BRAVA Diagnostics

Website: www.BravaDx.com
Founded: August 2018, 3 employees
Seeking $4 million seed financing
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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 is ~$2.3 billion
- 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 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 simple point-of-care test that meets guidelines
- Multiplexing enables several tests to be analyzed in the same cartridge

Customer Problem

Emergency physicians focus on the immediate recognition heart attack to decide whether to administer "clot busters," admit the patient for revascularization, observe in the emergency department or discharge them safely. The standard of care is to test for troponin, a protein that is released from damaged heart cells. The assay must measure very low concentrations precisely and deliver results quickly. Labs take an hour or more to deliver results.

Our Solution

Our initial product is a high-sensitivity troponin assay for chest pain assessment. 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.

This combination of features will give our high-sensitivity troponin assay a significant competitive advantage over the core lab because emergency physicians need accurate results quickly. Clinical teams need better tools to guide treatment, whether it's admitting the patient without delay for a stent or bypass surgery, observation or safe discharge. We expect to meet the precision guidelines from the American College of Cardiology for AND deliver results in 20 minutes or less. No other point-of-care test meets these new guidelines.

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

We plan to launch in the U.S. initially. 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 an 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

FDA recently cleared three high-sensitivity troponin assays for the core lab. While these tests meet American College of Cardiology (ACC) guidelines for sensitivity (detection level) and precision, turn-around time is often more than 60 minutes. The Brava hs-TnI test will meet the performance guidelines with a simple whole blood assay AND deliver results in <20 minutes. No existing point-of-care product meets ACC guidelines.

	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	√	√	√

Management

Byron Hewett, Founder and Chief Executive Officer

Byron founded Brava Diagnostics in August 2018. Byron has led healthcare and life science companies for more than 30 years, in multi-national firms, development-stage and start-up companies. His expertise is in general management, strategy, business development and sales and marketing.

David Okrongly, Ph.D., Co-Founder and Chief Operating Officer

Dave joined Brava in January 2019. Dave has been a business executive and R&D leader in the diagnostics industry, ranging from start-up to multi-national companies. He brings expertise in instrument and assay development, clinical trials, regulatory affairs and operations.

Carrie Mulherin, Co-Founder and Chief Marketing Officer

Carrie joined Brava in August 2018. She is a marketing and sales executive with extensive start-up experience and 31 product launches. Carrie's expertise is in the diagnostics industry and she brings deep experience with product development teams, clinical development and FDA submissions.

Learn More

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