Transdermal Diagnostics

Revolutionary technologies to transform the diagnosis, monitoring and prevention of disease

Executive Summary

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Company Name: Transdermal Diagnostics Ltd. **Company Number:** 13566819

Sector: Medical Diagnostics/ Non-invasive Continuous Glucose Monitoring

Company:

Transdermal Diagnostics (TD) is a MedTech start-up dedicated to developing and commercialising innovative technologies to monitor disease biomarkers continuously. We aim at reinventing patient care, leading the commercialisation of pioneering medical devices to improve the diagnosis, management and prevention of diseases and to enhance healthcare outcomes. Currently, we are developing the world's first 100% needle-free (and pain-free) device to help people with diabetes continuously monitor their blood sugar levels.

Management Team:

Dr Luca Lipani: Co-founder & CEO. Innovator, expert in biosensing and non-invasive medical devices. Interdisciplinary background from nanotechnology and (electro)chemistry to real-world applications.

Dr Adelina Ilie: Co-founder & CSO. Inventor and physicist, leader in functional nanomaterial design. Decades of experience leading teams researching and implementing new nanotechnologies.

Prof Richard Guy: Co-founder & Director. Pharmaceutical scientist with life-long expertise in skin barrier function. Pioneer in transdermal monitoring.

Advisors:

Dr Ben Miles: Commercial Advisor & NED. CEO of Spin Up Science. Co-founder of the Science Angel Syndicate. Serial entrepreneur and University spinout specialist. He has helped launch 40+ Deep Technology companies in the UK.

Prof Chris Jones: Product Development Advisor & NED. Over 30 years of experience in the pharmaceutical industry. Formerly a global executive at Astra-Zeneca. NED of Rosa Biotech and Halo Therapeutics.

Dr Philip Brown: NED. Head of Technology Transfer at the University of Bath, he has supported the technology from its inception and has a good understanding of the market.

Dr Marc Atkins: Clinical Advisor. Diabetes clinical lead. Marc has been the clinical lead for developing an integrated diabetes care service in the UK.

Dr Donald de Korte: Regulatory Advisor. CEO at HALO Research & Technology. Medical Doctor with 30+ years experience in clinical research, regulatory affairs, and marketing of pharmaceuticals and medical devices in global health organisations, including IDF.

Dr Mohammad Golbabaee: Technical Advisor. University of Bath academic. Expert in developing Artificial Intelligence (AI) algorithms, biomedical signal/image processing and compressed sensing.

Innovation:

TD's innovation is a technology platform for the transdermal extraction, using reverse iontophoresis, of interstitial fluid bathing the skin cells via skin appendages (e.g., hair follicles), and in-situ monitoring/co-monitoring of one or several biologically relevant substances. The first application focuses on glucose (and co-analytes).

Product:

Our key product is the first entirely non-invasive and calibration-free continuous glucose monitoring (CGM) device for people with diabetes. The device is wearable and consists of a disposable adhesive skin patch, with an in-built miniaturised array of sensing units, connected to a non-disposable, rechargeable electronic transmitter. The array of multiple sensors ensures calibration-free and increased measurement accuracy by exploiting multiple channels of data. The transmitter communicates wirelessly to dedicated software (including a mobile app) that processes the signals and then displays regular and real-time glucose readings, keeping records over days, weeks and months. The game-changing concept is a wearable CGM device for diabetes management that is user-friendly, 100% needle-free, permits flexible usage, and is competitively affordable (~£2 per daily disposable).

We believe this technology will be adopted by both insulin-injecting and non-insulin-dependent individuals with diabetes, who are already performing multiple daily finger sticks for BG management, and by the population at high risk of progressing towards diabetes, who will use the device as a diagnostic/screening tool.

Intellectual property:

TD's core intellectual property is International Patent Application WO2017-186783, "Multiplexed Transdermal Extraction and Detection Devices for Non-Invasive Monitoring of Substances and Methods of Use"; co-inventors: R. Guy, A. Ilie, L. Lipani, F. Dougmene and B. Dupont. The patent has been granted in the US and Japan and is pending in Europe, Canada and China. The University of Bath granted a royalty-free exclusive licence to Transdermal Diagnostics; all the IP rights will be assigned to Transdermal after raising an equity financing of £1 million in aggregate.

Market:

Blood glucose (BG) monitoring is required in diabetes management and the market is segmented into blood glucose test strips (BGT) and continuous glucose monitors (CGM). In 2021, the BGT market was $10B with a CAGR estimated at >7% over 6 years [Mordor Intelligence]; major players include Abbott, Roche, Lifescan etc. Income from CGM was $4B with a CAGR estimated at >14% from 2022 to 2027 [Mordor Intelligence]; Dexcom, Abbott and Medtronic dominate this market. Invasive CGMs target people with Type 1 diabetes and are presently used by ca. 5 M patients worldwide.

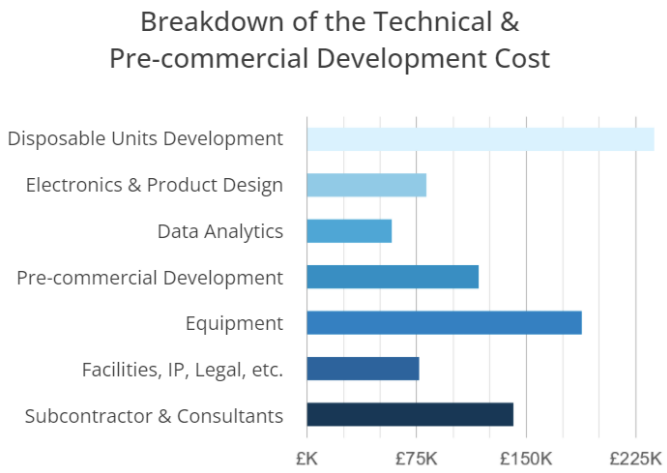
TD's innovation intersects BGT and CGM and is uniquely positioned to exploit this market opportunity and disrupt healthcare provision for T1D, T2D and the at-risk pre-diabetic population. Bottom-up calculations estimate TD's Serviceable Obtainable Market (SOM) at more than £1.4B.

Competition:

Abbott, Dexcom and Medtronic are established needle-based CGM competitors. These devices require implantation into the skin, following which they work for 14 days; the products are expensive and specifically target Type 1 diabetics using insulin pumps. Emerging technologies include Nemaura's SugarBEAT, which requires a finger prick blood sample calibration, has a short operational time, and is prone to inducing skin irritation; devices based on sweat (Graphwear), tear (NovioSense) or saliva (Nutrix) analysis do not satisfy accuracy standards, provide false readings and, typically, only single-point measurements; microneedle technology (e.g., Biolinq) is yet to satisfy safety concerns around repetitive skin disruption over larger areas. Transdermal Diagnostics is the best all-rounder, demonstrating clear competitive advantages including affordability, non-invasiveness, flexible usage, high accuracy, and a much broader pool of users, namely people with Type 1-, Type 2- and pre-diabetes.

Funding Needed:

TD has been awarded a ~£300,000 grant from Innovate-UK and is seeking a minimum equity investment of £600,000 for an 18-month development programme, the breakdown cost of which is shown in the bar chart below. This programme will create a robust and optimised portable device and deliver prototype disposable units, a prototype portable transmitter, preliminary human trials and business development. Subsequently, TD will enter the productisation phase which includes electronics miniaturisation, product design and integration, software and mobile app realisation and further pre-clinical trials. Scaled-up production, controlled clinical trials and regulatory approval will then follow.



Financial Projections:

Transdermal Diagnostics plans to enter the EU+, UK and US markets in 2027 following CE/UKCA/FDA certifications. Total revenue is projected at more than £200M, five years after market entry, with a net profit margin close to 70%; this is based on a market penetration of 0.2% corresponding to a pool of 200,000 end-users, a number in line with companies in the glucose monitoring arena at a similar age.

Likely exit is acquisition within 8 years by a large player in the diabetes market (e.g., Abbott, Dexcom, Medtronic) or technology companies with existing and growing interest in 'wearables' (e.g., Samsung, Apple, Google and Huawei).