

# **Emerging Company Research**

## **BG Medicine** — Initiating With Outperform (1)

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# **High-Profile Partnerships Driving Unique Diagnostics Assets**

**Summary:** BG Medicine is focused on the discovery, development, and commercialization of high-value clinical biomarkers and diagnostic tests. The company's proprietary biomarker discovery platform and experienced management team have resulted in partnerships and initiatives which provide the company with unique access to highly valued, well-characterized patient samples, from which novel biomarkers can be discovered. The company's lead product is a test for galectin-3, a protein shown to be involved in cardiac remodeling in heart failure physiology. Also in the pipeline are AMIPredict, a cardiovascular disease risk screening test; LipidDx, a test to aid in management of patients with lipid disorders; as well as a handful of programs in CNS, autoimmune and other cardiovascular/metabolic disease areas.,

- **Potent Biomarker Discovery Engine.** BGMD's partnerships with leading companies and consortia have provided unique access to well characterized samples and access to discovery of proprietary biomarkers.
- Commercialization Partners Are A "Who's Who" In Diagnostics. Development and commercialization agreements have been secured with Abbott, Alere, bioMerieux, and Siemens, providing BGMD access to a significant portion of the world's leading diagnostic labs.
- **Targeting Attractive Market Opportunities.** BGM Galectin-3, AMIPredict, and LipidDx target significant (about \$2Bn) market opportunities within cardiovascular disease screening and risk assessment.

BGMD (03/17)	\$8.30	Reve	enue \$MM						
Mkt cap	\$195.9MM	FY	<u>2010</u>	<u>201</u>	1 <u>E</u>	201	<u>2E</u>	<u>201</u> 3	<u>3E</u>
Dil shares out	23.6MM	Dec	Actual	Prior	Current	Prior	Current	Prior	Current
Avg daily vol	34.3K	Q1	_	_	0.0	_	0.4	_	_
52-wk range	\$7.0-9.5	Q2	_	_	0.1	_	1.1	_	_
Dividend	Nil	Q3	_	_	0.1	_	2.1	_	_
Dividend yield	Nil	Q4	_	_	0.2	_	4.1		
BV/sh	\$-25.57	Year	0.8	_	0.5	_	7.6	_	68.6
Net cash/sh	NA	EV/S	_	_	286.9x	_	18.9x	_	2.1x
Debt/cap	NA								
ROIC (LTM)	NA								
- 6 16									
5-yr fwd EPS	NA	EPS \$							
5-yr fwd EPS growth (Norm)	NA	EPS \$	<u>2010</u>	<u>201</u>	<u>IE</u>	<u>201</u>	<u>2E</u>	<u>201</u> :	<u>3E</u>
,	NA			<u>201</u> Prior	<u>IE</u> Current	201 Prior	<u>2E</u> Current	<u>201:</u> Prior	<u>BE</u> Current
,	NA	FY	<u>2010</u>						
,	NA	FY Dec	2010 Actual		Current		Current		
,	NA	FY Dec Q1	<u>2010</u> Actual —		<b>Current</b> (0.34)		<b>Current</b> (0.40)		
,	NA 1273.7	FY Dec Q1 Q2	2010 Actual — —		(0.34) (0.34)		(0.40) (0.39)		
growth (Norm)		FY Dec Q1 Q2 Q3	2010 Actual — —		(0.34) (0.34) (0.33)		(0.40) (0.39) (0.37)		
growth (Norm)		FY Dec Q1 Q2 Q3 Q4	2010 Actual — — —		(0.34) (0.34) (0.33) (0.32)		(0.40) (0.39) (0.37) (0.32)		Current — — — —



## **Positives**

- 1. High profile partnerships feed discovery, development, and commercial strategy
  - a. Initiatives and partnerships provide access to highly valued samples BGMD's proprietary biomarker discovery platform has allowed the company to establish collaborations and partnerships with leading companies and consortia in the area of cardiovascular disease such as the Framingham Heart Study, Humana, and Merck. These collaborations provide the company a unique avenue through which to discover and develop proprietary biomarkers.
  - b. Established partnerships with leading IVD instrument vendors BGMD has established partnerships with diagnostics instrumentation leaders including Abbott, bioMeriuex, Alere, and Siemens. These provide the company with access to a significant portion of higher volume testing labs in the world. These partnerships allow BGMD to access the market without the need to invest in its own instrumentation platform.
- 2. Targeting large market opportunities BGM Galectin-3, AMIPredict, and LipidDx target significant market opportunities within the screening and risk assessment portions of the cardiovascular diagnostics market. We estimate that in aggregate, these tests target a market opportunity exceeding \$2B.

## **Negatives**

- 1. Regulatory BGMD's strategy is to pursue 510(k) clearance for its tests in the US. The 510(k) process has received much scrutiny over the past few years and there is a risk FDA will increase the amount of data required from diagnostic providers, which would impact test approval timelines and investment requirements.
- 2. Reimbursement BGMD Galectin-3 should be able to cross-walk to CPT codes for BNP to achieve consistent reimbursement. However, when working without an analyte specific code, there is always a risk that reimbursement will be less than the company expects or may not be reimbursed at all, which would materially impact uptake.
- 3. Reliance on partners Although BGMD has done an impressive job of establishing partnerships with leading industry players, the company is reliant upon these partners for development and commercialization of its key tests.
- 4. Pre-commercial stage, relatively low visibility While the diagnostic markers being developed by BGMD have ample clinical evidence, and market potential exists, the company remains a very early commercial stage and had sub \$1MM in revenue in 2010. Furthermore, uncertainty regarding reimbursement makes visibility on uptake and market potential somewhat difficult to quantify at this point. The company is likely to burn through a material portion of its cash position over the next several quarters. Given the uncertainty regarding product launch and the cash burn, timing and execution risk for the company will remain high.



## **Company Overview**

BG Medicine is a company focused on the discovery, development, and commercialization of high-value clinical biomarkers and diagnostic tests. The company's proprietary biomarker discovery platform and experienced management team have resulted in partnerships and initiatives that provide the company with unique access to highly valued well-characterized patient samples, from which novel biomarkers can be discovered. The company's lead product is a test for galectin-3, a protein shown to be involved in cardiac remodeling in heart failure physiology. A manual version of the BGM Galectin-3 test received 510(k) in Q4:10 and will be provided to clinicians through LabCorp. Automated versions of the test will be developed through partnerships with leading diagnostics players including Abbott, Alere, Siemens, and bioMerieux. Through a series of label expansions within large cardiovascular disease market segments, the potential market for BGM Galectin-3 is significant (~\$800MM). Further in the pipeline are: AMIPredict, a cardiovascular disease risk screening multivariate test which addresses a ~\$1Bn market opportunity; LipidDx, a test to aid in management of patients with lipid disorders; as well as a handful of programs in CNS, autoimmune and other cardiovascular/metabolic disease areas.

#### **Investment Thesis**

BG Medicine expects a series of regulatory and clinical milestones in 2011-2012. Although initially launched in the U.S. in Q1:2011, the full market launch for BGM Galectin-3 will likely not commence until closer to 2013, which is also when a higher ASP could come through via an analyte-specific CPT code. This is expected to coincide with launches of AMIPredict and LipidDx, which could make 2013 a year of explosive growth. We believe the company needs to penetrate only a small fraction of its target markets, which we estimate exceed \$2Bn, to significantly surpass our revenue forecasts over the next 18-24 months. Because its tests are proprietary and run on well established platforms, BGMD should also be viewed as a potential acquisition target for a variety of large players who are always looking to add to their test "menus." Given the steady series of milestones beginning in 2011 and the significant markets being addressed, we believe BGMD is an attractive asset for risk-tolerant long term investors.

## **Key Milestones / Catalysts**

Milestone / Catalyst	Est. Timing
Manual Galectin-3 test ramp through LabCorp	H1:2011
510(k) clearance for automated Galectin-3 test through partners	By YE2011
Galectin-3 label extension: Post MI prognosis assessment	Late 2011
Galectin-3 label extension: Crestor (rosuvastatin) response assessment	Late 2011
AMIPredict initial launch (manual test version)	2012
LipidDx initial launch (manual test version)	2012

Source: Company reports and Cowen and Company estimates



#### Introduction to BG Medicine

BG Medicine was founded in 2000 as Beyond Genomics, Inc. (name changed to BG Medicine in 2004). BG Medicine is a company focused on the discovery, development and commercialization of novel blood-based diagnostic tests based on biomarkers for high-value market opportunities. The company believes its tests will provide clinicians with improved information to better detect and characterize disease states and enable physicians to achieve better patient outcomes and contain healthcare costs. BG Medicine will pursue three distinct paths for commercialization of its diagnostic tests, including sales of manual versions of its diagnostic tests through laboratory service providers, sales by the company through certified clinical laboratories and sales of automated versions of the company's diagnostic tests through leading diagnostic instrument manufacturers for use on their instruments. The company is focused on developing and commercializing assays or "content" that can be run on common laboratory instrumentation and therefore be able to leverage the distribution channels and installed bases of various partners and avoid the significant costs associated with developing an instrumentation platform and building out a significant sales and marketing infrastructure.

#### Partnerships Drive Discovery and Commercialization Strategy

#### **Commercialization Strategy Overview**

BG Medicine will pursue three distinct paths for commercialization of its diagnostic tests; all involve partnerships - 1) sales through lab service providers; 2) sales by BGM through certified clinical labs; and 3) sales through leading diagnostic instrument manufacturers.

- Sales through lab service providers As a means to reach the market as quickly as possible, the company has, and will continue to, pursue 510(k) clearance for manual versions (microtiter based) of tests. These will be offered to clinicians through laboratory service providers. The recently announced partnership with LabCorp for the BGM Galectin-3 manual assay is an example of this.
- Sales by BGM through certified clinical labs More complex assays such as AMIPredict will be marketed as laboratory services to clinicians through partnerships with select specialty reference labs. In this model, tests would be run at partner labs but BG Medicine would be responsible for collection of fees.
- Sales through leading diagnostic instrument vendors The company believes that automated instrument versions of its tests will be required to achieve broad customer acceptance and clinical adoption. This will be achieved through partnerships with companies with extensive testing laboratory installed bases and distribution channels. In most cases, the partners will be responsible for development and manufacturing of BG Medicine's tests for their automated instruments and additionally be responsible for distribution and sale of the test to clinical laboratories that operate their instruments. Examples of such partnerships for the galectin three tests are agreements with Abbott, Alere, bioMérieux, and Siemens.

Acknowledging the risks associated with relying on strategic partners, we view BGMD's commercialization strategy as a smart and differentiated one, as a commonly experienced challenge for young diagnostics companies is established the "footprint" within testing labs, in a market dominated by large players.



#### **Discovery Strategy Overview**

In addition to the commercialization-focused partnerships described above, BG Medicine has leveraged its cutting-edge biomarker discovery platform into partnerships with leading providers, prospective cohorts, foundations, disease consortia and diagnostic and biopharma companies which allow the company to discover and advance development of novel biomarker candidates. A notable example is the HRP ("high-risk plaque") initiative for atherothrombotic cardiovascular diseases. This initiative, which BG Medicine began in 2006, is sponsored by Abbott, AstraZeneca, Merck, Philips, and Takeda. These sponsors have provided an aggregate of approximately \$25MM to the company to conduct studies that aim to discover and validate novel biomarkers that may be used to detect a patient's risk for atherothrombosis. In consideration for leading the HRP initiative, the company has acquired certain rights to use the samples collected in the studies and the data generated from the studies for product discovery and development studies. In addition to the HRP initiative, in 2009, BG Medicine partnered with the National Heart, Lung, and Blood Institute, and Boston University to access samples and data from the Framingham Heart Study to conduct biomarker discovery studies.



## **Product / Candidate Overview**

BG Medicine's only currently marketed test is a manual version of the BGM Galectin-3 test to aid in the assessment of prognosis in patients diagnosed with heart failure; this test received 510(k) in Q4:2010. Beyond this, BGM is expecting to expand the indications / label for the galectin-3 test as well as add other diagnostic products for cardiovascular disease. The company expects to follow the 510(k) pathway for these other product candidates in the U.S.

- **Galectin-3 related products** as a predictor of heart failure development in patients following heart attack or related conditions; and as an indicator of efficacy of Crestor (rosuvastatin) in patients with high cholesterol;
- **AMIPredict** to identify patients with a high risk of suffering a heart attack or stroke within the following two to four years; and
- **LipidDx** a novel protein biomarker, to aid in the management of common lipid disorders.

#### **Galectin-3**

Galectins are a family of proteins that play many important roles in inflammation, immunity, and cancer. Galectin-3, a member of this family of proteins, has been shown to play an important role in heart failure in animal and human studies. BG Medicine has obtained an exclusive worldwide license to certain galectin-3 rights from ACS Biomarker, a company that was spun out of the University of Maastricht in The Netherlands. The company has since filed several additional patent applications related to galectin-3.

The manual version of the BGM Galectin-3 test was 510(k) cleared in Q4:2011 and has been made available to the clinical community by LabCorp. The approval indication supports use of the BGM Galectin-3 test along with clinical evaluation as an aid in assessing the prognosis of patients diagnosed with chronic heart failure. An automated version of the test is being developed through partnerships with Abbott, bioMerieux, Siemens and Alere; 510(k) filing is expected by year-end 2011. Label extensions for post MI prognosis and efficacy of rosuvastatin are also expected in the next 18-24 months.

Existing and expected galectin-3 test-based products:

- Manual BGM Galectin-3 test: as an adjunct to clinical exam is assessing prognosis in patients diagnosed with CHF.
- Automated BGM Galectin-3 test: as an adjunct to clinical exam is assessing prognosis in patients diagnosed with CHF.
- Label extension: as a marker of responsiveness to rosuvastatin (Crestor) in CHF patients.
- Label extension / Supplemental: as an aid is assessing prognosis of patients at elevated risk of heart failure following a heart attack.

#### Galectin-3 in Heart Failure

Heart failure (HF; or chronic heart failure, CHF) is a condition caused by a combination of diseases or factors that damage or overwork the heart muscle,



resulting in its inability to pump blood efficiently to meet the needs of other body organs. Heart failure may lead to serious complications and is a leading cause of death. The most common cause of heart failure is coronary artery disease, including heart attack and unstable angina. Heart failure can be caused by many other factors including high blood pressure, diabetes, and defects of the heart valves or muscle itself. According to the American Heart Association, an estimated 5.7MM Americans suffer from heart failure, with an approximate 670,000 new cases occurring each year. The prevalence and incidence of heart failure is believed to be similar in Europe. It is estimated that heart failure is responsible for over 277,000 deaths per year in the US.

The cardiac injury caused by coronary artery disease often results in the development of adverse remodeling. Patients with heart failure typically exhibit non-specific signs and symptoms such as swollen legs or ankles, shortness of breath or weight gain. Although CHF is usually progressive, the rate of progression varies markedly between individuals from no noticeable deterioration over multiple years to rapidly progressive, resulting in death in just weeks or months.

Galectin-3 measurement has been shown to be associated with prognosis in patients diagnosed with chronic heart failure. Galectin-3 measurement in these patients may aid physicians in: spacing of patients visit intervals, assessing need for referral to a cardiologist / specialist, determining proper timing of hospital discharge and appropriate patient care following discharge and evaluating patients for advanced therapeutic options.

#### Standard of Care in Assessing Prognosis in CHF Patients

Patients with heart failure are commonly classified based on signs and symptoms using the New York Heart Association, or NYHA, functional classification scale based on a patient's symptoms. The scale ranges from Class I (least severe) to Class IV patients (most severe). However, the NYHA functional classification scale does not specifically correlate with underlying disease process. Galectin-3 dependent heart failure represents a common cause of heart failure development and rapid progression.

Natriuretic peptides such as BNP and NT-proBNP do not segment patients with heart failure on the basis of a specific underlying disease process, but the presence of these hormones rather reflects the degree of pressure or volume overload in the heart. In other words, increases in natriuretic peptides reflect the degree of cardiac overload, not the actual underlying cause. Consequently, galectin-3 and natriuretic peptides provide the clinician with information on two independent processes and important incremental clinical information.

#### **BGM Galectin-3 Clinical Development in CHF Patients**

Galectin-3 levels in the healthy population follow a normal distribution and are relatively stable, although in about 15-25% of individuals with diagnosed heart failure, galectin-3 levels change materially and a segment of these patients have been associated with a higher risk prognosis. This provides impetus for repeat testing.

Galectin-3 has been further studied in eight controlled studies involving more than 5,300 patients with chronic or acute heart failure. In these studies, galectin-3 was found to be a strong independent predictor of mortality or hospitalization, the



primary end-points of these studies, meeting the criteria for statistical significance. Together, these data support the premise that galectin-3 may be used to segment and stratify heart failure patients and that patients with higher levels of galectin-3 have a more progressive form of the disease associated with increased hospital utilization and premature death.

#### Summary of Studies Submitted in Support of 510(k) Application

	Study I – Multicenter; EU	Study II – Multicenter; US, CA
Sample Size; Profile	N=582 NYHA class II, III and IV subjects. Mean age = 71; 38% female	N=895 CHF patients with left ventricular dysfunction and NYHA class II, III or IV symptoms. Mean age = 58; 29% female
Follow Up Time	Median >18 months	Median 30 months
Primary Endpoint	Composite of all-cause mortality and hospitalization for heart failure	Composite of all-cause mortality and all- cause hospitalization

Source: Company reports, product label

Results from Study II, the US / Canada validation study, are detailed in the table below. In summary, after accounting for other baseline risk factors, an elevated baseline galectin-3 level (>17.8 ng/mL) had an approximate 1.4-fold increased hazard of death or hospitalization for heart failure, relative to patients with low galectin-3 levels.

#### End Point Event Hazard Ratios by Galectin-3 Status For CHF Subjects in Validation Study

	Hazard Ratio (95% CI, p value)					
Galectin – 3 Category	<17.8ng/mL	17.8ng/mL-25.9ng/mL	>25.9ng/mL			
Number of Subjects	647	170	78			
Hazard Ratio-all cause mortality and hospitalization*	1.0	1.35 (1.10-1.65, p=0.004)	1.46 (1.11-1.92, p=0.006)			
Hazard Ratio-CV mortality events*	1.0	1.91 (1.28-2.86, p=0.002)	2.33 (1.43-3.80, p<0.001)			
Hazard Ratio-all cause mortality events*	1.0	1.84 (1.28-2.64, p=0.001)	2.06 (1.31-3.23, p=0.002)			

<sup>\*</sup> adjusted for baseline risk factors: age, gender, NYHA functional classification, left ventricular ejection fraction, diabetes status, and smoking status. Source: product label

Importantly, as shown in the data table below, measurement of galectin-3 and NT-proBNP provides independent and complementary information on the prognosis of patients with CHF. This provides an opportunity for galectin-3 testing uptake to be catalyzed by bundling with BNP tests. BG Medicine partner Alere is a market leader in the BNP and NT-proBNP diagnostics market estimated at ~\$650MM 2010.

#### All-Cause Mortality and All-Cause Hospitalization Events By Galectin - 3 Status and NT-ProBNP

	Galectin-3 <17.8ng/mL and proBNP < median	Galectin-3 <17.8ng/mL and proBNP > median; or Galectin-3 >17.8ng/mL and proBNP < median	Galectin-3 >17.8ng/mL and proBNP > median
Event rate at 6 months	19.4%	31.8%	42.7%
Event rate at 12 months	32.0%	50.0%	58.0%
Event rate at 24 months	55.3%	71.1%	85.7%
Event rate at 36 months	76.1%	85.8%	93.0%

Source: product label





# Looking to Extend 510(k) Label to Include Galectin-3 as a Marker of Response to Crestor in Heart Failure Patients

BG Medicine is pursuing studies to examine whether patients with galectin-3-dependent heart failure may respond differently to medications than patients with other forms of heart failure. One of these studies is a prospective substudy of the CORONA study (Controlled Rosuvastatin in Multinational Trial in Heart Failure) sponsored by AstraZeneca. The study was designed to investigate whether galectin-3 can be used to identify segments of patients with heart failure that derive a clinical benefit from rusovastatin (Crestor) treatment. This study, completed in Q4:2010, demonstrated that a beneficial response to rusovastatin was limited to patients with low galectin-3 levels (<19.0 ng/mL). The company is in discussions with FDA regarding extension of the 510(k) label to include the indication of galectin-3 as a marker of beneficial response to Crestor in patients with CHF.

#### Galectin-3 to Identify Patients at Risk for HF Post MI

BG Medicine is examining whether elevated levels of galectin-3 in patients following a heart attack/MI is associated with an elevated risk of heart failure development. Concurrently, the company is investigating this premise in acute coronary syndrome (ACS), a condition which includes unstable angina and heart attack. An estimated 20–40% of individuals in the United States who suffer a heart attack develop heart failure within five years. According to the American Heart Association, an estimated 8.5MM Americans alive today have suffered a heart attack, with an approximate 935,000 new or recurring heart attacks occurring each year in the U.S.

This potential indication has been studies in collaboration with the TIMI Study Group of Harvard Medical School and affiliated hospitals. Initial results suggest elevated galectin-3 levels are associated with an increased risk for the development of heart failure in patients following acute coronary syndrome. The company is currently conducting additional clinical validation studies and expects to seek a 510(k) supplemental indication for periodic galectin-3 testing in patients following a heart attack, or in the broader indication following acute coronary syndrome, to identify patients at elevated risk of heart failure development before the onset of signs and symptoms. The company expects a first generation manual test kit in 2011 and any automated versions in 2012 or thereafter.

#### **AMIPredict**

BG Medicine's product candidate with the largest potential market opportunity is AMIPredict. AMIPredict is a multi-biomarker (currently 7 proteins) blood-based test aiming to identify patients with a relatively higher risk of suffering a heart attack or stroke within the next two to four years. Most (>75%) heart attacks and strokes occur as the consequence of acute atherothrombosis in individuals with low or intermediate risk profiles according to traditional risk factor-based approaches such as Framingham Heart Study's Risk Score and the Women's Health Study; therefore, there is a need for more sensitive markers of risk. The potential market for a test to aid in assessing risk of MI or stroke in U.S. alone is significant - there are an estimated 43MM men aged 50 or over and 40MM women aged 55 or over in the US who may be at risk for developing vulnerable plaques. The company's goal is to commercialize a first generation manual AMIPredict product in 2012, and an automated product version through partnerships thereafter. The strength of AMIPredict's label will be key to determining the true market potential for this test.



#### **Discovery and Clinical Development Studies in Support of AMIPredict**

	Study I – CATHGEN based study	Study II – Copenhagen heart study
Sample Size; Profile	N=140; case-control	N=750; case-control
Comparison	Patients who underwent angiography and 1) cases - developed a heart attack or stroke within two years following the angiography; 2) controls - patients similar to cases at time of angiography, but who did not develop cardiovascular event	1) cases - N=250 patients who suffered first heart attack within 4 yrs of enrolling; 2) controls - N=500 matched controls
Outcome / Goal	Discovered multivariate biomarker of	Corroborated Study I results and further
	prognosis post angiography	refined assay

Source: Company reports

BG Medicine has initiated development of an automated version of AMIPredict using the Abbott ARCHITECT automated platform. Additional validation studies are being conducted and are expected to be completed in H1:2011. The company's commercialization strategy for AMIPredict is to initially offer a FDA-cleared laboratory service through partnerships with specialty reference labs. Longer term, the company will pursue development of an automated version of the test through partnerships with immunoassay system vendors.

#### **LipidDx**

Through collaboration with Merck, BG Medicine is developing a blood-based protein assay to aid in the management of common lipid disorders and to assess its contribution to cardiovascular risk assessment. An estimated 36MM adults in the US have elevated levels of cholesterol [of greater than 240 mg/dL]. Despite the recognition of its importance and the availability of a variety of generally effective therapeutic means to reduce cholesterol and triglycerides, of those patients treated, only about one-third are achieving their goal for LDL.

The company expects to conduct one or more clinical validation studies then seek FDA input on requirements for 510(k) clearance for this indication. Currently, the company estimates that it will commercialize a first generation manual LipidDx product in 2012, with automated versions pursued thereafter.

March 18, 2011



## **Market Opportunity Overview**

The global in vitro diagnostics market is estimated to approximate over \$30Bn. The most relevant subsegments for BG Medicine are Immunoassays (~\$6Bn) and Point of Care (~\$2Bn). Leading IVD manufacturers include Abbott, Siemens, Roche, Ortho Clinical Diagnostics and Beckman Coulter. In addition to developing advanced diagnostic laboratory instruments, these manufacturers have established significant manufacturing and supply chain logistics and sales and marketing infrastructures for the diagnostic reagents used by their systems. Core to BG Medicine's strategy is the belief that the installed base of automated instruments offers an opportunity to make novel biomarker tests available to laboratories globally without the need for investment in development and commercialization of instrumentation specific to the "content" of the tests.

#### **Galectin-3 Related Tests**

The market opportunity for BGM Galectin-3 tests in heart failure patients, in terms of test volume, is significant. According to the American Heart Association, there are almost 6MM individuals in the U.S. with heart failure. These patients have about 2.3 outpatient physician visits per year; this equates to roughly 13.8MM outpatient visits per year by heart failure (HF) patients in the U.S. The table below walks through market opportunity estimates for the galectin-3 family of tests by indication. Not including the Crestor indication, we estimate the market opportunity for BGM Galectin-3 to approximate \$700MM.

Galectin-3 in Heart Failure - Market Opportunity Overview by Indication

	Indication	Market Opp – Volumes	Market Opp - Revenue	Economics
BGM Galectin- 3 – manual	With clinical evaluation as an aid in assessing the prognosis of patients diagnosed with chronic heart failure	6MM HF pts in US     2.3 visits / pt / yr     ~14M tests / year	•\$7.5 ASP / test •~\$104MM / yr US •+ EU 50% of US •Total = ~\$155MM	BGMD receives \$5-10 per test from LH      BGMD pays low single digits revenue royalty to ACS (licensor)
BGM Galectin 3 – automated	TBD. With clinical evaluation as an aid in prognosis of patients with heart failure	• 6MM HF pts in US • 2.3 visits / pt / yr • ~14M tests / year	•\$12.5 ASP / test •~\$173MM / yr US •+ EU 50% of US •Total = ~\$258MM  •Note: This estimate overlaps with estimate for manual test above	BGMD receives \$10-15 per test from partners     BGMD pays low single digits revenue royalty to ACS (licensor)     BGMD pays single digit revenue royalty to LH for first 3y of automated test commercialization
BGM Galectin 3 – automated - Label extension	TBD. Identify patients at elevated risk of heart failure following a heart attack	8MM post MI; 9MM     ACS pts in US     1.5 tests / pt / yr     ~25M tests / year	•\$12.5 ASP / test •~\$319MM / yr US •+ EU 50% of US •Total = ~\$478MM	Assume same as above
BGM Galectin 3 – automated - Label extension	TBD. Identify patients who will benefit / not benefit from Crestor (rosuvastatin) treatment for lowering cholesterol and slowing plaque buildup	•TBD	•TBD	Assume same as above

Source: Company reports and Cowen and Company estimates



#### Reimbursement

BG Medicine expects to obtain an analyte specific CPT code for Galectin-3 in 2013. In the meantime, the company expects cross walk to the BMP test code (83880) to be achieved without too much difficulty based on the clinical value of galectin-3 testing. Average reimbursement for BMP testing is \$47 (thus providing about a \$30 per test cushion for partners net of payment to BG Medicine). A less favorable scenario would be cross walk to high sensitivity C-reactive protein (hsCRP) tests, which achieve reimbursement of \$14-16.

#### **AMI Predict**

BG Medicine's product candidate with the largest potential market opportunity is AMIPredict. AMIPredict is a multi-biomarker (currently 7 proteins) blood-based test aiming to identify patients with a relatively higher risk of suffering a heart attack or stroke within the next two to four years. The potential market for a test to aid in assessing risk of myocardial infarction (MI) or stroke in U.S. alone is significant there are an estimated 43MM men aged 50 or over and 40MM women aged 55 or over in the U.S. who may be at risk for developing vulnerable plaques. Assuming about 10% of these patients are relatively higher risk, this equates to about 80MM tests per year in the U.S. The company's goal is to commercialize a first generation manual AMIPredict product in 2012, and an automated product version through partnerships thereafter. The strength of AMIPredict's label will be key to determining the true market potential for this test.

#### **AMIPredict - Market Opportunity Overview**

	Indication	Market Opp – Volumes	Market Opp - Revenue	Economics
AMIPredict	TBD. Identify patients at	•8MM individuals at	•\$100 ASP / test	• TBD
	high risk of near term	higher risk for MI in US	•~\$800MM / yr US	<ul> <li>Code stacking achieves</li> </ul>
	antithrombotic event	• 1.0 visits / pt / yr	• + EU 50% of US	>\$100 per test
		•~8MM tests / year	• Total = ~\$1,200MM	, ,

Source: Company reports and Cowen and Company estimates

### **Other Pipeline Candidates**

Although targeting high profile areas, the market opportunities for other tests in BG Medicine's pipeline remains difficult to characterize. These include LipidDx, markers of TNF alpha response and markers of multiple sclerosis disease activity.



## **BGMD - Test Pipeline Summary Chart**

	Indication	Partnerships (announced)	Platforms	Market Opportunity	Regulatory	Launch Timing	Economics
BGM Galectin-3 – manual	With clinical evaluation as an aid in assessing the prognosis of patients diagnosed with chronic heart failure	• LabCorp (Jan 2011)	Manual, ELISA microtiter format	14M tests / year US; <1% underlying growth, underpenetrated	510(k) received Nov 2010; CE Mark EU Oct 2009	Launched EU and US	BGMD receives \$5-10 per test from LH     BGMD pays low single digits revenue royalty to ACS (licensor)
BGM Galectin 3 – automated	TBD. With clinical evaluation as an aid in prognosis of patients with heart failure	• Abbott (Nov 2009); • Siemens (Jan 2011); • bioMerieux	Abbott ARCHITECT;     Abbott iStat;     bioMerieux VIDAS;     Alere TRIAGE;     Siemens TBD	14M tests / year US; <1% underlying growth, underpenetrated	510(k). Expect partners to file with FDA by end of 2011	Estimate H1:2012 US commercial launch	BGMD receives \$10-15 per test from partners BGMD pays low single digits revenue royalty to ACS (licensor) BGMD pays single digit revenue royalty to LH for first 3y of automated test commercialization
BGM Galectin 3  – automated - Label extension	TBD. Identify patients at elevated risk of heart failure following a heart attack	• Abbott (Nov 2009); • Siemens (Jan 2011); • bioMerieux	Abbott ARCHITECT;     Abbott iStat;     bioMerieux VIDAS;     Alere TRIAGE;     Siemens TBD	25M tests / year US based on post MI and ACS	510(k) Supplement. Estimate late 2011.	Estimate late 2012, early 2013	BGMD receives \$10-15 per test from partners BGMD pays low single digits revenue royalty to ACS (licensor) BGMD pays single digit revenue royalty to LH for first 3y of automated test commercialization
BGM Galectin 3 – automated - Label extension	TBD. Identify patients who will benefit / not benefit from Crestor (rosuvastatin) treatment for lowering cholesterol and slowing plaque buildup	• Abbott (Nov 2009); • Siemens (Jan 2011); • bioMerieux	Abbott ARCHITECT;     Abbott iStat;     bioMerieux VIDAS;     Alere TRIAGE;     Siemens TBD	TBD	510(k) supplement. Estimate filing no later than Q3:2011	Estimate early 2012	BGMD receives \$10-15 per test from partners BGMD pays low single digits revenue royalty to ACS (licensor) BGMD pays single digit revenue royalty to LH for first 3y of automated test commercialization
AMIPredict	TBD. Identify patients at high risk of near term antithrombotic event	• Abbott	Abbott ARCHITECT	80M people in US could be eligible for testing; 8MM considered higher risk	TBD. May pursue LDT with 510(k) for this IVDMIA a longer term strategy	Estimate manual test launch in 2012; automated test thereafter	TBD     Code stacking achieves >\$100 per test
LipidDx	TBD. As an aid in management of patients with lipid disorders	• Merck (Feb 2010)	TBD	TBD	TBD	Estimate manual test launch in 2012; automated test thereafter	TBD
Autoimmune disorders – TNF alpha blockers	Markers of treatment response	TBD	TBD	TBD	TBD	TBD	TBD



## **BG Medicine**

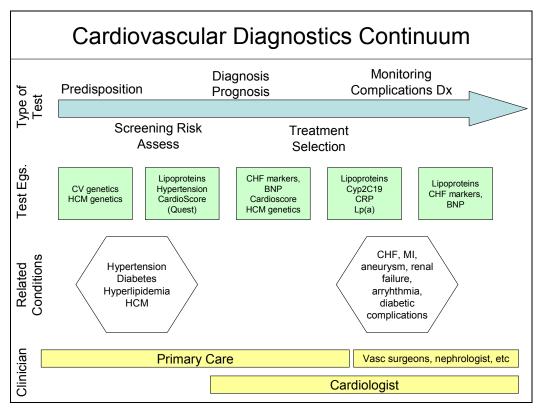
CNS disorders –	Markers of disease	TBD	TBD	350K in US; 3MM	TBD	TBD	TBD
Multiple	activity			WW			
Sclerosis							
Cardio-	Multiple projects.	TBD	TBD	TBD	TBD	TBD	TBD
Metabolic	Collaborations with						
disorders	Framingham Heart						

Source: Company reports and Cowen and Company



## Competition

Cardiovascular disease is the #1 killer in the developed world, a key driver of US health care costs, and current diagnostics are inadequate for assessing CV event risk. For these reasons, a number of companies are developing a variety of tests for various segments of the CV market. It is important to note that competition should be assessed within relatively specific clinical sub segments of CV disease such as: CHF, metabolic syndrome, arterial thrombosis, aneurysm, atherosclerosis and arrhythmias, to name a few. Given their relatively low costs and potential to significantly reduce the overall costs of treating CV disease patients, there is plenty of room for many winners from a clinical test perspective (if not from an instrumentation perspective) if incremental clinical value is demonstrated. BG Medicine's partnerships with leading vendors should give galectin-3 and follow-on tests the channels through which to compete in the market – success of course will be driven by convincing the clinical community.



Source: Cowen and Company, Quest Diagnostics

#### Galectin-3 and BNP/proBNP Testing

Within CHF, where galectin-3 sits, our checks suggest there remains an unmet clinical need to identify patients with CHF and those CHF patients who need additional therapy. Experts consider the field as relatively wide open beyond BNP. BNP is standard of care and validates the market opportunity for routine CV diagnostics – the BNP / proBNP diagnostics market is estimated at ~\$650MM. BNP testing is used for: ruling out CHF in symptomatic individuals, determining prognosis in individuals with CHF or other CV disease, and maximizing therapy in individuals with CHF. On the surface then, it appears that galectin-3 would be competing with BNP testing. However, BG Medicine has demonstrated that galectin-3



and proBNP measurements provide independent and complementary information on the prognosis of patients with CHF. The underlying biological roles of BNP and galectin substantiate these results. This provides an opportunity for galectin-3 testing uptake to be catalyzed by bundling with BNP tests. For this reason, the success of BNP may actually benefit uptake of galectin-3 testing, although a good amount of physician education and marketing will be required to convince clinicians of the incremental value provided by galectin-3 testing. That said, we are aware of a variety of tests such as IL-33 and next gen BNP peptides for CHF characterization in development by large reference laboratories and IVD manufacturers that should begin entering the market over the next 18-24 months. We reiterate however, that almost 6MM heart failure patients in the U.S. alone, there is plenty of room for multiple winners in this space.

#### **AMIPredict**

AMIPredict aims to identify patients with a relatively higher risk of suffering a heart attack or stroke within the next two to four years. The market opportunity for such a test - a screening / risk assessment test within CV disease - is large. This should be expected to attract a number of players into the space as well. Traditional tests for CV risk include analysis of lipoproteins (LDL, HDL) and hypertension. These measurements are standard of care and relatively cheap, but have significant limitations as predictors of CV disease risk. Reference labs are pursuing panel tests or multivariate biomarker tests to try to increase risk prediction. Quest's Cardioscore (in development) for example will combine a number of markers with strong published evidence such as sPLA2 and oxLDL.



## **Financial Projections and Valuation**

#### **Revenue Model**

Beginning in 2011, BGMD's revenues will come almost exclusively from the sale of tests kits and services, as large service contracts such as HRP are completed. Initial product revenues will come from BGM Galectin-3. We expect BGM Gelectin-3 to see only modest uptake in 2011 due to the availability of only the manual version of the assay. With automated versions of the assay due for submission to FDA by the end of 2011 through one of BGMD's partners (likely Abbott or Alere first), we expect to see a significant ramp in revenue beginning in 2012. ASPs for this test are expect to increase steadily as well during this period as the proportion of higher ASP volumes from the automated test become a greater proportion of overall volumes. ASP for BGM Galectin-3 could see another significant bump in 2013 if the company is able to garner an analyte-specific CPT for its test in 2013, as the company currently forecasts. We do not reflect this potential in our model and it should thus be considered upside. This will coincide with a number of peer reviewed publications and potential label extensions for the Crestor response indication and post PI/ACS assessment. We expect these factors to result in a steep ramp in galectin-3 test volumes and revenues beginning in 2013 and continuing thereafter.

**BGMD - Summary Product Revenue Forecast** 

REVENUES ('000)	2010	2011E	2012E	2013E	2014E
IVD Kits	\$2,700	\$406,250	\$4,396,029	\$22,973,962	\$45,070,326
CLIA Lab IVD	\$0	\$30,000	\$3,250,000	\$45,650,000	\$104,995,000
Total Products Revenue	\$2,700	\$436,250	\$7,646,029	\$68,623,962	\$150,065,326
ASP	\$4	\$7	\$15	\$25	\$27

Source: Cowen and Company estimates

Initial manual versions of LipidDx and AMIPredict are expected to reach market sometime in 2012, with automated versions arriving likely beginning in 2013. We expect AMIPredict to become BGMD's largest contributor to sales in 2013, demonstrating the significant market opportunity the test is addressing. This growth is expected to come from underlying volume growth but also because AMIPredict is expected to yield ASPs almost 10x that of galectin-3. We note that our 2014 AMIPredict volume forecast equates to <1% penetration of the market opportunity for that test (80MM high risk Americans; 8MM higher risk).

**Key Milestones / Catalysts** 

Milestone / Catalyst	Est. Timing
Manual Galectin-3 test ramp through LabCorp	H1:2011
510(k) clearance for automated Galectin-3 test through partners	By YE2011
Galectin-3 label extension: Post MI prognosis assessment	Late 2011
Galectin-3 label extension: Crestor (rosuvastatin) response assessment	Late 2011
AND BUILD HALL IN THE STATE OF	2012
AMIPredict & LipidDx initial launch (manual test version)	2012



#### P&L

We currently expect BGMD to reach profitability in 2013, reflecting the significant revenue ramp we expect that year from the full launch of the automated BGM Galectin-3 assay, and automated test version launches of AMIPredict and LipidDx.

Gross margins for the galectin-3 assay are expected to be healthy, with the majority of COGS coming from royalty obligations totaling about 10% of product sales (lower royalty obligations for the manual version as the company is required to pay LabCorp a royalty on sales through automation partners). We have conservatively modeled for gross margins to increase from 52% in 2011 to 70% in 2014, but believe improved product economics could drive better results. We note that if the company is able to secure an analyte specific CPT code in 2013 as the company anticipates, gross margins would be better than our model.

**BGMD - Annual Income Statement** 

BUMD - Allitual Income Sta	tement				
(in thousands. except EPS)	2010	2011E	2012E	2013E	2014E
Total Revenue	\$819	\$451	\$7,646	\$68,624	\$150,065
Cost of Sales	786	218	3,312	21,588	45,020
Gross Profit	33	233	4,334	47,036	105,046
R&D SG&A	6,539 8,100	11,000 16,500	15,000 22,000	18,032 26,584	21,009 33,014
Operating Expenses	14,639	27,500	37,000	44,616	54,024
Income (loss) from Operations	(14,606)	(27,267)	(32,666)	2,420	51,022
Other income (expenses)	2,556	2,400	2,400	2,400	2,500
Pre-Tax income (loss)	(17,162)	(29,667)	(35,066)	20	48,522
Taxes	0	0	0	7	16,983
Net Income Shares Outstanding	(17,162)	<b>(29,667)</b> 23,600	<b>(35,066)</b> 25,200	<b>13</b> 26,200	<b>31,539</b> 27,200
<b>EPS</b>	(\$6.12)	(\$1.26)	(\$1.39)	\$0.00	\$1.16
Margin Analysis (% of sales)	40/	500/	F70/	000/	700/
Gross Profit	4%	52%	57%	69%	70%
R&D SG&A	798% 989%	2438% 3657%	196% 288%	26% 39%	14% 22%
Operating Expenses	969% 1787%	6094%	484%	59% 65%	36%
Income (loss) from ops	-1783%	-6043%	-427%	4%	34%
Taxes (% of pre tax income)	0%	0%	0%	35%	35%
Net Income	-2095%	-6574%	-459%	0%	21%
Growth Analysis (%y/y)					
Total Revenue	_	-44.9%	1594.4%	797.5%	118.7%
Gross Profit	-	606.4%	1759.1%	985.3%	123.3%
R&D	-	68.2%	36.4%	20.2%	16.5%
SG&A	-	103.7%	33.3%	20.8%	24.2%
Operating Expenses	-	87.9%	34.5%	20.6%	21.1%
Income (loss) from ops	-	-	-	-	2008.2%
Pre-Tax income (loss)	-	-	-	-	-
Net Income	-	-	-	-	-

Source: Company reports and Cowen and Company estimates



We expect operating expenses to grow steadily albeit not tightly in proportion to sales as the company is able to leverage the R&D and sales and marketing infrastructures of its sizable partners. We believe the company's close collaborations with its commercial partners as well as others such as Merck will continue to offer opportunities for BGMD to offset some R&D expense from year to year.

#### **Valuation**

On a price / sales ratio basis, BGMD is currently trading at 18.6x, 2.7x, and 0.9x our 2012, 2013, and 2014 sales forecasts. Although these metrics are at a premium to a comp group including other diagnostics providers (service and instrument/assay providers), we believe that even modest penetration of the market addressed by BGMD's tests will lead to significant upside to our revenue forecasts. For example, we note that our 2014 AMIPredict volume forecast equates to <1% penetration of the market opportunity for that test (80MM high risk Americans; 8MM higher risk). For every incremental 1% of the high risk market opportunity captured equates to roughly \$80MM, or about 50% upside to our 2014 total revenue forecast. Folding this upside in, BGMD shares could, on a 2013-2014 price / sales perspective, quickly appear attractive relative to current levels. We initiate with an Outperform on the basis of this significant revenue upside potential.

#### **Comp Table**

			Price	12 Month	Ent. Val.	Mkt. Cap	Net Cash/	'10/12	'10/12	EV/ Ca	lendar Reve	enue	EV	/ EBITDA		Ca	endar P/ I	<b>=</b>
Company	Ticker	Rating	3/17/11	High - Low	(\$MM)	(\$MM)	Share	Rev CAGR	EPSCAGR	2011E	2012E	2013E	2011E	2012E	2013E	2011E	2012E	2013E
Life Science Tools																		
Celera	CRA	NR	\$6	\$8 - \$5	\$194	\$510	\$3.85	14.2%	#NUM!	1.5x	1.3x	1.1x	NM	NM	53.3x	NM	NM	230.0x
Gen Probe	GPRO	Neutral	\$63	\$66 - \$42	\$3,048	\$3,038	-\$0.20	12.7%	17.9%	5.2x	4.7x	4.1x	14.5x	12.7x	10.9x	26.8x	22.8x	19.3x
Cepheid	OPHD .	NR	\$25	\$28 - \$14	\$1,472	\$1,545	\$1.19	23.6%	245.2%	5.8x	4.8x	3.8x	66.9x	29.0x	16.0x	355.9x	54.8x	29.9x
Myriad Genetics	MYGN	Neutral	\$19	\$26 - \$14	\$1,284	\$1,675	\$4.35	8.3%	NM	3.3x	3.0x	2.8x	8.1x	7.5x	NM	18.3x	15.8x	NM
QIAGEN	QGEN	Neutral	\$19	\$24 - \$17	\$4,498	\$4,487	-\$0.04	9.8%	14.5%	3.8x	3.5x	3.2x	11.6x	10.2x	9.5x	19.8x	17.3x	15.1x
Genomic Health	GHDX	NR	\$24	\$27 \$12	\$622	\$692	\$2.39	17.1%	151.9%	3.0x	2.6x	2.2x	43.4x	24.6x	NM	112.1x	50.7x	17.7x
GenMark Diagnostics	GNMK	NR	\$4	\$6 \$3	\$20	\$44	\$2.06	157.6%	-31.9%	3.9x	1.2x	0.6x	NM	NM	NM	NM	NM	NM
										EV/ Ca	lendar Reve	enue	EV	/ EBITDA		Ca	endar P/ I	<b>=</b>
									LSTools	2011E	2012E	2013E	2011E	2012E	2013E	2011E	2012E	2013E
									Mean	3.8x	3.0x	2.5x	28.9x	16.8x	22.4x	106.6x	32.3x	62.4x
									Median	3.8x	3.0x	2.8x	14.5x	12.7x	13.4x	26.8x	22.8x	19.3x
									High	5.8x	4.8x	4.1x	66.9x	29.0x	53.3x	355.9x	54.8x	230.0x
									Low	1.5x	1.2x	0.6x	8.1x	7.5x	9.5x	18.3x	15.8x	15.1x
BGMD	BGMD		\$8	\$9 - \$7	184.383	\$187	\$0.10	1133.2%	NM	408.6x	24.1x	2.7x	NM	NM	76.2x	NM	NM	16957.5x

Source: Company reports and Cowen and Company estimates. (MYGN - Covered by Ian Sanderson)

We believe BGMD has the profile to make it an attractive acquisition target for a variety of players in the diagnostics industry. The company's strategy of producing proprietary tests that can be run on well established instrumentation platforms make it easy to see BGMD as a nice strategic fit for instrumentation providers who are always looking to expend their testing "menus" with proprietary assays. The table on the following page highlights precedent M&A transactions in the diagnostics space to serve as an indicator of valuations placed on comparable companies. Since 2006 there have been 48 public diagnostic M&A transactions, totaling >\$17B. These precedent transactions suggest BGMD, based on our 2012-2013 revenue forecasts, could be valued at >3x current levels to a strategic buyer.



## **Precedent M&A Transaction In Diagnostics**

Date Of			Enterprise	LTM	EV/ Revenue	
Announc.	Target	Acquiror	Value	Revenue	LTM	Subsector
4/26/2010	RedPath Integrated Pathology, Inc.	ExonHit Therapeutics SA.	\$22.5	\$6.0	3.75x	Diagnostics
4/14/2010	diaDexus, Inc.	VaxGen, Inc.	\$18.8	\$11.7	1.61x	Diagnostics
1/11/2010	Diagnostic Hybrids, Inc.	Quidel Corporation	\$130.0	\$38.0	3.42x	Diagnostics
9/3/2009	B.R.A.H.M.S. AG	Thermo Fisher Scientific Inc.	\$470.0	\$105.0	4.48x	Diagnostics
6/23/2009	Monogram Biosciences, Inc.	LabCorp	\$135.7	\$61.6	2.20x	Diagnostics
12/8/2008	PML Microbiologicals Inc.	bioMerieux SA	\$29.6	\$24.0	1.23x	Diagnostics
10/1/2008	Biotage AB Biosystems Business	Qiagen N.V.	\$53.0	\$16.9	3.14x	Diagnostics
8/14/2008	The Bitech Group	Nanogen, Inc.	\$99.1	\$74.2	1.34x	Diagnostics
6/11/2008	Immunicon Corp.	Johnson & Johnson	\$21.6	\$17.3	1.25x	Diagnostics
6/9/2008	Third Wave Technologies, Inc.	Hologic, Inc.	\$545.8	\$32.8	16.64x	Diagnostics
4/25/2008	Innogenetics NV	Solvay Pharmaceuticals SA	\$321.9	\$74.2	4.34x	Diagnostics
2/25/2008	Oriticare Systems, Inc.	Opto Grouits (India) Ltd.	\$62.6	\$34.1	1.83x	Cancer Diagnostics
1/21/2008	Oncotech, Inc.	Exigon A/S	\$36.4	\$12.6	2.89x	Diagnostics
12/11/2007	BBI Holdings	Inverness Medical	\$186.8	\$29.3	6.37x	Diagnostics
10/10/2007	Excel-Tech Ltd. (XLTEK)	Natus Medical Incorporated	\$46.8	\$33.0	1.42x	In Vitro / In Vivo Diagnostics
10/3/2007	Bio-Stat Healthcare Group Limited	Inverness Medical Innovations Inc.	\$33.4	\$29.5	1.13x	Diagnostics
8/6/2007	HemoSense Inc.	Inverness Medical Innovations, Inc.	\$234.5	\$28.1	8.35x	Diagnostics
7/25/2007	Dade Behring Holdings	Semens AG	\$7,217.7	\$1,782.7	4.05x	Diagnostics
6/18/2007	Quality Assured Services Inc.	Inverness Medical Innovations, Inc.	\$25.0	\$16.9	1.48x	Diagnostics
6/4/2007	Cholestech	Inverness Medical Innovations, Inc.	\$277.4	\$70.9	3.91x	Diagnostics
4/16/2007	AmeriPath Inc.	Quest Diagnostics Inc.	\$2,000.0	\$782.1	2.56x	Diagnostics
4/5/2007	Biosite, Inc.	Inverness Medical Innovations, Inc.	\$1,600.1	\$308.6	5.19x	Diagnostics
3/14/2007	Instant Technologies, Inc.	Inverness Medical Innovations, Inc.	\$48.5	\$23.0	2.74x	Diagnostics
2/12/2007	Adeza Biomedical Corporation	Cytyc Corp.	\$353.3	\$52.0	6.80x	Diagnostics
2/5/2007	First Check Diagnostics LLC	Inverness Medical Innovations, Inc.	\$24.7	\$11.0	2.25x	Diagnostics
2/1/2007	HemoQue AB	Quest Diagnostics Inc.	\$420.0	\$90.0	4.67x	Diagnostics
10/2/2006	Lumigen, Inc.	Beckman Coulter, Inc.	\$185.0	\$33.0	5.61x	Diagnostics
4/27/2006	Diagnostic Products Corporation	Semens AG	\$1,695.2	\$496.9	3.41x	Diagnostics
2/24/2006	ACON Laboratories, Inc.	Inverness Medical Innovations, Inc.	\$175.0	\$50.0	1.98x	Diagnostics
					EV/ Revenue	
				Mean	3.79x	
				Median	3.14x	
				High	16.6x	
				Low	1.1x	

Source: Company reports and Cowen and Company estimates



## **Partnerships / Initiatives Overview**

As noted, partnerships for discovery, development and commercialization are core to BG Medicine's strategy. Key partnerships and initiatives are summarized below.

#### **Abbott**

In November 2009, BG Medicine and Abbott entered into a strategic collaboration to develop and commercialize Galectin-3 assay kits for use on Abbott's Architect Immunochemistry Diagnostics Platform and other Abbott diagnostic instruments; in March 2010 an amendment was executed to include the iSTAT point of care platform. Based on the Abbott relationship, BGM has the right to enter into up to four additional galectin-3 related licenses during the five year period from the date on which Abbott makes its first commercial sale of galectin-3 products. Abbott has been granted "favored nations" and will therefore not have inferior economic terms relative to subsequent partners. Since the execution of the Abbott agreement, BG Medicine has entered into three similar agreements with Alere, bioMérieux, and Siemens; leaving the ability to execute one more similar partnership.

#### **Siemens**

In January 2011, BG Medicine announced an agreement with Siemens Healthcare Diagnostics for the development and commercialization of a galectin-3 test for Siemens' automated immunoassay platforms.

#### bioMerieux

In May 2010, BG Medicine announced an agreement with bioMerieux for the development and commercialization of a galectin-3 test for bioMerieux's VIDAS platform.

#### **Alere**

In April 2010, BG announced an agreement with Alere for the development and commercialization of a galectin-3 test for Alere's Triage Meter Pro system.

#### LabCorp

In May 2010, BG Medicine entered into an agreement with LabCorp; LabCorp agreed to make manual galectin-3 tests available in the US within 45 days of 510(k) clearance. LabCorp was granted a semi-exclusive worldwide license (BG Medicine can not license to specific LabCorp competitors) related to galectin-3 testing services using the manual galectin-3 test. LabCorp pays BG Medicine ~\$5-10 per test kit. For helping develop the market for galectin-3 testing, BG Medicine has agreed to pay LabCorp a single digit royalty on the sales of future automated versions of gelectin-3 for three years following the initial commercialization of automated tests.

#### Humana

In May 2007, BG Medicine entered into a strategic agreement with Humana to collaborate with the goal of accelerating the development of blood-based biomarkers and identifying the role of blood-based biomarkers in improving health outcomes and containing healthcare costs through individualized medicine. BG can conduct biomarker discovery and validation studies among Humana members. BG



will offer any blood-based biomarker diagnostic products it develops from data or services provided by Humana to Humana on preferred terms. In addition, BG will make certain payments to Humana if it commercializes blood-based biomarker diagnostic products under this partnership.

#### Merck

In January 2010, BG Medicine entered into a research collaboration agreement with Merck for the purpose of development and validation of an immunoassay for a novel biomarker for use in patients with certain lipid disorders, or at elevated risk for cardiovascular disease because of such disorders – this biomarker is referred to as "LipidDx." BG will perform validation of the assay in approximately 1,000 samples provided by Merck. Merck is required to perform certain data analyses upon receipt of the biomarker data. Under the agreement, Merck granted BG a non-exclusive license to certain rights towards development of an in vitro diagnostic test.

#### **HRP Initiative**

In 2006, BG Medicine initiated the HRP initiative for atherothrombotic cardiovascular disease. The HRP initiative consists of a series of pre-competitive, multi-party research and development projects, which are administered and coordinated by BG Medicine through agreements with Abbott, AstraZeneca, Merck, Philips and Takeda. The overall goals of the HRP initiative are to provide a roadmap for the development and registration of screening, diagnostic and therapeutic interventions for high-risk plaque and to promote the use of these interventions by patients, pharmaceutical companies and third-party payors.

Pursuant to the participation agreements, each of Abbott, AstraZeneca, Merck, Philips and Takeda has provided the aggregate of \$5.0 million to support the HRP initiative. BGM will own any inventions and data that are conceived in the conduct of the HRP initiative and have agreed to grant each participating company a non-exclusive, perpetual, royalty-free license to all such inventions and data for any and all uses.

#### Framingham Heart Study and Boston University

The Framingham Heart Study (FHS) is a prospective, community-based, family study that began in 1948 among residents of Framingham, Massachusetts, to study the development of cardiovascular disease over time. FHS has previously provided insights that have led to new clinical paradigms related to hypertension, lipid disorders, obesity and smoking. In Q1:2009 was awarded a contract to perform biomarker discovery studies involving blood samples and data from the Framingham Heart Study - this was the first time that the Framingham Heart Study is partnering with a commercial entity in a CRADA research project. BG Medicine maintains certain commercial rights to biomarker inventions resulting from this research.



## **Senior Management**

**Pieter Muntendam, M.D. - President and CEO.** Dr. Muntendam joined BG Medicine as President in November 2004 and was appointed as Chief Executive Officer in December 2005. He also has served as a member of our board of directors since November 2004. He is a biopharmaceutical and healthcare executive with over 20 years of business experience ranging from early stage enterprises to multinational corporations. Dr. Muntendam joined BG Medicine from NetNumina Solutions, Inc., a professional services company. Prior to joining NetNumina, he co-founded Vitivity Inc., a subsidiary of Millennium Pharmaceuticals, Inc., and served as Vice President, Medicine. Earlier in his career, Dr. Muntendam held a variety of positions at ProMedex Inc., Glaxo Wellcome (now GSK), Organon International Inc. and Johnson & Johnson. Dr. Muntendam received his M.D. from Leiden University in the Netherlands.

**Michael W. Rogers - Executive VP, CFO.** Mr. Rogers joined BG Medicine in June 2009 as Executive Vice President, Chief Financial Officer and Treasurer. Prior to joining BG Medicine, Mr. Rogers served as Executive Vice President, CFO and Treasurer at Indevus Pharmaceuticals, Inc. and prior to that Executive Vice President and CFO and Chief Corporate Development Officer at Advanced Health Corporation. Earlier in his career, Mr. Rogers was a member of the investment banking groups at Lehman Brothers and PaineWebber. Mr. Rogers received an M.B.A. from the Darden School at the University of Virginia and a B.A. from Union College.

**Neal F. Gordon, Ph.D.** - **Senior VP, Biomarker Discovery.** Dr. Gordon joined BG Medicine in January 2009 as Senior Vice President, Biomarker Discovery. Dr. Gordon has 20 years of experience in the biotechnology industry serving both as a senior executive and in product development. Dr. Gordon has held various positions at Epitome Biosystems, Antigenics Inc. and PerSeptive Biosystems (now part of Life Technologies). Dr. Gordon obtained a B.S. in chemical engineering from McGill University, and a Ph.D. in biochemical engineering from Massachusetts Institute of Technology.

**Wayne K. Shepherd - VP, Sales and Marketing.** Mr. Shepherd joined BG Medicine in June 2009 as Vice President, Market Development. In May 2010, Mr. Shepherd was promoted to Vice President, Sales and Marketing. Mr. Shepherd has over 15 years of experience in the biotechnology and device industry. Prior to joining BG Medicine, Mr. Shepherd held senior positions at Biosite. Notably, Mr. Shepherd managed a sales team responsible for selling capital cardiac diagnostic equipment and reagent sales at Biosite and held the position of Senior BNP Product Manager at BiositeMr. Shepherd received an M.B.A. from Averett University and a B.S. in Marketing Education at Virginia Tech.

**Anastasia Rader - Senior VP, Executive Operations & Human Resources.** Ms. Rader joined BG Medicine in January 2004 as Vice President, Human Resources and was appointed Senior Vice President, Executive Operations & Human Resources in January 2010. Prior to joining BG Medicine, Ms. Rader was a Vice President at Flagship Ventures and Vice President, Human Resources, of NewcoGen. Prior to joining Flagship, Ms. Rader was Corporate Director of Worldwide Employment and Staffing for Applera Corporation (now Life Technologies). Ms. Rader holds a B.S. from Babson College.



## **BG Medicine - Quarterly Income Statement**

(in thousands)	Q1:11E	Q2:11E	Q3:11E	Q4:11E	Q1:12E	Q2:12E	Q3:12E	Q4:12E	Q1:13E	Q2:13E	Q3:13E	Q4:13E	2010	2011E	2012E	2013E	2014E
Total Revenue	29	62	117	243	417	1,088	2,065	4,077	5,654	14,353	20,348	28,270	819	451	7,646	68,624	150,065
Cost of Sales	10	29	59	122	208	544	929	1,631	1,979	5,024	6,104	8,481	786	218	3,312	21,588	45,020
Gross Profit	20	34	59	122	208	544	1,136	2,446	3,675	9,329	14,243	19,789	33	233	4,334	47,036	105,046
R&D SG&A	2,900 4,000	2,800 4,100	2,700 4,200	2,600 4,200	3,750 5,100	3,750 5,400	3,750 5,700	3,750 5,800	4,240 5,654	4,306 6,459	4,680 7,122	4,806 7,350	6,539 8,100	11,000 16,500	15,000 22,000	18,032 26,584	21,009 33,014
Operating Expenses	6,900	6,900	6,900	6,800	8,850	9,150	9,450	9,550	9,894	10,765	11,802	12,156	14,639	27,500	37,000	44,616	54,024
Income (loss) from Operations	(6,881)	(6,867)	(6,842)	(6,678)	(8,642)	(8,606)	(8,314)	(7,104)	(6,219)	(1,435)	2,442	7,633	(14,606)	(27,267)	(32,666)	2,420	51,022
Other income (expenses)	600	600	600	600	600	600	600	600	600	600	600	600	2,556	2,400	2,400	2,400	2,500
Pre-Tax income (loss)	(7,481)	(7,467)	(7,442)	(7,278)	(9,242)	(9,206)	(8,914)	(7,704)	(6,819)	(2,035)	1,842	7,033	(17,162)	(29,667)	(35,066)	20	48,522
Taxes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	7	16,983
Net Income Shares Outstanding	<b>(7,481)</b> 22,000	<b>(7,467)</b> 22,200	<b>(7,442)</b> 22,400	<b>(7,278)</b> 22,600	<b>(9,242)</b> 23,000	<b>(9,206)</b> 23,400	<b>(8,914)</b> 23,800	<b>(7,704)</b> 24,200	<b>(6,819)</b> 24,600	<b>(2,035)</b> 25,000	<b>1,842</b> 25,400	<b>7,033</b> 25,800	(17,162)	( <b>29,667)</b> 23,600	( <b>35,066</b> ) 25,200	<b>13</b> 26,200	<b>31,539</b> 27,200
EPS	(0.34)	(0.34)	(0.33)	(0.32)	(0.40)	(0.39)	(0.37)	(0.32)	(0.28)	(0.08)	0.07	0.27	(6.12)	(1.26)	(1.39)	0.00	1.16
Margin Analysis (% of sales)																	
Gross Profit R&D	67% 10000%	54% 4516%	50% 2308%	50% 1069%	50% 900%	50% 345%	55% 182%	60% 92%	65% 75%	65% 30%	70% 23%	70% 17%	4% 798%	52% 2438%	57% 196%	69% 26%	70% 14%
SG&A	13793%	6613%	3590%	1727%	1224%	496%	276%	142%	100%	45%	35%	26%	989%	3657%	288%	39%	22%
Operating Expenses	23793%	11129%	5897%	2795%	2125%	841%	458%	234%	175%	75%	58%	43%	1787%	6094%	484%	65%	36%
Income (loss) from ops	-23726%	-11075%	-5847%	-2745%	-2075%	-791%	-403%	-174%	-110%	-10%	12%	27%	-1783%	-6043%	-427%	4%	34%
Taxes (% of pre tax income)	0%	0%	0%	0%	0%	0% -846%	0%	0%	0%	0%	0%	0% 25%	0%	0%	0%	35%	35% 21%
Net Income	-25795%	-12043%	-6360%	-2992%	-2219%	-846%	-432%	-189%	-121%	-14%	9%	25%	-2095%	-6574%	-459%	0%	21%
Growth Analysis (% y/ y)																	
Total Revenue Gross Profit					1336.2%	1655.2%	1664.6%	1575.9%	1257.4%	1218.9%	885.5%	593.5%	-	-44.9% 606.4%	1594.4% 1759.1%	797.5% 985.3%	118.7% 123.3%
R&D					29.3%	33.9%	38.9%	44.2%	13.1%	14.8%	24.8%	28.2%	-	68.2%	36.4%	20.2%	16.5%
SG&A					27.5%	31.7%	35.7%	38.1%	10.9%	19.6%	24.9%	26.7%	-	103.7%	33.3%	20.8%	24.2%
Operating Expenses					28.3%	32.6%	37.0%	40.4%	11.8%	17.6%	24.9%	27.3%	-	87.9%	34.5%	20.6%	21.1%
Income (loss) from ops					-	=	=	-	-	-	-	-	-	-	=	-	2008.2%
Pre-Tax income (loss) Net Income					-		-	-	-	-	-	-	-	-	-	-	-

Source: Company reports and Cowen and Company estimates



**BG Medicine – Annual Balance Sheet Statement** 

BO MEGICINE - Allitual Balance	Sheet Statemen	<u>.                                    </u>			
(in thousands)	2010	2011E	2012E	2013E	2014E
ASSETS	0.405	40.075	(00.470)	(47.475)	04.045
Cash & Equivalents	2,425	12,875	(23,176)	(17,475)	61,615
Accounts Receivable Inventories	786 0	903 44	956 83	1,372	1,501 113
Other Current Assets	405	405	451	108 765	1,372
Total Current Assets	3,616	14,226	(21,687)	(15,230)	64,601
Total Current Assets	3,010	14,220	(21,007)	(15,230)	04,001
Property, Plant & Equipment	604	704	804	904	1,004
Intangible Assets	541	541	541	541	541
Other	2,266	2,266	2,266	2,266	2,266
TOTAL ASSETS	4,761	15,471	(20,342)	(13,785)	66,146
LIABILITIES					
Ourrent Liabilities	10,715	109	331	432	450
Payables	1,380	2,181	2,208	1,799	2,251
Total Current Liabilities	12,095	2,290	2,539	2,231	2,701
Short torm Dobt	240	240	240	240	240
Short term Debt	248	248	248	248	248
Long Term Debt Total Debt	0 248	0 248	0 248	0 248	0 248
IOLAI DOUL	240	240	240	240	240
Other Liabilities	0	0	0	0	0
Equity	(7,582)	12,932	(23,129)	(16,264)	63,197
Total Liabilities & Equity	4,761	15,471	(20,342)	(13,785)	66,146
nventories	0	44	83	108	113
00GS	786	218	3,312	21,588	45,020
NVENTORY METRICS					
nventory Turnover	3.0x	5.0x	40.0x	200.0x	400.0x
%change	3.0x	3.0x	40.08	200.0x	400.08
Days To Sell					
% change					
RECEIVABLES METRICS					
Accounts Receivable	786	903	956	1,372	1,501
Bales	819	451	7,646	68,624	150,065
Receivables Turnover	1.0x	0.5x	8.0x	50.0x	100.0x
% change					
Days Outstanding					
%change					
PAYABLES METRICS					
Accounts Payable	1,380	2,181	2,208	1,799	2,251
OOGS	786	2,161		21,588	45,020
	700	210	3,312	21,566	45,020
Payables Turnover	0.6x	0.1x	1.5x	12.0x	20.0x
% change					
of Days To Pay					
% change					
OTHER CURRENT ASSETS	405	451	765	1,372	1,501
% of Sales	49%	100%	10%	2%	1%
	10,715	100	224	420	450
	701/75	109	331	432	450
	,			20/	40/
% of COGS	1363%	50%	10%	2%	1%
OTHER CURRENT LIABILITIES % of COGS  NET WORKING CAPITAL (Ex. Cash, Debt)	,			2% 622	1% 413

Source: Company reports and Cowen and Company



## **BG Medicine – Annual Cash Flow Statement**

(in thousands)	2010	2011E	2012E	2013E	2014E
Net Income (loss) add back:	(\$17,162)	(\$29,667)	(\$35,066)	\$13	\$31,539
D&A	900	1,080	1,296	1,555	1,866
stock comp expense	2,500	3,000	3,500	4,000	45,000
other	0	0	0	0	0
Changes in working cap	265	961	119	33	585
Accounts Receivables	100	117	53	417	128
Inventories	75	44	39	25	5
Accounts Payable & Other	90	801	27	(409)	452
Other	2,000	0	0	0	0
Net cash from Operations	(\$11,497)	(\$24,626)	(\$30,151)	\$5,601	\$78,990
CF from Investments:					
PP&E	(40)	100	100	100	100
Net cash from Investments	(\$40)	\$100	\$100	\$100	\$100
Proceeds on financing events	6,000	40,000	0	0	0
Payments on financings	(2,100)	(3,000)	(6,000)	0	0
Net cash from Financing	\$3,900	\$37,000	(\$6,000)	\$0	\$0
Net cash in period	(7,637)	12,475	(36,051)	5,701	79,090
Starting cash balance		400	12,875	(23,176)	(17,475)
Ending cash balance	\$400	\$12,875	(\$23,176)	(\$17,475)	\$61,615

Source: Company reports and Cowen and Company



#### **Addendum**

#### STOCKS MENTIONED IN IMPORTANT DISCLOSURES

Ticker	Company Name	
BGMD	BG Medicine	
GPRO	Gen Probe	
MYGN	Myriad Genetics	
QGEN	Qiagen	

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Rating	Definition
Outperform (1)	Stock expected to outperform the S&P 500
Neutral (2)	Stock expected to perform in line with the S&P 500
Underperform (3)	Stock expected to underperform the S&P 500

(a) Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period.

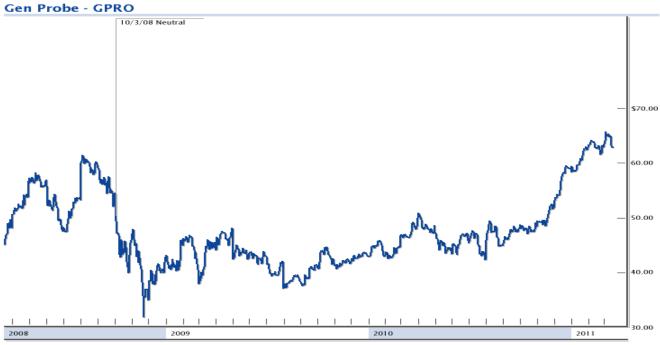
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Rating	Pct of companies under coverage with this rating	Pct for which Investment Banking services have been provided within the past 12 months
Buy (b)	49.5%	3.8%
Hold (c)	46.2%	1.5%
Sell (d)	4.3%	0.0%

(a) As of 12/31/2010. (b) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions (see above). (c) Corresponds to "Neutral" as defined in Cowen and Company, LLC's ratings definitions (see above). (d) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions (see above). Note: "Buy," "Hold" and "Sell" are not terms that Cowen and Company, LLC uses in its ratings system and should not be construed as investment options. Rather, these ratings terms are used illustratively to comply with NASD and NYSE regulations.

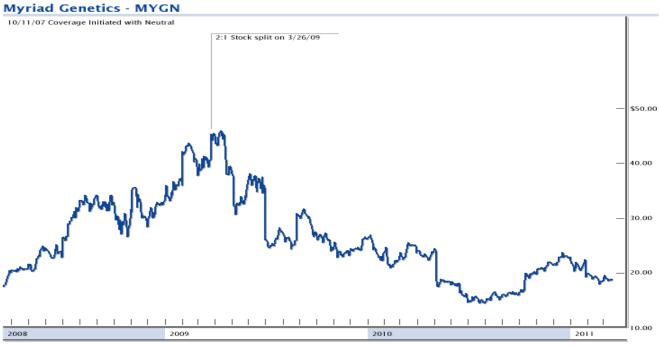


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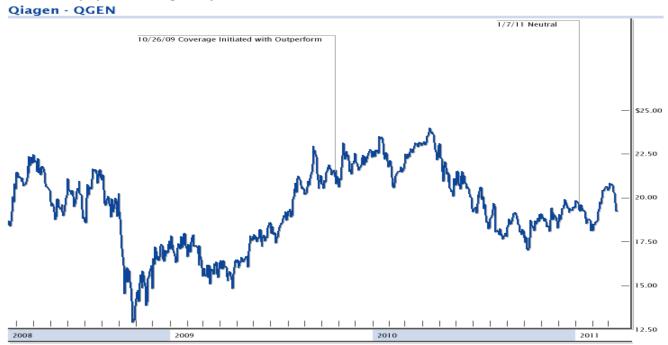
Cowen and Company Price and Ratings History



Pricing data provided by Reuters America. Chart as of 3/17/11 in USD.



Cowen and Company Price and Ratings History



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