Presents

VEWS®

Vascular Early Warning System

VEWS® is a registered trademark of Dialog Devices Ltd.

Non-confidential

Information Memorandum

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THE OPPORTUNITY

- Dialog Devices is a medical device company with a novel, CE marked, optoelectronic diagnostic device - VEWS, the Vascular Early Warning System - for automated detection of peripheral arterial disease (PAD)
- The next exciting steps for VEWS are:
  - launch within Europe,
  - regulatory clearance and launch in the USA and major markets globally, and
  - rapid development and launch of further products exploiting the VEWS technology
- A trade sale is being sought to maximise the commercial return for VEWS
- This opportunity will be of interest to Medtech wishing to expand their portfolio or to Pharma wanting to augment a cardiovascular franchise

MARKET SUMMARY

- PAD has an overall prevalence of 9% to 23% among people 55 years and older
  - 5 – 12 million people in the USA
  - 6 – 16 million people in Western Europe
- VEWS can reliably detect PAD in **all patients** including those with incompressible arteries. For example:
  - Diabetics are at high risk of developing PAD. Up to 35% of diabetics have incompressible arteries. VEWS allows routine monitoring of diabetic patients and detection of PAD before foot and leg problems occur
  - VEWS can be used to monitor patients undergoing renal dialysis and to detect PAD before the onset of obvious foot or leg problems
- VEWS can be used to screen patients with swollen and/or ulcerated legs without significant discomfort
- Patients with PAD have other vascular problems, including a 5 fold increase of heart attack or stroke
- Up to 75% of PAD is asymptomatic or symptoms are unrecognised: VEWS offers the potential for early diagnosis and institution of secondary prevention measures –including therapeutic intervention

THE PRODUCT

- VEWS employs optoelectronic technology to provide fast, reproducible and automated detection of PAD
- VEWS is simple to use, does not require a trained specialist and results are operator-independent
- VEWS has high sensitivity and specificity for detecting PAD as confirmed by the gold standard method of colour duplex ultrasound (CDU) or magnetic resonance angiography (MRA) in clinical trials
- VEWS provides accurate results in patients with highly calcified arteries, including diabetics and patients with renal insufficiency
- VEWS is capable of detecting mild disease since it measures blood flow in the microvasculature
- VEWS is patent protected in key territories with substantial scope for further applications

THE VEWS FAMILY

- The optoelectronic technology used in VEWS can be harnessed to produce a range of products with or without additional capabilities:
  - PAD measurement only, using toe & dorsum sensors or toe sensors alone
  - PAD and other arterial measurements, such as pulse wave velocity (PWV) or pulse contour analysis (PCA)
  - PAD and venous investigations
- A range of products will allow for differential pricing in different markets and maximise return

MARKET POTENTIAL

PAD is the narrowing/blockage of arteries due to build-up of plaque inside arteries resulting in reduced blood flow. It has an overall prevalence of 9% to 23% among people 55 years and older, equating to **5 – 12 million people in the USA and 6 – 16 million people in Western Europe.**

PAD is **significantly under-diagnosed** in clinical practice. Ankle Brachial Pressure Index (ABPI) is the technique used to assess patients for the presence of PAD, but has limitations: taking an **ABPI requires a highly trained clinician or nurse**, the **results are operator-dependent**, and **ABPI does not give a reliable result in many patients**, largely due to the presence of highly calcified arteries.

Markets with the biggest unmet medical need for reliable, first-line diagnosis and monitoring of PAD include:

DIABETIC PATIENTS

There are approximately **350 million patients worldwide with diabetes**, 90% of whom have type-2 disease, and the prevalence is increasing year on year. Diabetics are at **higher risk of developing PAD** than the non-diabetic population; over forty percent of patients with PAD have diabetes, and **PAD progresses more rapidly** in these patients. Diabetics also frequently have **peripheral neuropathy which masks the pain** arising from PAD. Up to **35% of diabetics have incompressible arteries,** and so PAD can't be diagnosed using ABPI.

PATIENTS WITH LEG ULCERS

Patients requiring compression bandaging to treat leg ulcers also require monitoring for PAD to ensure the bandaging is not too tight. **Patients with swollen legs and feet are often not screened with ABPI** due to the discomfort of the pressure cuffs. In addition, many of these patients have **incompressible arteries**.

PATIENTS ON RENAL DIALYSIS

Patients undergoing renal dialysis are at risk of PAD and a **significant percentage of patients have incompressible arteries**. The first signs of PAD are often leg pains or the onset of wounds on the feet.

PATIENTS WITH OTHER VASCULAR PROBLEMS

Reduced lower limb perfusion leads to critical limb ischemia, but more insidiously, **patients with PAD have other vascular problems:**

- 40% – 90% have Coronary Heart Disease
- 5% - 50% have Cerebrovascular Disease
- Patients with PAD have **5 fold increase of heart attack or stroke**

The survival rate for individuals with undetected peripheral arterial disease is worse than the outcome for many other serious diseases, including many common cancers

PAD is significantly under diagnosed because **up to 75% of patients are asymptomatic or symptoms are not recognised** and there is **no fast, automated, easy to use method for detecting PAD in primary care**.

Clinical guidelines worldwide indicate that **secondary prevention measures for cardiovascular disease (CVD) including therapeutic intervention** should be followed for patients with established coronary and other atherosclerotic vascular disease, including **PAD**.

MORE DETAILS ON VEWS

VEWS employs a simple and low-cost optical technique that can be used to detect blood volume changes in the micro-vascular bed of tissue.

The VEWS **technology platform** is a miniature multi-channel NIR discrete spectroscopy system with unique features of multiple wavelength sensing with precise, fully protected constant current control LED drivers. This permits multiple sites to be monitored simultaneously. Ambient light interference is compensated using a time division multiplex system at over 1kHz. VEWS has a powerful 32-bit internal processor which enables sophisticated signal processing and analysis to be performed digitally for increased stability

Electronics are housed in the handheld **VEWS device**, featuring a 4.3'' colour touch-screen with a clear and concise user interface for ease of use.

VEWS uses **red and infrared optical sensors** placed on the toe and dorsum of the foot. Readings are taken for 45 seconds with the patient lying flat, and for another 45 seconds with the patient's leg supported on a 30cm block to maintain the foot above the heart. The functional test is an automation of the Pole Test and Buerger's test, and a bilateral assessment can be performed in about 10 minutes.

In healthy patients blood flow in the raised position is not compromised, but in patients with narrowing of the arteries the blood flow in the raised position is reduced. The algorithm within VEWS then calculates a score for each leg using the ratios of flows detected in raised and lowered positions.

In contrast to ABPI, testing with VEWS does not require the patient to be rested before taking readings, nor does VEWS rely on *blood pressure readings* or require pressure cuffs. VEWS is automated, limited training is required and results are operator independent, making it a perfect diagnostic tool for use in primary care.

VEWS has the **option to be used with dorsum and toe sensors or with toe sensors only**. The latter configuration is ideally suited for rapid assessment of patients in primary care.

VEWS has **high sensitivity and specificity** for detecting PAD as confirmed by the gold standard method of colour duplex ultrasound (CDU) or magnetic resonance angiography (MRA) in clinical trials.

A **CE Mark Class 2a** and **accredited quality system** are in place. A premarket notification (**510k) application** is drafted ready for submission to US FDA.

Devices and associated accessories are currently available. **Sourcing and volume manufacturing plans** are well developed.

Granted **patent protection for the VEWS family,** covering hardware, software and method is available in the UK, Europe, Australia and China, with applications pending in the USA, Japan, Brazil, Canada and India. **Additional patent applications** have been filed.

VEWS PRODUCT FAMILY

The optoelectronic technology used in VEWS can be harnessed to produce a range of products with or without additional capabilities. This product range could include but is not limited to:

- **PAD measurement only**, using toe and dorsum sensors or **toe sensors alone**. The latter configuration is ideally suited for **rapid assessment of patients in primary care**.

- **PAD and other arterial measurements**: for example, pulse wave velocity (PWV) might be measured by using reflective sensors on the carotid artery or transmission sensors on the finger in conjunction with toe sensors. VEWS software could also be adapted to perform pulse contour analysis (PCA) of the waveforms.

- **PAD and venous investigations**: for example, using a reflective sensor on the calf to examine venous insufficiency

At the current stage of VEWS development and commercialisation, all options are possible thereby allowing the **acquirer to adapt the technology** to meet customer needs.

A range of products will allow for differential pricing in different markets and maximise return.

PROJECT OVERVIEW

The next step for Dialog Devices is to **launch VEWS in Europe**

European **pre-launch activities are currently underway** and include:

- Placement of demonstration devices in clinics to secure endorsement from Key Opinion Leaders and feedback from primary care healthcare professionals
- Research on commercial models, pricing options and target customers for market entry
- Assimilation of all feedback and research into refinement of launch plans for VEWS
- Priming supply chain partners in preparation for production of devices and consumables

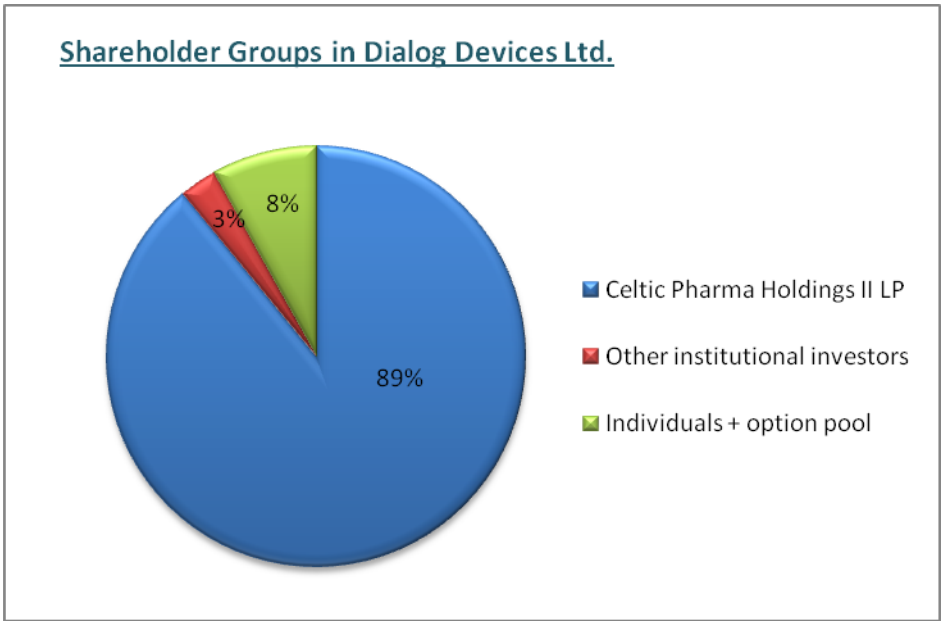
Thereafter, **the next set of activities** will be to:

- Support full manufacture of VEWS devices and accessories for European launch
- Undertake marketing and promotional activities for European launch
- Register and launch VEWS in the USA and major markets globally, and
- Maximise potential for the VEWS product family

Priorities and plans **can be tailored** to meet the needs of the acquiring company

FINANCIAL OVERVIEW

Total **investment in Dialog Devices** and **VEWS to date: £4.5m ($6.75m)**



The Board of Dialog Devices has a majority of directors from Celtic Pharma Holdings II LP, commensurate with the shareholding.

UPCOMING PRESENTATIONS

Come and **meet us** at:

- BioTrinity 2013; 14th to 16th May; Newbury
- Investment In Innovation (IN³) Medical Device 360°; 24th to 26th June; Boston