BRAVA Diagnostics

Website: www.BravaDx.com
Founded: November 2018, 4 employees
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Company Summary

Brava Diagnostics is developing diagnostic products for acute care, starting with cardiac markers. Our first test is a high-sensitivity troponin assay to assess chest pain in the emergency department.

Unmet Need/Opportunity

- The market for cardiac markers will reach $2.45 billion by 2025. The POC segment will reach $806 million by 2025.
- European and U.S. guidelines are driving a shift to high-sensitivity troponin assays to improve diagnosis of heart attack and to discharge low-risk patients safely.

Superior Technology

Our evanescent planar waveguide platform delivers lab-quality results at the point-of-care.

- Whole blood sample
- Simple test procedure
- Results in <15 minutes compared to 1 hour or more from the lab.
- Limitations of current POC methods prevent achieving metrics in the guidelines.

Competitive Advantages

- Meets American College of Cardiology and European Society of Cardiology guidelines for sensitivity and precision.
- Sensitivity at pg/mL concentrations
- Precision CV <10% at the 99th percentile of healthy subjects.

Customer Problem

Emergency physicians need precise lab results, ideally within 15 minutes, to guide treatment or safe discharge for patients with chest pain. New guidelines from the European Society of Cardiology (ESC) and the American College of Cardiology (ACC) are driving the shift to high-sensitivity troponin assays (hs-cTn). Central lab tests suffer from turnaround time of more than an hour. Point-of-care (POC) assays are widely used, but the, care team must compromise performance for speed. Neither lab nor POC tests meet the need.

Our Solution

Brava can fill this large market gap with a high-sensitivity troponin test that delivers lab-quality performance at the point-of-care in 15 minutes. Our evanescent planar waveguide technology is a different approach to POC diagnostics that enables a low-cost instrument and high margin consumable cartridges. MBio developed the core technology over ten years and has commercialized products outside of human health, significantly de-risking product development. Brava will build on these accomplishments by adapting the instrument for the healthcare market, developing in vitro diagnostic assays and executing clinical trials.

The LightDeck System offers these advantages:

- Analytical sensitivity: Delivers precise results at very low concentrations (pg/mL), comparable to the core lab.
- Rapid, simple format: Whole blood assays report results in less than 15 minutes using a “load-and-go” workflow.
- Multiplexing: Multiplexing improves precision. Positive and negative controls run in parallel with tests. This system may achieve CLIA waiver.
- Cost-effective: The design of the disposable cartridge is scalable and enables commercialization with high margins.

New Guidelines Drive Testing with High Sensitivity Assays

The American College of Cardiology and European Society of Cardiology issued new guidelines for implementing serial testing with high-sensitivity troponin (hs-cTn) assays. Troponin is a biomarker that indicates damage to the heart muscle and is the standard of care for diagnosis of heart attack. The guidelines set a cut-off at the 99th percentile of the healthy subjects to diagnose a heart attack. Assays must have high precision (CV of <10%) at very low concentrations (10-20 pg/mL). Current FDA-cleared central lab tests have a turn-around time of 60 minutes or more. Current point-of-care tests do not meet the guidelines and traditional technology may make it difficult to meet the new standards.

We expect the Brava test to meet the guidelines for sensitivity and precision AND deliver results in 15 minutes or less. We expect to capture market share rapidly.

	Core Lab		Point-of-Care			
	hs-cTn	cTn	Brava	i-STAT	h-232	Triage
High sensitivity	√	X	√	X	X	X
CV <10% at the 99th %ile	√	√	√	X	X	X
< 15-minute TAT	X	X	√	√	√	√
Whole Blood	X	X	√	√	√	√
Multiplex	X	X	√	X	X	√
Cost-effective	X	X	√	√	√	√

Accomplished Executive Team of Diagnostic Industry Veterans

Byron Hewett Co-Founder and Chief Executive Officer	CEO, SomaLogic Chairman and CEO, BioBDx CEO, Immunicon	Senior executive positions at Qiagen, Bayer, Chiron, Abbott
David Okrongly, PhD Co-Founder and Chief Operating Officer	President, OPKO Diagnostics COO, Exosome Diagnostics President and CEO, Quanterix	Senior executive positions at Siemens, Bayer
Carrie Mulherin Co-Founder and Chief Marketing Officer	VP Diagnostics, SomaLogic VP Marketing and Sales, BioBDx VP Marketing and Sales, Immunicon	Executive positions at Orasure, ThauMDx, Intracel, ITC

Investment Summary

Market need is defined	Fast, sensitive, precise, low-cost, lab quality
Large, established market	POC $513 M (2018) growing to $806 (2025)
Product proof-of-concept Instrument hs-cTn Assay	Technology is proven Core platform launched Feasibility demonstrated
Clinical development plan	Informed by 3 FDA-cleared assays
Regulatory plan	510(k)/CE Mark for initial assays
Reimbursement	Use existing codes
Scientific/Medical Advisors	7 experts in cardiac markers
Management Team	Highly accomplished in the diagnostics industry
Exit plan	Sale to a large Dx company within 4 years

Please contact Byron Hewett to schedule a meeting. e-mail: BHewett@BravaDx.com • phone: 661-993-4085