from the date of receipt of the Notices. Janssen maintains that it has not utilized, and does not utilize, Alkermes' NanoCrystal technology licensed under the agreements. Alkermes strongly disagrees with Janssen's position and will explore all options at its disposal to enforce its contractual rights and address any unauthorized use of its intellectual property.

"For years, Janssen has highlighted the use of our NanoCrystal[®] technology in its long-acting INVEGA[®] products and has paid us know-how royalties consistent with this fact. We are not aware of any changes that have occurred to these products that would have altered their use of our intellectual property. We will continue our efforts to engage with Janssen to explore if a mutually agreeable resolution can be reached and will consider all options to enforce our contractual and intellectual property rights," said Richard Pops, Chief Executive Officer of Alkermes. "Over the last several years, we have been engineering the business to become less reliant on revenues from partnered products. For the expected growth drivers within our commercial portfolio – LYBALVI[®], ARISTADA[®], VIVITROL[®] and VUMERITY[®] – nothing has changed. We are energized by the opportunities in our pipeline and remain focused on advancing the assets that we believe will drive the future growth of the business and value for our shareholders."

"With the exception of VUMERITY, royalty revenue streams have become less core to Alkermes' growth. We had been planning for a wind down of the Janssen royalty payments in the coming years and, while the potential earlier loss of these royalty streams will adversely impact our cash flow over the next few years, our long-term outlook remains unchanged," stated Iain Brown, Chief Financial Officer of Alkermes. "We do not expect any impact on our 2021 financial results related to these events. As we look ahead to 2022, we will incorporate any necessary changes from these developments when we provide our financial expectations for the year in February. We will continue to focus on driving operational efficiencies and managing expenses across the business, and we believe we are well-positioned to advance our business objectives and drive profitable growth in the business in the long-term."

Conference Call

Alkermes will host a conference call and webcast at 5:00 p.m. ET (10:00 p.m. GMT) on Monday, Nov. 8, 2021. 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 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.

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 the expected impacts of the partial terminations by Janssen, the company's continued focus on operational efficiencies and managing expenses across the business, and the company's ability to deliver, and the expected drivers of, growth, profitability and value creation; the potential therapeutic and commercial value of the company's marketed products and development pipeline; and the company's plans to explore all options to enforce its contractual rights and address any unauthorized use of its intellectual property. 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 unfavorable outcome of 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; 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; 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 FDA or regulatory authorities outside the U.S. may make adverse decisions regarding the company's products; whether LYBALVI will be commercialized successfully; 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.

VIVITROL® is a registered trademark of Alkermes, Inc.; ARISTADA®, LYBALVI® and NanoCrystal® are registered trademarks of Alkermes Pharma Ireland Limited; INVEGA®, INVEGA SUSTENNA® and INVEGA TRINZA® are registered trademarks of Johnson & Johnson Company; and VUMERITY® is a registered trademark of Biogen MA Inc., used by Alkermes under license.

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