

Regulated information – inside information

Nazareth (Belgium)/Rotterdam (The Netherlands), 23 Dec 2024 – 7AM CET

Fagron updates on FDA communication regarding the June 2024 inspection at Wichita

Following the FDA's routine inspection at Fagron's Wichita facility conducted in June 2024, the Company received a warning letter from the FDA (Warning Letter) on December 19, 2024.

The Warning Letter requires Fagron to enhance processes for investigating discrepancies, and validations of future manufacturing capacity. The majority of these improvements have already been addressed, and Fagron is collaborating with the FDA to clarify any outstanding items and achieve a satisfactory resolution.

After the June inspection, the Company responded to the FDA on July 19, August 30, September 27, October 25, and November 22, 2024 addressing the Agency's observations. Additionally, on August 15, 2024, out of an abundance of caution, the Company initiated a voluntary, class 2, batch-specific recall in good faith with the Agency. Fagron has not received any adverse events related to this recall, and there has been no material impact on the business.

Fagron's top priority is providing safe and effective sterile drug products to our customers and their patients. We are very confident in our robust systems and the quality and safety of the products we produce. Against the backdrop of elevated regulatory requirements, we remain close to our customers and partners to collectively enhance quality standards across the industry.

Management will host a conference call for investors and analysts to address any questions on December 23, 2024 at 09:30am CET. Dial in details are as follows:

Dial in numbers

USA Local: +1 786 697 3501
USA Toll Free: 866 580 3963
Brussels: +32 (0) 2 789 8603
Belgium Toll Free: 0800 746 68
Berlin: +49 (0) 30 3001 90612
Amsterdam: +31 (0) 20 708 5073
Netherlands Toll Free: 0 800 022 9132
UK Toll Free: 0808 109 0700

Further information

Karin de Jong
Chief Financial Officer
investors@fagron.com

About Fagron

Fagron is a leading global company active in pharmaceutical compounding, focusing on delivering personalized medicine to hospitals, pharmacies, clinics and patients in more than 30 countries around the world.

Belgian company Fagron NV has its registered office in Nazareth and is listed on Euronext Brussels and Euronext Amsterdam under the ticker symbol 'FAGR'. Fagron's operational activities are managed by the Dutch company Fagron BV, which is headquartered in Rotterdam.



Important information regarding forward-looking statements

Certain statements in this press release may be deemed to be forward-looking. Such forward-looking statements are based on current expectations and are influenced by various risks and uncertainties. Consequently, Fagron cannot provide any guarantee that such forward-looking statements will, in fact, materialize and cannot accept any obligation to update or revise any forward-looking statement as a result of new information, future events or for any other reason.

In the event of differences between the English translation and the Dutch original of this press release, the latter prevails.