

Company Summary

Brava Diagnostics is developing acute care diagnostic products, starting with cardiac markers. Our first tests will assess heart attack and heart failure in the emergency department. Seed funding will be used to complete product development for for clinical trials by 1Q2020.

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
- Multiplex analysis improves precision and turn-around time

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.
- Multiplexing: Improves precision and turn-around time.
- 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 cartridges is scalable and enables commercialization with high margins.



This combination of features gives Brava a significant competitive advantage for our troponin assay, where physicians need accurate results quickly. We expect to meet the precision guidelines from the American College of Cardiology for high sensitivity troponin assays AND deliver results in 20 minutes or less. No other point-of-care test meets these new guidelines. We expect to capture market share rapidly.

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.

Targets

Health system executives are motivated by cost avoidance, cost savings, quality metrics (including patient experience) and health outcomes. Emergency physicians need better tools to guide treatment, whether it's admitting the patient for a stent or bypass surgery, observation or safe discharge. Brava tests will inform decisions to deliver the most appropriate interventions to improve health outcomes while reducing costs.

Sales and Marketing Strategy

We will use a key accounts selling strategy to market our products to executives in U.S. health systems initially. 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. Clinical champions include emergency medicine and critical care physicians and laboratory leaders.

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. We will employ a key accounts sales team to call on health system executives, physicians and laboratory leaders. Marketing strategy will focus on building awareness and education.

Competition

Three high sensitivity troponin assays recently have been FDA-cleared for the core lab. While these tests meet American College of Cardiology 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, 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.

Carrie Mulherin, 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