

## Company Summary

Brava Diagnostics is developing diagnostic products for acute care, starting with cardiac markers. Our first tests will assess chest pain and shortness of breath in the emergency department. Seed funding will be used to adapt the instrument for the healthcare market and to develop a high-sensitivity troponin assay.

### Unmet Need/Opportunity

Physicians need accurate, fast results to guide treatment decisions in acute care settings.

- The market for cardiac markers will reach \$3.5 billion by 2021
- Sepsis costs U.S. health systems \$24 billion annually. 5.3 million intent-to-screen patients

### Products

Our platform technology uses a simple fluorescence reader and planar waveguides to deliver highly sensitive and precise results from whole blood in <20 minutes.

- First assays assess heart attack and heart failure
- Follow-on applications in sepsis

### Competitive Advantages

- Accurate measurement of low concentrations (pg/mL) to guide confident decisions
- Superior performance in a point-of-care test that meets American College of Cardiology guidelines
- Multiplexing enables several tests to be analyzed in the same cartridge

## Customer Problem

Rapid triage of patients presenting with chest pain and diagnosis of heart attack is critical to saving lives and improving quality of care in the emergency department. There are 6.9 million visits to U.S. emergency departments for chest pain, with 1.3 million patients ultimately receiving a diagnosis of heart attack.

All patients receive an electrocardiogram (EKG), but this only detects approximately 6% of heart attacks, leaving the vast majority of patients in need of further assessment, including a troponin blood test. Diagnostic uncertainty, caused in large part by delays in obtaining blood test results, leads to an excessive number of chest pain patients being admitted to the hospital. Inappropriate admissions result in more than \$7 billion in excess cost to the U.S. healthcare system annually.

## Our Solution

Our initial product will be a high-sensitivity troponin assay for chest pain assessment. Our rapid results will help guide treatment decisions, whether it's administering a "clot buster," admitting the patient without delay for a stent or bypass surgery, observation or safe discharge. 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 20 minutes using a simple "load-and-go" workflow.
- Cost-effective: The design of the disposable cartridge is scalable and enables commercialization with high margins.



## Business Model and Exit Strategy

The Brava business model is a classic razor/razor blade model that is common in the diagnostics industry. We project gross profit margin in excess of 90% five years post-launch. Exit strategy alternatives include sale to a large diagnostics company with valuation >\$500 million.

## Sales and Marketing Strategy

Brava tests will inform decisions to deliver the most appropriate interventions to improve health outcomes while reducing costs. We will use a key accounts selling strategy to market our products to executives in health systems, emergency medicine and critical care physicians, and laboratory leaders. An integrated delivery network (IDN) is a collaborative network that links health care providers economically and clinically. By targeting the 806 IDNs, we can efficiently reach 4,791 hospitals within the networks.

Generating compelling data and publication in prestigious journals are key elements of our commercial strategy. We will engage a world-class medical/scientific advisory board and conduct rigorous clinical studies to support regulatory and customer requirements. Marketing strategy will focus on building awareness through print and digital channels and education through scientific meetings and peer-to-peer events.

## Competition

The American College of Cardiology issued new guidelines for implementing serial testing with high-sensitivity troponin 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 require assays to have high precision at very low concentrations. Current core lab tests have a turn-around time of 60 minutes or more. Current point-of-care tests do not meet the new guidelines and traditional technology may make it difficult to meet this new standard. The Brava test will meet the requirements for precision and sensitivity and deliver results in less than 20 minutes.

	Core Lab		Point-of-Care		
	hs-cTn	cTn	Brava	i-STAT	Triage
High sensitivity	√	X	√	X	X
CV <10%	√	√	√	X	X
< 20-minute TAT	X	X	√	√	√
Whole Blood	X	X	√	√	√
Multiplex	X	X	√	X	√
Cost-effective	X	X	√	√	√

## Executive Team: Diagnostic Industry Veterans

**Byron Hewett, Co-Founder and Chief Executive Officer:** Byron has led healthcare and life science companies ranging from start-up and development-stage companies to multi-national firms including Abbott, Bayer, Immunicon and SomaLogic. His expertise is in general management, strategy, and commercialization.

**David Okrongly, Ph.D., Co-Founder and Chief Operating Officer:** Dave has been a business executive and R&D leader, with past experience including Bayer, Siemens, Quanterix, and OPKO Health. He brings expertise in instrument and assay development, clinical trials, regulatory affairs and operations.

### Carrie Mulherin, Co-Founder and Chief Marketing Officer

Carrie brings expertise in strategic marketing, cross-functional team management and product commercialization, with past experience including Immunicon and SomaLogic.

## Learn More

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