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EKF Diagnostics Holdings PLC  
26 October 2023

## **RNS Reach**

### **EKF Diagnostics Holdings plc** ("EKF", the "Company" or the "Group")

#### **Opening of new US State-of-the-art Life Science Manufacturing Facility**

*Unique GMP capabilities, addresses a significant gap in the US market for scalable mid-volume manufacturing*

EKF Diagnostics Holdings plc (AIM: EKF), the AIM-listed global diagnostics business, announces the official opening of its new state-of-the-art Life Sciences manufacturing site in South Bend, Indiana, United States, one of the US's major Life Sciences and industrial centres/hubs.

EKF Life Sciences is a specialist global manufacturer of high-quality enzymes and custom products for use in diagnostic, pharmaceutical and industrial applications. The Company is at the forefront of supporting life sciences global demand in precision fermentation, enzyme applications and research, providing innovative biotechnology solutions to deliver breakthrough discoveries and advancements in healthcare and medicine.

The Company's state-of-the-art facilities and leading technical expertise in specialist enzyme production uses precision microbial fermentation and cutting-edge downstream processes, to isolate and deliver the highest quality enzymes and biomolecules that have been specially engineered to customer specifications.

The new 24,000 square foot state-of-the-art facility addresses a significant gap in the US market for mid-volume manufacturing and will enable EKF to meet the increasing demands of its growing customer base. As part of its investment programme, EKF has installed 10L, 65L, 300L, 1,500L, 3,000L and 14,500L units as well as key upstream and downstream process capabilities at its South Bend plant. The cutting-edge, intelligent design of the Group's modular platform includes bioreactors ranging from 5L to 14,500L to enable it to deliver an end-to-end service from bench/proof-of-concept through to full scale commercial production. This efficient and scalable platform allows

multiple batch cycles to run in parallel, enabling greater process control and precision to deliver effectively the desired yields.

The South Bend site is currently operating with full fermentation capabilities and is also expected to have all downstream processing capabilities fully operational by December 2023. As previously announced, the Company has already received the first purchase order for precision fermentation services for the new facility and has a strong contract pipeline, with onboarding underway for a number of existing OEM customers and the potential to develop into long-term strategic partnerships. During 2024, the Company expects to see a steady build-up of revenues generated from this new capacity and, as contracts scale-up, EKF Life Sciences is expected to deliver substantial, long-term sustainable growth.

The South Bend site is located in close proximity to the Company's existing 20,000 square foot facility in Elkhart. Both sites operate to the highest regulatory standards under cGMP (current Good Manufacturing Principles), ISO 9001 and ISO 13485 Quality Program.

**Julian Baines, Executive Chair, commented:** *"I'm delighted to announce the opening of our new state-of-the-art manufacturing facility in South Bend. The increased application of specialty enzymes is driving the demand for precision fermentation services and in the US market there is a large gap for specialist mid-volume, scalable manufacturing services. We believe EKF is the only Company in the US with the GMP capabilities and unique technical expertise to provide scalable, mid-volume manufacturing from 5L to 14,500L, so we are well placed to meet the distinctive needs of our growing customer base. This is a very exciting opportunity for EKF and we expect it to deliver significant long-term revenue growth."*

**EKF Diagnostics Holdings plc**

Julian Baines, Executive Chair

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## **About EKF Life Sciences**

EKF Life Sciences is a specialist global manufacturer of high-quality enzymes and custom products for use in diagnostic, pharmaceutical, and industrial applications.

EKF Life Sciences is at the forefront of supporting global demand in precision fermentation, enzyme applications and research, providing innovative

biotechnology solutions to deliver advancements in healthcare and medicine.

Utilising its unique technical expertise, the EKF Life Sciences uses precision microbial fermentation and advanced downstream processes to isolate and deliver the highest quality enzymes and biomolecules that have been specially engineered to customer specifications.

EKF Life Sciences has two state-of-the-art GMP manufacturing facilities, located within close proximity, in Elkhart and South Bend Indiana, one the US's major life sciences and industrial hotspots. It operates to the highest regulatory standards under cGMP principles, FDA certification and ISO 13485 Quality Program. The facilities include bioreactors ranging from 5L to 14,500L, enabling it to offer an end-to-end service from bench/proof-of-concept through to full scale commercial production, providing its customers with desired yields, precision at scale and cost-efficiency.

EKF Lifesciences is also one of the market leaders for the supply of  $\beta$ -HB, a reagent used to detect ketones for patients suffering from diabetic ketoacidosis, as well as many other clinical applications.

**About EKF Diagnostics Holdings plc** ([www.ekfdiagnostics.com](http://www.ekfdiagnostics.com))

EKF is an AIM-listed global diagnostics business focussed on:

- **Point-of-Care** analysers in the key areas of Hematology and Diabetes, as well as Central Laboratory products including clinical chemistry reagents, analysers and centrifuges.
- **Life Sciences** services provide specialist manufacture of enzymes and custom products for use in diagnostic, food and industrial applications, as well as other higher value Contract Manufacturing services.

EKF has headquarters in Penarth (near Cardiff) and operates five manufacturing sites across the US and Germany, selling into over 120 countries world-wide.

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33862673 A Thu, 10/26/2023 - 07:00 LSE RNS Company Announcement - General EKF