

Lexington BioSciences

OTCQB: LXGTF | CSE: LNB

Revolutionary Cardiovascular Health Monitoring

Developers of a simple and effective personal vascular health device for early identification of heart disease.

INTRODUCING



Lexington BioSciences introduces HeartSentry, a simple, yet revolutionary technology for personalized measurement and monitoring of vascular health to detect the potential for cardiovascular disease at its earliest stages. The device measures the function of the endothelium, the cells that line all arteries and are critical to the prevention of atherosclerosis, heart attacks and stroke.

PROBLEM: HEART DISEASE

Nearly 1 in 3 deaths in the USA are caused by heart disease and stroke. Of the approximately 1.5 million people suffering heart attacks annually in the U.S., more than 250,000 will die within one hour of their incident. Nearly 1/3 of the ~ 600,000 annual cardiovascular disease deaths in the U.S. **could be prevented** through changes in lifestyle habits. Unfortunately, for up to 50% of these individuals, the **FIRST SYMPTOM** of coronary artery disease is sudden cardiac death, or a heart attack. -Source: World Health Organization / Center for Disease Control (CDC) Atlanta,

Atherosclerosis is the most common cause of death in developed countries. It is the deposition of cholesterol and fatty material, or **plaque deposits**, on the inner walls of arteries. Most heart attacks and strokes are caused by these fatty deposits breaking free of the artery wall, then lodging downstream and blocking blood flow.

Early assessment is key to prevention through proactive lifestyle modification, physician care and ongoing monitoring. **However, blood pressure and cholesterol monitoring are only partial indicators of cardiovascular health.** Most cardiovascular disease is related to plaque buildup and inflammation within the arteries (**atherosclerosis**).

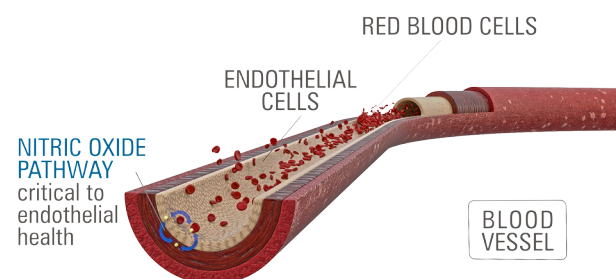
“Cholesterol and blood pressure tests **do not** provide a complete picture of cardiovascular health”

Jonathan S. Maltz, Ph.D.
Lexington Scientific Advisor

SOLUTION: EARLY DETECTION

The **only way** to detect that arteries are vulnerable to atherosclerosis is to assess **endothelial function**. This is a test of the endothelial cells that line all the arteries in the body. The **endothelium** is the single layer of cells that line various organs and cavities, especially the heart, blood and lymphatic vessels. These cells act as a shield, preventing plaque from forming inside the artery wall, and produce substances that stop blood clots from developing in the vessel.

Healthy endothelial cells release **nitric oxide (NO)**, which is responsible for most of the protective functions of these cells in the artery.



In an at-risk individual, the endothelial cells do not produce enough NO, or the NO produced is deactivated by chemicals in the bloodstream before it can prevent deposits from forming in the arterial wall.

OPPORTUNITY: HIGH GROWTH SELF-MONITORING SECTOR

By 2020, \$2.6 billion Global monitoring instruments market will increasingly shift to the high-growth home segment.



HeartSentry™ has been developed to measure the function of the endothelium, the cells that line all arteries and are critical to the prevention of atherosclerosis, heart attacks and stroke.

HeartSentry targets the **rapidly growing self-measurement medical device sector** and is designed for both personal and clinical use. Simplicity and functionality are key elements of the design.

Designed to efficiently measure increases in arterial volume which occur when the endothelial cells of the artery are stimulated, and the muscles in the wall of the artery relax. Initial studies demonstrated a strong correlation to ultrasound results.

How it Works

The proprietary **HeartSentry™ inflatable cuff** utilizes specialized algorithms to interpret changes in the volume of blood in the arm. In a relaxed, dilated artery, the volume change over the cardiac cycle is much greater than baseline levels, typically by more than 80% in healthy subjects.

The **fully automated** device is compact and **inexpensive** enough for commercial use in the **home care** market and **primary care** physician offices. Its integrated Bluetooth technology can communicate with nearby smart applications which can act as a portal to cloud-based technologies enabling advanced ongoing monitoring opportunities between patient and clinical care providers. There is a potential for generated data to be valuable to bioinformatics providers. Integration with additional data streams allows further predictive ability for assessing cardiovascular disease progression.

HeartSentry™ is a combination device that measures BOTH blood pressure and endothelial function. This ADDED FEATURE increases the value and interest in purchasing a blood pressure and endothelial function monitoring device, and is designed to deliver a more accurate picture of cardiovascular health.

Initially targeted at the clinic based professional market, the product ultimately will be marketed direct to consumers.



Development Plan

- Develop regulatory plan and meet with FDA to confirm
- Create test platform for algorithm development
- Establish scientific advisory board
- Create quality system
- Identify and sign contract with manufacturing partner
- Manufacture units
- Acute calibration study
- Clinical study comparing cFMD to uFMD (or other standard) and show positive correlation
- Submit for FDA approval with calibration study data

TEAM: EXPERT LEADERSHIP

The principals, directors and advisors of Lexington BioSciences have been individually and collectively involved in raising extensive capital funding for their private and public companies. Team members have held numerous executive leadership positions encompassing biotechnology, and medical device companies, as well as multi-national corporations. The team includes inventors, scientists, and business people who have successfully started, built and grown multiple life science companies.

Find out more at:

www.lexingtonbiosciences.com/company/management

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