



PRESS RELEASE

Indigo Diabetes Business Update

- *SHINE clinical trial enrolment progressing well following positive results from the GLOW early feasibility trial*
- *Several key senior appointments made in Europe and the US, reflecting the growth and evolution from an early stage to a development stage organisation with clinical proof of concept*

BELGIUM – Ghent, 4 January 2023 – Indigo Diabetes N.V. ('Indigo' or the 'Company'), a pioneering developer of Continuous Metabolite Monitoring (CMM™) devices utilising proprietary nanophotonics technology, today provides an update on recent and ongoing business activities.

Indigo is developing a fully implantable CMM system for people living with diabetes to access accurate information on their glucose, ketones and lactate levels. The CMM sensor is inserted subcutaneously, avoiding the need for people with diabetes to wear an external device on their body. It is designed to give people living with diabetes and their caregivers instant access to the augmented metabolic information they need to better manage their diabetes and improve therapeutic decision-making.

Clinical study progress

In September 2022, Indigo announced the enrolment of the first participant in the SHINE clinical trial at the Antwerp University Hospital, Belgium. SHINE is designed to evaluate the longer-term stability of Indigo's continuous multi-metabolite ('CMM') device. This represented the first of up to 15 participants to be recruited in the trial across Belgium, France and Slovenia, the latter two sites of which are due to start enrolment in Q1 2023.

The GLOW clinical trial was a prospective, single-center early feasibility study conducted at the Antwerp University Hospital, Belgium to evaluate the safety of Indigo's CMM sensor and its short-term integration into the tissue. Data was collected from the seven trial participants (three healthy subjects, and four subjects with type 1 diabetes) and the results have helped progress the development of the device to allow real-time, continuous measurement of glucose, ketone, and lactate levels in adults with diabetes. The full GLOW trial results have recently been submitted to a peer reviewed journal.

Towards the end of 2022 Indigo received the ISO 13485:2016 medical recertification from TÜV SÜD for the provision of its design and development of biomarker sensing devices and services. This achievement is a significant milestone for Indigo highlighting the suitability of the Company's Quality Management System and its commitment to quality. ISO 13485:2016 is an internationally recognised quality standard specific to the medical device industry that ensures the quality of medical devices.

Key appointments

A number of senior hires were made during 2022 taking the total headcount to 45, reflecting the ongoing growth of the business and evolution from an early stage to a development stage organisation with clinical proof of concept.

In October, Indigo appointed Peter Devlin as President of Indigo Medical US Inc, establishing its presence in the US, a market that it has identified as having significant potential for its CMM devices.



Peter, who is based in Boston, is managing and overseeing Indigo Medical's activities. His focus is on accelerating product development for the Company's CMM devices, driving business development, and facilitating talent acquisition in the US.

Another key hire was made in May, with the appointment of Emmet Lydon as Chief Operating Officer. Emmet brings more than 30 years of experience working as a senior leader operating in a multinational life sciences environment with extensive experience in Asia, North America and Europe.

In addition, Indigo appointed Michael Malecha as VP, Digital. Michael now leads the software team, developing digital strategies for Indigo's CMM device.

Dr. Danaë Delbeke, CEO, Inventor and Co-founder of Indigo Diabetes, commented: *"2022 was a great year for the team at Indigo where we achieved a number of key milestones including the enrollment of the first participant in the SHINE trial and establishing our presence in the US. We look forward to the year ahead where we continue to work towards our mission to provide an innovative, accurate and convenient monitoring solution to light up the life of millions of people living with diabetes."*

Dr. Danaë Delbeke, CEO and Peter Devlin, President of Indigo Diabetes will be visiting San Francisco in January at the time of the 41st JP Morgan Healthcare conference and are currently arranging meetings with investors and partners. Please contact the company directly if you would like to arrange a meeting.

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Contacts

Indigo Diabetes N.V.

Dr Danaë Delbeke, CEO

Email: info@indigomed.com

Consilium Strategic Communications

Ashley Tapp, Alexandra Harrison

Tel: +44 (0)20 3709 5700

Email: indigodiabetes@consilium-comms.com

About Indigo Diabetes N.V.

Indigo Diabetes N.V. (Indigo) is a pioneering developer of medical devices that utilise proprietary nanophotonics technology. Indigo was founded by Danaë Delbeke and her team in 2016. Today Indigo is developing the world's first subcutaneously inserted sensor for people living with diabetes to address their need for continuous accurate glucose, ketone and lactate monitoring with nothing worn on the body. Indigo utilizes ground-breaking photonics technology to transform diabetes management. Indigo is based in Ghent, Belgium. Find out more at www.indigomed.com.

About Indigo Diabetes's CMM™ sensor

Indigo Diabetes's CMM™ sensor is the world's first, subcutaneously inserted evanescent field sensor to measure multiple metabolites *in vivo* simultaneously and continuously. The inert, miniature



integrated silicon photonics chip measures the absorption of light in interstitial fluid to quantify the concentration of a broad range of metabolites simultaneously without the use of enzymes or fluorophores. Once inserted under the skin the CMM sensor is invisible to the naked eye and will connect securely and wirelessly to mobile devices to show and capture the concentration profiles of the metabolites for the user. A rechargeable sensor battery powers the measurements. It is expected that the sensor will have a lifetime up to 2 years. Preclinical studies have successfully demonstrated proof of concept with promising accuracy with GLOW early feasibility study results providing further validation.