

## BG MEDICINE, INC. (BGMD)

Two Practice Changing Studies and 4 FDA Filings Likely by End of 1H12; Galectin-3 Reimbursement Story De-risked. Initiating Coverage with BUY Rating and \$8.25 PT.

Investment Rating BUY  
Price Target \$8.25

Price (12/20/11) \$4.25  
52 Week Range \$3.25 - \$10.44  
Shares Outstanding 19.3 MM  
Market Capitalization \$82.0 MM  
Cash (September 30, 2011) \$28.0 MM  
Volume (avg. daily) 25,464

S&P 500 Index (12/20/11) 1,241.29  
NASDAQ Composite (12/20/11) 2,603.73

FY (Dec 31)	2010A	2011E	2012E
Revenues (MM)	\$0.8	\$1.4	\$0.8
EPS (F.D.)	(\$5.78)	(\$1.02)	(\$0.99)

EPS (Qtr.)	1Q	2Q	3Q	4Q
2011E	(\$0.26)A	(\$0.25)A	(\$0.25)A	(\$0.26)
2012E	(\$0.27)	(\$0.27)	(\$0.22)	(\$0.24)

### Company Description

BG Medicine commercializes diagnostic tests based on content discovered by its biomarker discovery research group. The Waltham, MA-based company's lead program, a test for the galectin-3 biomarker, is FDA-cleared for use in staging of heart failure patients. The company's pipeline includes tests for predicting heart attack risk and for predicting risk of lipid disorders. BG Medicine sells its tests through commercial partners and has no plans for a significant direct sales effort.

Kevin DeGeeter  
212.409.2027  
kdegeeter@ladenburg.com

### Investment Summary

Initiating coverage of BG Medicine (BGMD) with a BUY rating and \$8.25 price target. We view the likely presentation in March 2012 of Framingham cohort validation data for galectin-3 as a marker for risk of heart failure at the ACC meeting as a potentially practice changing study. Additionally, we believe many investors underestimate the importance of the November 2011 AMA decision to issue a CPT code for galectin-3 and we expect the test to receive favorable reimbursement following a July 2012 review. We view both events as potentially transformative for the galectin-3 franchise. With the expected submissions by partner in 1H12 of 2 FDA filings for the automated version of galectin-3, we believe the test is well positioned to become the standard of care for heart failure prognosis and risk assessment. Our peak sales forecast is \$300M. BGMD appears to be on track to launch its AMIPredict multivariate assay for identifying unstable plaque by 4Q12. While the company has offered limited disclosure on design and performance, the test would serve a large market and offers significant potential upside to our forecast. Lastly, we believe BGMD's long commitment to a content-driven business model and focus on clinical validation is unique in the diagnostic industry and positions BGMD as a development partner of choice as regulatory pressures place greater emphasis on clinical utility.

- **Issuance of CPT Code a Key Step in De-risking Galectin-3 Story.** We believe many investors failed to fully appreciate the importance of galectin-3 receiving a CPT code from the AMA's editorial review panel in November 2011. While the reimbursement level will not be set until after a separate meeting in July 2012 and take effect in 2013, we'd note standard for receiving a code are high and require the expectations of widespread near term adoption. Given the substantial body of published data demonstrating clinical utility, we believe the reimbursement story is largely de-risked and are optimistic galectin-3 will be reimbursed at levels similar to BNP (\$48 a test). Peak sales estimate is \$300M.
- **2 Validation Studies and 4 FDA/EMEA Reviews in the Next 6 Months.** We expect BGMD to present validation data for AMIPredict in 1Q12 and results of the Framingham study of galectin-3 for assessing risk of developing heart failure at the ACC meeting in March. By the end of 1H12, we expect partners to complete FDA and EMEA filings for galectin-3 on 2 different automated platforms, an expanded label for galectin-3 as a marker for heart failure risk and for AMIPredict. We believe each event is material but are particularly focused on the Framingham data in March 2012 as being potentially practice changing.
- **AMIPredict.** Potential 4Q12 launch of AMIPredict to assess risk of heart attack due to unstable plaque offers upside our forecast. BGMD has provided limited details on design and performance of the multivariate assay. As such, our model – and Street expectation – incorporates modest economic contribution despite the large market opportunity of 60 million Americans. We have included peak net economics of roughly \$10M annually in our financial forecast but will await details on strategy for commercialization and confirmation of clinical utility before including a detailed revenue forecast.
- **\$8.25 PT Based on Discounted EPS Model.** We base our valuation on a peer group PE multiple of 26x times applied to EPS for the second full year of profitability (\$0.71 for 2017) discounted back at cost of capital of 20%.

Disclosures and Analyst Certifications can be found in Appendix A.

NEW YORK, NY MELVILLE, NY PRINCETON, NJ MIAMI, FL BOCA RATON, FL

520 Madison Avenue, New York, NY 10022 • Telephone: 212-308-9494

Member: NYSE, NYSE Amex, FINRA, all other principal exchanges and SIPC

## INVESTMENT THESIS

### Initiating Coverage with a BUY Rating

We are initiating coverage of BGMD with a Buy rating and \$8.25 price target. In our view, 2012 is likely to be a transformational year for BGMD with 1) establishment of a unique reimbursement code for galectin-3, 2) presentation of data from the Framingham cohort which has the potential to establish galectin-3 as standard of care for predicting heart failure risk, and 3) validation data, FDA clearance and launch of a second product, the AMIPredict multivariate assay for identifying unstable plaque and people at high risk of a heart attack. These milestones combined with what we expect to be likely FDA clearance of galectin-3 on 1 or more automated platforms should lay the groundwork for significant revenue and earnings leverage in 2013 and beyond.

### Reimbursement – Heavily De-risked With Issuance of CPT Code

In our view, many investors are overlooking an important step BGMD has already achieved in the process for gaining reimbursement coverage of its proprietary galectin-3 marker for heart failure. Based on discussions with regulatory experts (and confirmed by management), we believe BGMD received a CPT code for galectin-3 following a November 2011 meeting with the AMA editorial review board. Testing for galectin-3 will be widely reimbursed beginning in early 2013. The primary open question is price. While receiving a CPT code from the AMA editorial board is a somewhat opaque and often political process, in our view, we consider the process for establishing pricing to be relatively transparent and data driven.

Rather than engage in laborious pharmacoeconomic discussion regarding reimbursement levels, BGMD is seeking to “crosswalk” reimbursement to the same reimbursement level as NT-proBNP, which is reimbursed at about \$48. We’d note that crosswalking to BNP reimbursement has been a common and successful strategy over the past five years for other cardiovascular tests including myeloperoxidase (MPO) testing for risk of atherosclerosis. While the crosswalk strategy can yield unexpected outcomes, we believe the substantial body of published clinical data on galectin-3 combined with data from a hospital readmissions study and upcoming publication on the use of galectin-3 to guide patient selection for expensive CRT procedures provides a strong foundation for favorable reimbursement. Our model calls for peak gross revenues from galectin-3 testing of \$300M.

### Strong Biological Link Between Galectin-3 & Heart Failure; Preventive Steps Available

Over the past 10 years cardiologists have been inundated with new biomarkers demonstrating an association between the biomarker and the risk of cardiovascular disease. However, the biologic link between many of these biomarkers and disease was often not well characterized and clinical utility of testing was often unclear. A study published in the February 2010 issue of *JAMA* highlighted the shortcomings of many highly publicized biomarkers. In a study of 19,313 women enrolled in the Women's Genome Health Study, traditional clinical measures of disease such as LDL cholesterol were a better predictor of risk than a panel of 12 SNPs often associated with cardiovascular risk.

Due in part to this biomarker fatigue, in our view, BGMD faced a skeptical audience during the validation process for galectin-3. We believe the significant body of published data and a long list of collaborators including the Framingham cohort, drug companies such as GlaxoSmithKline, payers such as Humana and various academic groups, attest to the impressive progress BGMD has made in establishing support for galectin-3 testing among thought leaders.

We believe the key to this success is based on 1) a clear link between galectin-3 and biology, 2) actionable steps allowing for changes in galectin-3 levels and 3) demonstrated clinical utility in selecting treatment options for heart failure. Both pre-clinical and human studies have shown a clear link between high galectin-3, increased left-ventricular collagen deposits and progressive fibrosis. Additional studies demonstrated a reduction of galectin-3 levels due to changes to diet or dietary supplements resulted in lower levels of left-ventricular collagen and lower risk of heart failure. Lastly, data has demonstrated galectin-3 levels may help predict benefit from statin treatment and CRT procedures.

### Unique Content-Driven Model

While most of the advances in molecular diagnostics over the past 10 years have been driven by improved technology for processing samples or clever strategies for combining panels of biomarkers, BGMD is one of a handful of companies dedicated to identifying and commercializing new markers. BGMD focuses solely on demonstrating clinical utility of the content and interacting with regulators and payers. For galectin-3, the company partnered with four of leading laboratory equipment vendors (Abbott, Alere, bioMérieux and Siemens) to distribute the test. We believe this singular focus on developing content offers an important and sustainable competitive advantage as reimbursement in the United States is increasingly driven by higher standards of clinical validation.

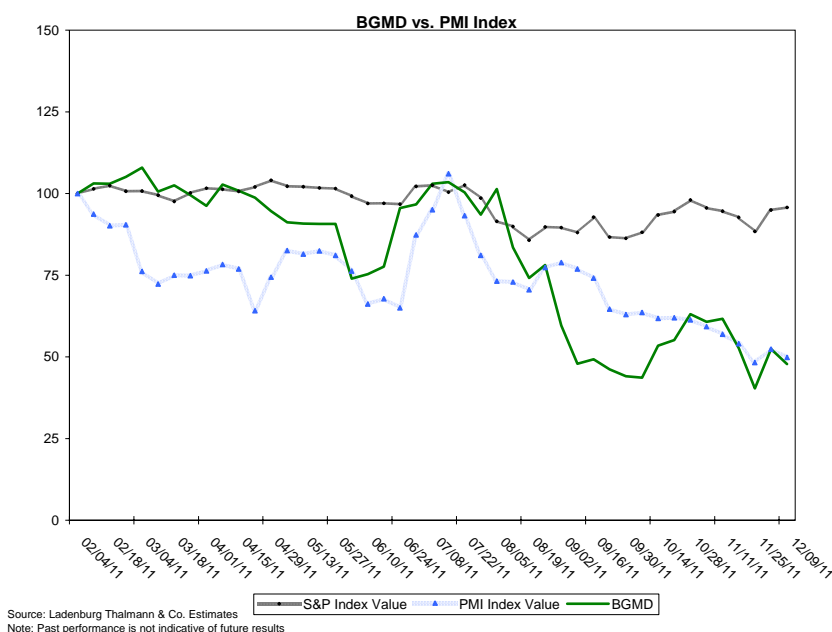
### AMIPredict

AMIPredict is the byproduct of a five-year, \$25M development effort to commercialize a diagnostic test for identifying plaque at high risk of rupture and atherothrombosis. While the test serves a larger potential market than galectin-3, the exact design and performance of the multivariate assay has not been disclosed and consequently we believe most investors assign little or no value to the program. We expect AMIPredict to gain more traction with investors following the presentation of results from the 6,822-patient Biolmage study in 1Q12. We expect the test to be launched in 4Q12 and offer a second important source of near term revenue growth.

### BGMD and Molecular Diagnostic Sector Lag the Overall Market

Lastly, while shares of BGMD have underperformed the S&P 500 and other broad market indices over the past six months, we attribute the weakness to soft performance for the molecular diagnostic sector as investors weigh an uncertain regulatory and reimbursement outlook for the group. Specifically, we believe the twin reimbursement overhangs of a prolonged AMA process for revising CPT codes and plans by Medicare administrator Palmetto to implement test-specific z-codes in 2012 are weighing on the group. On the regulatory front, the FDA continues to reiterate its intent to implement greater oversight of laboratory developed tests (LDTs) and other molecular diagnostics. However, the timing for the announcement of draft guidance remains unclear and, in our view, significant changes to the regulatory environment is unlikely prior to the 2012 federal elections. As highlighted in Table 1, shares of BGMD have traded in line with our Personalized Medicine Index (PMI) of molecular diagnostic stocks in recent months. Details on the PMI are on Page 27.

**Table 1.**



## VALUATION: \$8.25 PT

Our \$8.25 price target for BGMD is based primarily on a discounted EPS analysis with additional support from a comparable company analysis. In our view, a discounted EPS analysis more accurately captures the value of companies, such as BGMD, that are crossing the inflection point to profitability than price/sales-based valuation metrics.

Our model calls for BGMD to be cash flow breakeven and report a small profit of \$0.04 per share in 2015. The base year for our discounted EPS valuation is the second full year of profitability (2017), which we believe offers a more appropriate picture of the company's earnings power. Our \$8.25 price target assumes a 26x multiple on pro forma fully taxed 2017 EPS of \$0.71 discounted back at a 20% cost of capital.

**Table 2.**

		Discount Rate							
Forward P/E Ratio		28.0%	25.5%	23.0%	20.5%	18.0%	15.5%	13.0%	10.5%
	7.0x	\$ 1.64	\$ 1.79	\$ 1.96	\$ 2.15	\$ 2.36	\$ 2.60	\$ 2.87	\$ 3.17
	12.0x	2.81	3.07	3.36	3.68	4.05	4.45	4.92	5.44
	17.0x	3.97	4.34	4.75	5.22	5.73	6.31	6.96	7.70
	22.0x	5.14	5.62	6.15	6.75	7.42	8.17	9.01	9.97
	27.0x	6.31	6.90	7.55	8.28	9.10	10.02	11.06	12.23
	32.0x	7.48	8.18	8.95	9.82	10.79	11.88	13.11	14.50
	37.0x	8.65	9.45	10.35	11.35	12.47	13.74	15.16	16.76
	42.0x	9.82	10.73	11.75	12.88	14.16	15.59	17.20	19.03
	47.0x	10.99	12.01	13.15	14.42	15.84	17.45	19.25	21.29

Source: Ladenburg Thalmann estimates

Use of a 26x EPS multiple was based on a review of trading multiples for comparable companies defined as molecular diagnostic companies with commercial sales. The P/E multiple for our peer group of diagnostics companies (in Table 2) ranges from 14.4-47.1x 2012 EPS with a median of 21.0x. In the intermediate term, we view Genomic Health as the nearest comparable company. While the companies focus on different markets – BGMD in cardiovascular disease and Genomic Health in oncology – both companies have content driven business models based on driving adoption through extensive clinical validation of proprietary content.

**Table 3.**

(\$ in millions, except for per share data)														
Ticker	Company Name	Rating	Price 12/16/2011	% of 52 Week High	52-Week Low	52-Week High	Revenue (\$M) 2012E	Cash & Equiv.	LTD	Market Value	Tech Value <sup>(1)</sup>	EV/ Revenue	2012 EPS <sup>(2)</sup>	2012 P/E
GHDX	Genomic Health	B	\$26.30	90%	\$19.00	\$29.34	\$240	\$79	\$0	\$810	\$732	3.0x	\$0.56	47.1x
GPRO	Gen-Probe	NR	\$56.50	65%	\$53.92	\$86.96	642	302	0	2,661	2,359	3.7	\$2.69	21.0x
RGDX	Response Genetics	N	\$1.20	39%	\$0.81	\$3.05	24	3	0	23	21	0.9	(\$0.15)	NA
MYGN	Myriad Genetics	B	\$19.96	77%	\$17.51	\$25.89	483	350	0	1,737	1,388	2.9	\$1.38	14.4x
NGNM	NeoGenomics	B	\$1.47	80%	\$0.96	\$1.84	50	3	4	63	65	1.3	\$0.04	37.5x
OGEN	Qiagen	NR	\$13.52	61%	\$12.47	\$22.20	1,254	486	798	3,220	3,532	2.8	\$1.04	13.0x
BGMD	BG Medicine	B	\$4.25	41%	\$3.25	\$10.44	\$1	\$28	\$0	\$82	\$54	68.5	(\$0.99)	NA
Notes:							\$	1,254	\$ 486	\$ 798	\$ 3,220	\$ 3,532	3.7x	\$2.69 47.1x
(1) Represents equity market value plus long-term debt less cash.							Mean:	449	204	134	1,419	1,350	2.4	\$0.93 26.6
							Median:	362	190	0	1,274	1,060	2.8	\$0.80 21.0
							Minimum:	24	3	-	23	21	0.9	(\$0.15) 13.0
B = Buy; NR = Not Rated														
Source: Company reports, Ladenburg Thalmann estimates for rated companies, Factset for not rated companies.														

Mention of specific companies not covered by Ladenburg Thalmann & Co. Inc. is not a recommendation to buy, hold, or sell the securities mentioned.

## EXPECTED NEAR TERM EVENTS

We expect BGMD to be an event-driven story over the next 12 months based on a steady flow of significant clinical, regulatory and commercial milestones including presentation of two potentially practice changing studies, notification of the reimbursement level for galectin-3, up to 4 FDA decisions for galectin-3 and commercial launch of two important new products (automated galectin-3 and AMIPredict for identifying unstable plaque).

We encourage investors to focus on the release in March of data from the Framingham cohort the on use of galectin-3 for assessing risk of heart failure following acute myocardial infarction or acute cardiovascular event and on the reimbursement decision for galectin-3 (early 4Q12).

We believe numerous published studies have validated galectin-3 as an important prognostic marker for patients diagnosed with heart failure. Several small studies have suggested the biomarker also provides useful insight for predicting risk of heart failure in patients at high risk of developing the disease. The risk assessment market is roughly 3x (see table 9) the prognostic market, in our view, and has the potential to expose galectin-3 testing to a broad segment of the cardiology community. Additionally, use of the Framingham cohort, which is among the best annotated and widely respected cohorts in cardiology research, has the potential to rapidly expand awareness of galectin-3 with both thought leaders and physicians in small community practices, in our view.

Winning early reimbursement for new tests has been increasingly challenging over the past five years as payers have sought greater levels of clinical validation prior to establishing specific reimbursement levels. We believe BGMD cleared a critical hurdle in November with the commitment from AMA to issue a unique CPT. We expect Galectin-3 will be reimbursed by insurance companies beginning in early 2013. The exact rate of reimbursement will be determined based on evidence to be presented at a meeting in July with an announcement by early 4Q12. Based on the strong clinical validation of galectin-3, we expect a favorable outcome on reimbursement. Our base case assumes galectin-3 is reimbursed at the same rate as NT-proBNP, which is a widely used marker used for assessing the level of heart volume and stress in heart failure patients.

Lastly, AMIPredict is an important wildcard for 2012. The test was developed based on over \$25M in cooperative funding in the search for markers of high risk plaque. While BGMD expects to launch the test in 2012, disclosure on the design, performance, commercial model and price has been limited. As the profile of this product comes into clearer view – 1<sup>st</sup> step is likely to be presentation of BiImage validation study in 1Q12 – we expect many investors to revisit this important second leg of potential source of growth for BGMD.

**Table 4.**

Expected Near-term Events		
Event	Time	Importance
Present BiImage Validation Study for AMIPredict	1Q12	High
Present Framingham Validation Study for Galectin-3 as Risk Marker for HF	March 2012	High
1st FDA Filing for Automated Galectin-3 Test	1Q12	Low
2nd FDA Filing for Automated Galectin-3 Test	2Q12	Low
Publication of Framingham Validation Study for Galectin-3 as Risk Marker	1H12	Moderate
EMA Filing AMIPredict	1H12	Low
EMA Filing for 1 or More Automated Galectin-3 Tests	1H12	Low
Publication on Use of Galectin-3 for Predicting CRT Response (high risk patients)	1H12	Low
FDA Filing for Expanded Galectin-3 use to include Risk Assessment	1H12	Low
Meeting to Discuss Reimbursement Levels for Galectin-3 CPT Code	July 2012	Moderate
Publication on Use of Galectin-3 for Predicting CRT Response (low risk patients)	2H12	Moderate
FDA clearance for AMIPredict	2H12	Low
FDA clearance for 1st automated Galectin-3 Test	2H12	Moderate
FDA clearance for 2nd automated Galectin-3 Test	2H12	Low
EMA clearance of AMIPredict	2H12	Low
EMA clearance of 1 or more Automated Galectin-3 Tests	2H12	Low
Launch of AMIPredict	4Q12	Moderate
FDA Clearance of Expanded Label Indication for Galectin-3	4Q12	High
Announcement of Reimbursement Levels for Galectin-3 in 2013 Fee Schedule	4Q12	High
3rd FDA Filing for Automated Galectin-3 Test	4Q12	Low

Source: Ladenburg Thalmann estimates



## BUSINESS MODEL AND PRODUCT OVERVIEW

BGMD's expertise is in identifying new blood-based biomarkers and developing related diagnostic tests. By way of comparison, many of the publicly traded molecular diagnostic companies in BGMD's peer group are dedicated to tissue-based tests - primarily for oncology – or to commercializing a menu of widely used tests on proprietary analytical instruments. As mentioned above in our investment thesis, we believe BGMD's singular focus on developing content offers an important and sustainable competitive advantage, particularly as reimbursement in the United States is increasingly driven by higher standards of clinical validation.

In general, blood-based tests such as BGMD's galectin-3 test serve larger potential markets than tissue-based tests and yield a lower average selling price. To capture the full economic value of galectin-3, BGMD has partnered with four analytical equipment vendors to offer broad distribution coverage. While this model results in lower gross revenues than molecular diagnostics sold as laboratory developed tests (LDTs), we believe the commercial strategy offers attractive operating leverage and should accelerate clinical adoption of galectin-3.

We believe BGMD has been successful in establishing a broad network of collaborations to defray the cost of content development and accelerate time to market. The company has worked with a range of academic institutions and industry-driven collaborative research projects including the High Risk Plaque (HRP) initiative, which provided \$25M in funding and technical assistance from Abbott, AstraZeneca, Merck, Philips and Takeda. The collaboration led to development of BGMD's second test, AMIPredict. We expect content development collaborations to continue to be a central element of BGMD's business model.

Lastly, we believe BGMD's collaboration with Humana is unique in the molecular diagnostic industry. The arrangement allows BGMD to recruit patients with specified characteristics from Humana's membership in exchange for generating data on biomarkers of real world clinical response for given therapies or potential associations between specific biomarkers and disease. Additionally, BGMD receives feedback from a payer's perspective while a test is still in development. We believe these insights are valuable for both future reimbursement discussions and also in discussions with potential analytical platform partners seeking to fully understand a product's commercial model.

By way of background, the business was formed in 2000 as Beyond Genomics to apply expertise in systems biology matching genetic variations with certain phenotypes. The company signed research partnerships for its systems biology platform with pharma companies such as GlaxoSmithKline (GSK) and AstraZeneca. In October 2004, the company changed its name to BG Medicine and began transitioning the business model to biomarker discovery.

In February 2011, BGMD completed an IPO, selling 5 million shares at \$7 per share for gross proceeds of \$35M.

**Table 5.**

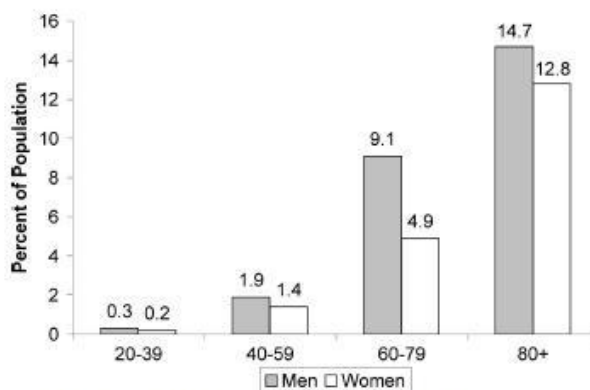
BG Medicine Product Overview					
Program	Indication/Detection	Development	Validation	Regulatory Review	Market
BGM Galectin-3 (manual)	Prognosis for patients with heart failure				2010
BGM Galectin-3 (automated)	Prognosis for patients with heart failure				
BGM Galectin-3 (automated)	Risk assessment for heart failure following a heart attack				
AMIPredict	Identify patients risk of near-term heart attack or stroke				
LipidDx	Aid in the management of patients with lipid disorders				
<b>Research Collaborations</b>					
Framington Heart Study	Biomarker discovery for cardiovascular metabolic disease				
MSRCNY	Biomarker of disease activity in multiple sclerosis				
Humana	Biomarker for response anti-TNF alpha drugs				

Source: Company reports and Ladenburg Thalmann estimates.

## HEART FAILURE OVERVIEW

Heart failure is characterized by the inability of the heart to pump enough blood due to damage or overuse of the heart muscle. Risk factors for disease include hypertension, obesity and systolic dysfunction. Roughly 75% of heart failure patients were previously diagnosed with hypertension. As with other circulatory diseases, diabetics are at increased risk of heart failure. Valve deformity and cardiomyopathy are also associated with increased risk. Increased age and male gender are also associated with higher rate of heart failure. As such, heart failure is typically not the sole cause of death and often only one several factors.

**Table 6.**



Prevalence of HF by sex and age (NHANES: 2003-2006).  
Source: Journal Circulation (February 2010)

Clinical symptoms of heart failure may include swollen legs or ankles, shortness of breath or weight gain. Onset of disease appears to be correlated with defined clinical thresholds with patients recording blood pressure of 160/90 mm Hg having twice the rate of heart failure as patients with blood pressure of 140/90 mm Hg, according to NHLBI.

Prevalence rate in the U.S. is about 10 per 1000 population after 65 years of age for a total of roughly 5.8 million cases, according to NHLBI. CMS estimated the direct and indirect cost of heart failure in the United States for 2010 at \$39.2 billion. Prevalence has traditionally been more closely linked to clinical risk factors and lifestyle than to gender or race. The highest rates of heart failure are among black men, white men and black women (16.9, 15.2 and 14.2 per 1,000 between ages 65 to 74 years, according to CHS and NHLBI).

Several studies have demonstrated the presence of left ventricular dysfunction - systolic or diastolic – is associated with increased risk of heart failure and all-cause mortality. Additionally, left ventricular dysfunction is present in more than 45% of heart failure patients, according to NHLBI.

Prognosis for patients hospitalized for complications from heart failure is poor. In the ARIC study conducted by NHLBI the 5-year case fatality rates was 42.3%. Roughly 20% of patients died within 12 months of being diagnosed with heart failure. However, a subset of heart failure patients report stable disease and have a relatively good prognosis. Distinguishing these patients with good prognostic from those with progressive heart disease cannot be determined using traditional clinical staging methods such as the New York Heart Association (NYHA) functional classification scale.

Table 7.

Heart Failure					
Population Group	Prevalence, 2006 Age $\geq 20$ y	Incidence (New Cases) Age $\geq 45$ y	Mortality (Any Mention), 2006 All Ages*	Hospital Discharges, 2006 All Ages	Cost, 2010
Both sexes	5 800 000 (2.6%)	670 000	282 754	1 106 000	\$39.2 billion
Males	3 100 000 (3.1%)	350 000	123 600 (43.7%)†	523 000	...
Females	2 700 000 (2.1%)	320 000	159 167 (56.3%)†	583 000	...
NH white males	3.2%	...	110 250	...	...
NH white females	2.1%	...	142 378	...	...
NH black males	3.0%	...	10 926	...	...
NH black females	3.6%	...	14 151	...	...
Mexican American males	1.7%	...	...	...	...
Mexican American females	1.8%	...	...	...	...

Ellipses (...) indicate data not available.

\*Mortality data are for whites and blacks and include Hispanics.

†These percentages represent the portion of total HF mortality that is for males vs females.

Sources: Prevalence: NHANES 2003–2006 (NCHS) and NHLBI. Percentages are age adjusted for Americans  $\geq 20$  years of age. Age-specific percentages are extrapolated to the 2006 US population estimates. These data are based on self-reports. Incidence: FHS, 1980–2003 from NHLBI Incidence and Prevalence Chart Book, 2006. Mortality: NCHS. HF as an underlying cause of death accounted for 60 337 of the any-mention deaths in 2006: 23 918 males and 36 419 females. Hospital discharges: NHDS, NCHS; data include those inpatients discharged alive, dead, or "status unknown." Cost: NHLBI; data include estimated direct and indirect costs for 2010.

Source: Journal Circulation (February 2010)

Most patients suspected of suffering from heart failure receive an N-terminal prohormone BNP (NT-proBNP) test introduced in 2003 by Biosite (now Alere). The market for NT-proBNP and BNP testing is \$800M worldwide including \$500M in the U.S., according to Alere. While NT-proBNP is effective in measuring the current level volume overload in the heart, the marker does not provide prognostic information regarding future worsening of disease.

## OVERVIEW OF GALECTIN-3

Galectin-3 is a carbohydrate binding protein first characterized as a potential prognostic marker for heart failure by Yigal Pinto of University of Maastricht in the Netherlands in 2003. Additional studies by Pinto's lab and the lab of James Januzzi at Massachusetts General Hospital demonstrated a correlation between galectin-3 and risk of re-occurrence of heart failure or death in heart failure patients within 60 days. Subsequent studies have shown that high galectin-3 levels play a role in at least 30% of chronic heart failure cases.

The galectin-3 protein is now well characterized in multiple organ systems. In the heart muscle aldosterone and inflammatory stimulation is believed to result in macrophage-based upregulation of galectin-3 expression. Galectin-3 expression has been linked to macrophage migration, fibroblast proliferation, development of fibrosis and a gradual stiffening of the heart muscle. As a consequence of the role of aldosterone in upregulating galectin-3, patients with galectin-3 mediated heart failure tend to be more responsive to aldosterone blockers such as spironolactone and eplerenone.

In a study of 1,092 healthy volunteers from the BiImage cohort, the mean galectin-3 levels in the general population was estimated to be 13.3 ng/mL with upper limit of 90% confidence interval at 19.0 ng/mL. The association between galectin-3 and heart failure prognosis is not linear. Patients with levels below 17.8 ng/mL generally have low risk of galectin-3 mediated heart failure. Risk increases rapidly between 17.8 ng/mL and about 22.0 ng/mL and begins to plateau. Patients transitioning from low galectin-3 levels to high levels have been shown to be at 2-3x increased risk of heart failure compared to those with continued low levels.

While galectin-3 levels tend to be stable over the short term, changes to diet can result in an increase or decrease in galectin-3 levels, which suggests testing of heart failure patients may be required two or three times annually. Importantly, consuming modified citrus pectin found in certain fruits or from dietary supplements has been shown to lower galectin-3 levels.



## CLINICAL VALIDATION SUPPORTING GALECTIN-3 510(k)

---

The company completed six studies of galectin-3 in more than 2,200 patients with heart failure prior to launch in the United States. Two of these studies formed the primary basis for its Elisa microtiter plate 510(k) application.

The first study evaluated 582 plasma samples drawn from heart failure patients in Europe. Subjects were classified as NYHA class II, III and IV with moderate to severe heart failure. All patients were defined as high galectin-3 (>25.9 ng/mL), medium galectin-3 (17.8-25.9 ng/mL) or low galectin-3 (<17.8 ng/mL). The primary endpoints were composite all-cause mortality and hospitalization for heart failure with median follow up of 18 months. Patients with high levels of galectin-3 had a 2.4-fold increased risk of all-cause mortality compared to low galectin-3 levels. Rates of hospitalization for heart failure were also increased in the high galectin-3 cohort. High galectin-3 levels predicted risk even after adjusting for baseline risk factors such as age, gender, NYHA score, left ventricular ejection fraction and smoking status.

The second had a similar design but enrolled patients in the United States and Canada. A total of 895 plasma samples were collected from heart failure patients with left ventricular dysfunction and NYHA class II, III or IV. All patients were stratified by galectin-3 with the same cutoff points. After 30 months of follow up, the high galectin-3 group had a 1.4-fold increased risk of death or hospitalization for heart failure.

## BGM GALECTIN-3

---

In May 2003, BGMD licensed worldwide development and commercialization rights to galectin-3 and a second biomarker, thrombospondin-2, from Dutch research group ACS Biomarker B.V., which serves as a technology transfer service from the Cardiovascular Research Institute Maastricht (CARIM) at University of Maastricht and the Academic Hospital Maastricht. Terms of the agreement call for BGMD to pay certain undisclosed milestone and royalty payments. The company also received preferential rights to develop other biomarkers from ACS Biomarker.

The agreement covers use of the intellectual property for blood-based biomarkers for congestive heart failure. Galectin-3 is intended to be used as a marker for identifying patients most likely to benefit from intensive therapy, monitoring and support. BGMD made payments of \$250,000 each year in 2007, 2008 and 2009. The company is obligated to make additional payments of \$250,000 upon 1) first regulatory approval of a product incorporating the biomarker 2) issuance of a U.S. or European Union patent covering a product that incorporates the corresponding licensed biomarker. These regulatory and patent payments will be credited against any future royalties.

An Elisa microplate version of the test under brand name BGM Galectin-3 received CE mark approval in Europe in October 2009 and FDA clearance in November 2010 for use in conjunction with clinical evaluation as an aid to assess the prognosis of patients diagnosed with chronic heart failure. However, the Elisa test is unlikely to win widespread clinical acceptance due to its relatively cumbersome 3.5 hour turnaround time.

The company expects material sales to follow introduction of automated tests from partners Abbott (Architect i1000SR and i2000SR), Alere (Triage Meter Pro), BioMérieux (VIDAS/miniVIDAS) and Siemens. The company expects two companies to file 510(k) applications for automated tests in 1H12. We believe the two companies are likely to be Abbott and Alere (both have a strong U.S. installed base).

The primary pharmacoeconomic and clinical rationale for galectin-3 testing in the prognostic setting is likely to be in determining timing of hospital discharge for heart failure patients. Roughly 27% of heart failure patients discharged from a hospital are readmitted within 30

days due to complications, according to data from CMS. Data presented in September 2011 at the Heart Failure Society of America meeting demonstrated that patients with galectin-3 levels above 17.8 ng/mL had a significantly higher risk of re-hospitalization. We believe these patients may be strong candidates for aggressive treatment including clinically effective but expensive cardiac-resynchronization therapy (CRT).

**Table 8.**

Association of galectin-3 and re-hospitalization risk by Cox regression, COACH study.

Model	Hazard Ratio (95% CI)	Chi-square	P-value
Galectin-3 only (>17.8 ng/mL)	2.35 (1.63-3.39)	21.1	<0.001
Age and sex adjusted	2.28 (1.57-3.31)	18.6	<0.001
Multivariable adjusted*	1.62 (1.04-2.52)	4.57	0.033

\* Adjusted for baseline age, gender, renal function (eGFR), NYHA class, NT-proBNP, LVEF

Source: HFSA Poster (2011)

## GALECTIN-3 REVENUE MODEL - \$300M IN PEAK SALES

Our galectin-3 revenue forecast is divided between three markets: 1) Elisa microplate test as a prognostic marker for heart failure, 2) automated tests as a prognostic marker for heart failure and 3) galectin-3 as a marker for heart failure risk following acute injury to the heart muscle from heart attack or chest pain.

About 5.9 million Americans suffer from heart failure and about 670,000 new cases are diagnosed each year, according to statistics from the American Heart Association. Given the strong clinical data supporting the prognostic value of galectin-3 levels above 17.8 ng/mL and lack of other new prognostic markers, we believe galectin-3 is likely to become the standard of care and used on all newly diagnosed heart failure patients. While our model defines market size based on each newly diagnosed patient being measured for galectin-3 only once, blood levels of the biomarker can be effected by long-term changes to diet and we expect regular galectin-3 testing to be included in long term follow up of heart failure patients.

Our model starts with the only commercial test, the Elisa microplate test as a prognostic marker for heart failure. The test was launched in 1Q11 and is sold through partnerships with LabCorp, HDL and other lab service companies. Our model assumes BGMD receives revenues of \$9 per test while recognizing gross margins of 50%. While initial adoption from LabCorp was slow, we expect the addition of other testing service companies to drive test volumes for the remainder of 2011 and to exit 2012 at a test volume run rate of 15,300 or about 2% of newly diagnosed patients. We believe the relatively slow turnaround time of 3.5 hours and significant labor inputs of Elisa testing will limit adoption of the test and expect market share to peak at 2-3% of newly diagnosed patients. Additionally, with the expected launch of automated tests beginning in 4Q12, we expect most hospitals in the U.S. to select an automated option.

Our model calls for the automated test to capture 95% of the market for newly diagnosed heart failure patients within five years of the launch of the first fully automated test expected in 4Q12. BGMD received a unique CPT code for galectin-3 in November 2011 but will not receive confirmation on the associated reimbursement level until after a July 2012 meeting. We expect the test to be priced at comparable levels as BNP (\$48 per test) with BGMD receiving \$13.50 per test. This is essentially a royalty to BGMD with gross margins approaching 90% after license payments. Our peak gross sales estimate for prognostic heart failure revenues is \$33M with BGMD recognizing more than \$9M annually.

The larger market opportunity for galectin-3 is assessing the risk of heart failure in patients with myocardial infarction (heart attack) or angina (chest pain). An estimated 20–40% of

individuals in the United States who suffer a heart attack develop heart failure within five years. For the U.S. heart failure risk market, we defined the target population at 16.9 million: 7.9 million people in 2010 suffering from a heart attack and 9.0 million reporting chest pain, according to statistics published by the American Heart Association.

We expect BGMD to publish validation data in 2012 describing use of galectin-3 as a marker predicting heart failure risk in patients with underlying coronary disease. If successful, we believe BGMD is likely to seek expansion in the labeled intended use for the test. Based on a target patient population of 18 million patients in our peak year of 2022, our model assumes peak test volume of about 2.5 million tests accounting for about 13% of the market. We assume all of these tests are run on the automated platform at \$48 per test with BGMD receiving \$13.50 per test, which translates to gross revenues of \$50M with BGMD receiving \$14M. In total for the U.S. market, our model calls for gross revenues of \$152M with BGMD receiving \$42.8M.

For Europe, we did not find reliable data for the prevalence of heart failure and newly diagnosed cases. The SHAPE study, which identified 14 million cases of heart failure and 3.6 million new cases each year, relies on statistical extrapolation from survey data and incorporates all populations from Eastern Europe. In our view, this survey methodology is subject to bias and the inability to separate the Western and Eastern European market masks the true addressable market for new diagnostic tests such as galectin-3.

As an alternative we reviewed the epidemiological literature for heart failure in three large Western European countries with robust health infrastructure for capturing heart failure population data. For France, we relied on data from a study published in the June 2002 issue of *Revue du Practicien* entitled "Epidemiology of heart failure," which found roughly 500,000 people in France with heart failure. For Germany, we referred to German Heart Foundation data suggesting between 1.3 million and 1.5 million Germans suffer from heart failure with about 200,000 new cases each year. For the U.K. we relied on British Heart Foundation data suggesting 890,000 people living with heart failure and 63,500 new cases each year. For the three countries, we estimate a total of 2.8 million heart failure patients with 383,500 new cases each year. Applying the widely referenced statistic of 40% mortality rate in newly diagnosed heart failure patients each year yields an annual death rate in the three countries of 153,000 people or roughly 5.5% of total diagnosed heart failure population. This is comparable to a rate of 4.7% in the United States.

For our EU market model, we focus solely on countries in Western Europe with advanced healthcare infrastructure. Based on 2008 data from the Eurostat division on the European Union, total population of European Union was 498 million. Excluding countries in Eastern Europe (Bulgaria, Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Romania, Slovenia and Slovakia), the population was 407 million. Our subgroup of France, Germany and U.K. had a population of 144 million or 35% of the total population for Western Europe, implying a scale factor of 2.84 to apply our subgroup analysis to all of Western Europe. After applying the scale factor of 2.84, we arrive at our target population of 8 million patients with heart failure in Western Europe, 1.1 million new cases each year and 435,000 deaths each year.

For the prognostic market, we assume galectin-3 achieves 90% market share among newly diagnosed patients within 5 years of launch of an automated test (2H13) resulting in peak test volumes of slightly more than 1 million tests annually, gross revenues of \$50M and revenues to BGMD of \$14.0M. Our model assumes comparable economics as the U.S. market. We expect European sales of galectin-3 Elisa tests to be de minimis and do not include the test in our revenue model.

We were unable to find reliable incidence rate for myocardial infarction and angina in Europe but a review of data from several national health services suggest an incidence rate of about 5% for the total population. Applying this rate to our population of Western Europe of 407 million yields an addressable market of 20.4 million. Our model calls for galectin-3 to capture

10% of market for peak gross revenues of \$98M and \$27.5M to BGMD. In total for the EU market, our model calls for gross revenues of \$148M with BGMD receiving \$41.6M.

Lastly, we see a role for galectin-3 in other markets with high rates of heart failure including South America, Eastern Europe and parts of Southern Asia (collectively grouped as ROW). We expect these markets to adopt a mix of automated tests and Elisa depending on patient volumes and price considerations. Our model assumes an average price of \$30 with BGMD receiving \$8 per test. Our model calls for ROW peak test volumes of 400,000 with gross revenues of \$12M and \$3.2M recognized by BGMD. On net, our forecast translates to peak annual sales of roughly \$300M in 2022 with BGMD recognizing \$87.5M.

Table 9.

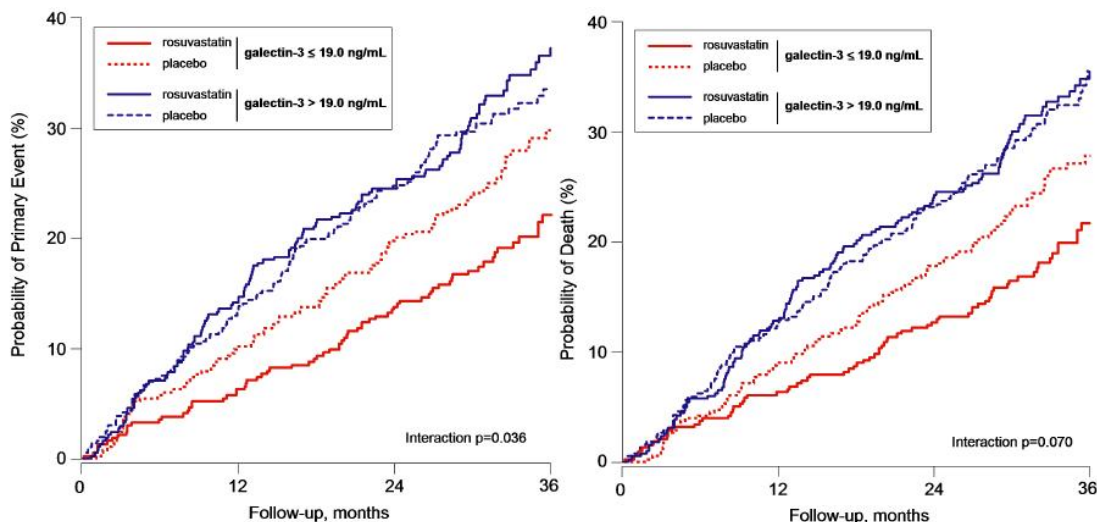
	2010A	2011E	2012E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
<b>Galectin-3 Worldwide Revenue Market Model</b>													
<i>U.S. Heart Failure Market</i>													
Americans Diagnosed with Heart Failure	5,900,000	6,289,124	6,677,043	7,050,092	7,408,747	7,753,712	8,085,659	8,405,229	8,713,032	9,009,650	9,295,636	9,571,516	9,837,792
New Cases of Heart Failure	670,000	673,350	676,717	680,100	683,501	686,918	690,353	697,274	700,760	704,264	707,785	711,324	
- Growth in New Cases of Heart Failure	NA	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%
Deaths from Heart Failure	277,000	284,226	288,798	307,051	324,846	341,954	358,406	374,235	389,470	404,142	418,278	431,905	445,048
- Death Rate for Heart Failure Patients	4.7%	4.5%	4.3%	4.4%	4.4%	4.4%	4.4%	4.5%	4.5%	4.5%	4.5%	4.5%	4.5%
<i>Galectin-3 Elisa Test - Prognostic</i>													
- Tests Delivered	0	3,500	12,688	15,348	15,558	15,558	15,558	15,558	15,558	15,558	15,558	15,558	15,558
Growth in Tests Delivered	NA	NA	262.5%	21.0%	1.4%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Market Share of Newly Diagnosed	0.0%	0.5%	1.9%	2.3%	2.3%	2.3%	2.3%	2.2%	2.2%	2.2%	2.2%	2.2%	2.2%
- Price per test	\$18.00	\$18.00	\$18.00	\$18.00	\$18.00	\$18.00	\$18.00	\$18.00	\$18.00	\$18.00	\$18.00	\$18.00	\$18.00
Gross Revenues from Galectin-3 Elisa Test (\$M)	\$0.0	\$0.1	\$0.2	\$0.3	\$0.3	\$0.3	\$0.3	\$0.3	\$0.3	\$0.3	\$0.3	\$0.3	\$0.3
- Revenue Per Test to BGMD	\$9.00	\$9.00	\$9.00	\$9.00	\$9.00	\$9.00	\$9.00	\$9.00	\$9.00	\$9.00	\$9.00	\$9.00	\$9.00
U.S. Revenues to BGMD from Galectin-3 Elisa Test (\$M)	\$0.0	\$0.0	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1
<i>U.S. Galectin-3 Automated Test - Prognostic</i>													
- Tests Delivered	0	0	8,000	163,000	411,050	572,170	636,017	656,538	663,104	669,735	676,432	683,196	690,028
Growth in Tests Delivered	NA	NA	NA	NA	152.2%	39.2%	11.2%	3.2%	1.0%	1.0%	1.0%	1.0%	1.0%
Market Share of Newly Diagnosed	0.0%	0.0%	1.2%	24.0%	60.1%	83.3%	92.1%	94.6%	95.1%	95.6%	96.0%	96.5%	97.0%
- Price per test	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00
Gross Revenues from Galectin-3 Automated Test (\$M)	\$0.0	\$0.0	\$0.4	\$7.8	\$19.7	\$27.5	\$30.5	\$31.5	\$31.8	\$32.1	\$32.5	\$32.8	\$33.1
- Revenue Per Test to BGMD	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50
U.S. Revenues to BGMD from Galectin-3 Automated Test (\$M)	\$0.0	\$0.0	\$0.1	\$2.2	\$5.6	\$7.7	\$8.6	\$8.9	\$9.0	\$9.0	\$9.1	\$9.2	\$9.3
<i>U.S. Acute Coronary Disease Market</i>													
Americans Diagnosed with Heart Attack	7,900,000	7,939,500	7,979,198	8,019,093	8,059,189	8,099,485	8,139,982	8,180,682	8,221,586	8,262,694	8,304,007	8,345,527	8,387,255
Americans Diagnosed with Chest Pain	9,000,000	9,045,000	9,090,225	9,135,676	9,181,355	9,227,261	9,273,398	9,319,765	9,366,363	9,413,195	9,460,261	9,507,562	9,555,100
American Diagnosed with Acute Coronary Disease	16,900,000	16,984,500	17,069,423	17,154,770	17,240,543	17,326,746	17,413,380	17,500,447	17,587,949	17,675,889	17,764,268	17,853,090	17,942,355
- Growth in Cases of Acute Coronary Syndrome	NA	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%
<i>U.S. Galectin-3 Automated Test - Risk Assessment</i>													
- Tests Delivered	0	0	2,000	115,000	407,750	809,113	1,129,787	1,377,883	1,624,703	1,839,440	2,041,348	2,245,483	2,470,031
Growth in Tests Delivered	NA	NA	NA	NA	254.6%	98.4%	39.6%	22.0%	17.9%	13.2%	11.0%	10.0%	10.0%
Market Share	0.0%	0.0%	0.0%	0.7%	2.4%	7.7%	6.5%	7.9%	9.2%	10.4%	11.5%	12.6%	13.8%
- Price per test	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00
Gross Revenues from Galectin-3 Automated Test (\$M)	\$0.0	\$0.0	\$0.1	\$5.5	\$19.6	\$38.8	\$54.2	\$66.1	\$78.0	\$88.3	\$98.0	\$107.8	\$118.6
- Revenue Per Test to BGMD	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50
U.S. Revenues to BGMD from Galectin-3 Automated Test (\$M)	\$0.0	\$0.0	\$0.0	\$1.6	\$5.5	\$10.9	\$15.3	\$18.6	\$21.9	\$24.8	\$27.6	\$30.3	\$33.3
Total U.S. Galectin-3 Gross Revenues (\$M)	\$0.0	\$0.1	\$0.7	\$13.6	\$39.6	\$66.6	\$85.0	\$97.9	\$110.1	\$120.7	\$130.7	\$140.9	\$152.0
Total U.S. Galectin-3 Revenues to BGMD (\$M)	\$0.0	\$0.0	\$0.2	\$3.9	\$11.2	\$18.8	\$24.0	\$27.6	\$31.0	\$34.0	\$36.8	\$39.7	\$42.8
<i>EU Heart Failure Market</i>													
Europeans Diagnosed with Heart Failure	7,946,400	8,585,476	9,216,855	9,814,441	10,379,557	10,914,023	11,419,562	11,897,802	12,350,278	12,778,441	13,183,657	13,567,218	13,930,343
New Cases of Heart Failure	1,088,373	1,089,461	1,090,551	1,091,641	1,092,733	1,093,826	1,094,920	1,096,015	1,097,111	1,098,208	1,099,306	1,100,405	1,101,506
- Growth in New Cases of Heart Failure	NA	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Deaths from Heart Failure	435,349	450,385	459,172	494,055	527,617	559,360	589,380	617,775	644,634	670,445	694,090	716,844	738,381
- Death Rate for Heart Failure Patients	5.5%	5.2%	5.0%	5.0%	5.1%	5.1%	5.2%	5.2%	5.2%	5.2%	5.3%	5.3%	5.3%
<i>EU Galectin-3 Automated Test - Prognostic</i>													
- Tests Delivered	0	0	0	16,000	126,000	434,000	788,375	919,111	992,033	1,009,325	1,019,418	1,029,612	1,039,908
Growth in Tests Delivered	NA	NA	NA	NA	687.5%	244.4%	81.7%	16.6%	7.9%	1.7%	1.0%	1.0%	1.0%
Market Share of Newly Diagnosed	0.0%	0.0%	0.0%	1.5%	11.5%	39.7%	72.0%	83.9%	90.4%	91.9%	92.7%	93.6%	94.4%
- Price per test	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00
Gross Revenues from Galectin-3 Automated Test (\$M)	\$0.0	\$0.0	\$0.0	\$0.8	\$6.0	\$20.8	\$37.8	\$44.1	\$47.6	\$48.4	\$48.9	\$49.4	\$49.9
- Revenue Per Test to BGMD	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50
EU Revenues to BGMD from Galectin-3 Automated Test (\$M)	\$0.0	\$0.0	\$0.0	\$0.2	\$1.7	\$5.9	\$10.6	\$12.4	\$13.4	\$13.6	\$13.8	\$13.9	\$14.0
<i>EU Acute Coronary Disease Market</i>													
Europeans Newly Diagnosed with Acute Coronary Disease	20,350,000	20,370,350	20,390,720	20,411,111	20,431,522	20,451,954	20,472,406	20,492,878	20,513,371	20,533,884	20,554,418	20,574,973	20,595,548
- Growth in New Cases of Acute Coronary Syndrome	NA	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
<i>EU Galectin-3 Automated Test - Risk Assessment</i>													
- Tests Delivered	0	0	0	15,000	183,000	448,500	700,650	958,395	1,234,630	1,492,191	1,684,722	1,853,194	2,038,513
Growth in Tests Delivered	NA	NA	NA	NA	1120.0%	145.1%	56.2%	36.8%	28.8%	20.9%	12.9%	10.0%	10.0%
Market Share	0.0%	0.0%	0.0%	0.1%	0.9%	2.2%	3.4%	4.7%	6.0%	7.3%	8.2%	9.0%	9.9%
- Price per test	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00	\$48.00
Gross Revenues from Galectin-3 Automated Test (\$M)	\$0.0	\$0.0	\$0.0	\$0.7	\$8.8	\$21.5	\$33.6	\$46.0	\$59.3	\$71.6	\$80.9	\$89.0	\$97.8
- Revenue Per Test to BGMD	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50	\$13.50
EU Revenues to BGMD from Galectin-3 Automated Test (\$M)	\$0.0	\$0.0	\$0.0	\$0.2	\$2.5	\$6.1	\$9.5	\$12.9	\$16.7	\$20.1	\$22.7	\$25.0	\$27.5
Total EU Galectin-3 Gross Revenues (\$M)	\$0.0	\$0.0	\$0.0	\$1.5	\$14.8	\$42.4	\$71.5	\$90.1	\$106.9	\$120.1	\$129.8	\$138.4	\$147.8
Total EU Galectin-3 Revenues to BGMD (\$M)	\$0.0	\$0.0	\$0.0	\$0.4	\$4.2	\$11.9	\$20.1	\$25.3	\$30.1	\$33.8	\$36.5	\$38.9	\$41.6
<i>ROW Galectin-3 Prognosis Testing</i>													
- Growth in Galectin-3 Prognosis Testing	NA	NA	NA	NA	11,700	33,700	65,313	108,783	159,630	202,650	232,799	256,079	281,687
ROW Galectin-3 Prognosis Testing	0	0	0	250	4,900	13,900	26,863	44,662	65,405	82,839	95,067	104,574	115,031
- Growth in Galectin-3 Prognosis Testing	NA	NA	NA	NA	183.7%	93.3%	66.3%	46.4%	26.7%	14.8%	10.0%	10.0%	10.0%
Total Galectin-3 Tests ROW	0	0	0	800	16,600	47,600	92,175	153,445	225,034	285,489	327,866	360,653	396,718
- Price per test	\$30.00	\$30.00	\$30.00	\$30.00	\$30.00	\$30.00	\$30.00	\$30.00	\$30.00	\$30.00	\$30.00	\$30.00	\$30.00
Gross Revenues for Galectin-3 ROW (\$M)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.5	\$1.4	\$2.8	\$4.6	\$6.8	\$8.6	\$9.8	\$10.8	\$11.9
- Revenue Per Test to BGMD	\$8.00	\$8.00	\$8.00	\$8.00	\$8.00	\$8.00	\$8.00	\$8.00	\$8.00	\$8.00	\$8.00	\$8.00	\$8.00
Galectin-3 Revenue for ROW to BGMD (\$M)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.1	\$0.4	\$0.7	\$1.2	\$1.8	\$2.3	\$2.6	\$2.9	\$3.2
Total Tests Delivered	0	3,500	22,688	325,148	1,159,958	2,326,941	3,362,562	4,080,930	4,755,062	5,311,738	5,765,344	6,187,696	6,650,757
Total Gross Galectin-3 Revenues	\$0.0	\$0.1	\$0.7	\$15.1	\$44.9	\$110.4	\$159.3	\$192.7	\$223.7	\$249.4	\$270.1	\$291.6	\$311.6
Total Galectin-3 Revenues to BGMD	\$0.0	\$0.0	\$0.2	\$4.3	\$15.5	\$31.1	\$44.8	\$54.2	\$62.9	\$70.1	\$76.0	\$81.5	\$87.5

Source: Ladenburg Thalmann estimates

## CORONA

In August 2011, BGMD announced results of a sub-study of the Controlled Rosuvastatin Multinational Trial in Heart Failure (CORONA) study at the European Society of Cardiology (ESC) meeting demonstrating patients with plasma levels of galectin-3 below the median (less than or equal to 19.0 ng/mL) received a 35% reduction in the probability of cardiovascular events ( $p < 0.05$ ) and a mortality benefit from the statin Crestor (rosuvastatin) while patients with galectin-3 levels did not report a benefit.

**Table 10. Outcome Data from CORONA Study Based on Galectin-3 Levels**



Source: ESC 2011 Poster Presentation

Topline results of the CORONA study had demonstrated no significant difference between Crestor and placebo in rates of myocardial infarction, stroke or death from cardiovascular event. The galectin-3 analysis was conducted in a subset of 1,462 subjects from the CORONA study (29% of the total enrollment). All subjects were age 60 years or older and were previously diagnosed with heart failure but LDL cholesterol levels below the threshold requiring intervention with a statin. Subjects were tested for galectin-3 levels at baseline and were also tested for NT-proBNP.

The primary endpoint was time to first event defined as a composite of cardiovascular mortality, non-fatal myocardial infarction and non-fatal stroke compared to placebo. The study confirmed heart failure patients derive an important mortality and morbidity benefit from statins unrelated to cholesterol control.

In clinical practice, the value of galectin-3 as a biomarker for guiding statin therapy in heart failure patients is likely to depend on previous prescribing patterns. Statin therapies such as Crestor are approved for the treatment of high LDL cholesterol but are widely used off label to manage a range of cardiovascular risk factors.



## GALECTIN-3 ASSOCIATED WITH MORTALITY AND HOSPITALIZATION

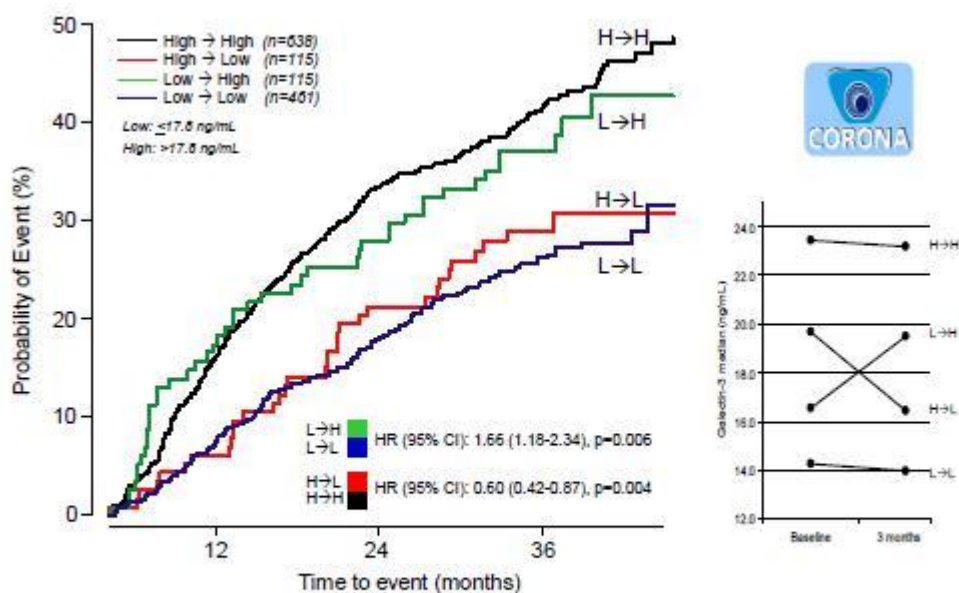
The CORONA findings were reaffirmed by a presentation in September 2011 at the Heart Failure Society of America (HFSA) demonstrating both absolute levels and change in levels of galectin-3 correlated with adverse clinical outcomes in heart failure patients. The poster presentation was entitled "changes in Galectin-3 Levels Over Time Predict Mortality and Morbidity in Heart Failure."

The study evaluated the correlation between change in galectin-3 and rates of mortality and morbidity in 1,653 heart failure patients. Subjects were stratified into cohorts based on galectin-3 levels above 17.8 ng/ml, below 17.8 ng/ml, patients starting above 17.8 ng/ml that fell below the threshold during therapy or patients starting below 17.8 ng/ml but increased above the threshold.

Response was defined as a change in galectin-3 levels between baseline and month 3 of greater than a 10% increase, greater than a 10% decrease or stable levels defined as  $\pm 10\%$ . A subset of 324 patients was also evaluated based on change in galectin-3 levels between baseline and month 6. Mortality and morbidity was evaluated after 3 years.

Subjects reporting a 10% increase in galectin-3 over 3 or 6 months reported 60% higher rate of mortality and morbidity regardless of baseline galectin-3 levels. Additionally, patients with high baseline levels above 17.8 ng/ml or whose galectin-3 levels increased from below 17.8 ng/ml to above the threshold during the study were also at elevated risk of adverse clinical outcomes.

Table 11.



Kaplan-Meier curves for CV Mortality and HF Hospitalization by categorical change in galectin-3 level from 0 to 3 months, CORONA. Right: median levels by category. The threshold value of 17.8 ng/mL corresponds to the FDA-approved test interpretation delineating elevated risk.  
Source: HFSA Meeting Poster (2011)

### Galectin-3 Also Associated with Lower Rates of Re-Hospitalization

In a separate study at the HFSA meeting, high galectin-3 levels were associated with higher rates of unplanned hospital re-admission for heart failure patients. The poster was entitled "Plasma Galectin-3 is Associated With Near-term Rehospitalization in Heart Failure: A Meta-Analysis."

In clinical practice, about 20% of heart failure patients discharged from a hospital are readmitted within 30 days and 50% within 180 days. A meta-analysis of 892 patients was drawn from 3 cohorts: COACH (Coordinating Study Evaluating Outcomes of Advising and Counseling in Heart Failure; n=582), PRIDE (Pro-BNP Investigation of Dyspnea in the Emergency Department; n=181) and UMD H-23258 (University of Maryland Pro-BNP for Diagnosis and Prognosis in Patients Presenting with Dyspnea; n=129). Blood draws for UMD H-23258 and PRIDE were taken at admission while the samples in COACH were taken at discharge. Unplanned hospital re-admission risk was evaluated at 30, 60, 90 and 120 days. galectin-3 levels were classified as high (above 17.8 ng/mL) or low (below 17.8 ng/mL).

The odds ratio for re-admission was between 2.57 and 3.01 in favor of re-admission for the high galectin-3 group in all time periods. Additionally, a hazard ratio analysis conducted on the COACH cohort demonstrated a hazard ratio of 1.62 (p=0.033) after adjusting for baseline age, gender, renal function (eGFR), NYHA class, NT-proBNP and left ventricular ejection fraction (LVEF).

**Table 12.**

Results of meta-analyses for unplanned hospital re-admission.

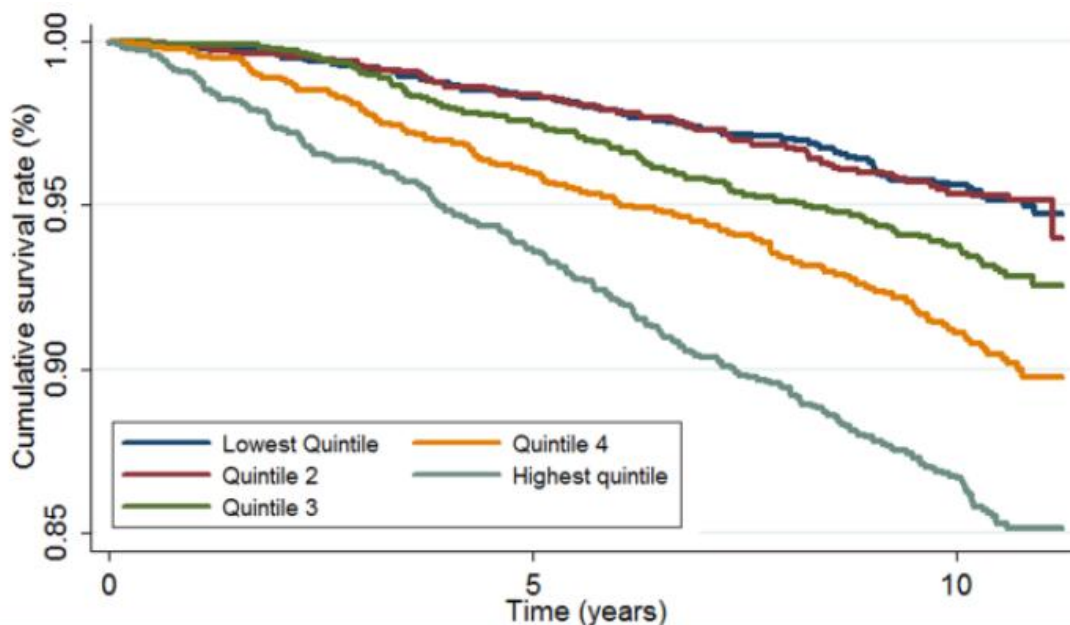
	Meta-analysis OR (95% CI) <i>Fixed effects</i> (Mantel-Haenszel)	Meta-analysis OR (95% CI) <i>Random effects</i> (DerSimonian-Laird)	p-value (Fixed effects)	Percentage of Patients Re-hospitalized for HF (across all studies)	
				<17.8 ng/mL	>17.8 ng/mL
30 days	2.80 (1.41-5.57)	2.78 (1.40-5.52)	0.003	3.0%	7.3%
60 days	2.61 (1.46-4.65)	2.57 (1.44-4.59)	0.001	4.5%	10.0%
90 days	3.01 (1.79-5.05)	3.01 (1.80-5.04)	<0.001	5.5%	13.6%
120 days	2.79 (1.75-4.45)	2.79 (1.75-4.44)	<0.001	7.3%	15.8%

Source: HFSA Poster (2011)

### EXPANDED INDICATION FOR GALECTIN-3 FOR RISK ASSESSMENT OF HF

We expect BGMD to file an application with the FDA during 2012 to seek an expanded intended use indication for galectin-3 testing to include risk assessment for heart failure following acute cardiovascular injury due to acute myocardial, stroke or other cardiovascular injuries. The filing will be based on results from Prevention of Renal & Vascular Endstage Disease (PREVEND) study, PROVE-IT-TIMI 22 data presented at the ACC meeting in April 2011 and results from the Offspring cohort of the Framingham Heart Study, which we expect to be presented at the ACC meeting in March 2012.

As described in our revenue model above, we believe the risk assessment market is roughly 3x the size of the prognostic testing market. Based on results of the PREVEND study, in our view, there is solid evidence suggesting galectin-3 levels may predict risk of death from cardiovascular disease in a general population but we await results from the Framingham cohort to verify the PREVEND findings.

**Table 13. PREVENT Study – Galectin-3 Levels Associated With Risk of Mortality**

Source: ESC Poster Presentation (August 2011)

The PREVENT study enrolled 7,968 patients in the Netherlands with an average age of 50 years and follow up of roughly 10 years. Enrollment included subjects with a wide range of underlying cardiovascular risk factors. Patients were segmented by baseline galectin-3 levels into quintiles. The breakdown by quintile was: 1) below 8.6ng/ml, 2) 8.7ng/ml - 10.1ng/ml, 3) 10.2ng/ml – 11.7ng/ml, 4) 11.8ng/ml – 13.7ng/ml, and 5) above 13.8ng/ml. Subjects with galectin-3 levels in the highest quintile (above 13.8 ng/ml) had a 3x greater risk of mortality compared to patients in the two lowest quintiles. The results demonstrate that galectin-3 levels correlate with risk of mortality from cardiovascular disease in an older population of average risk patients.

In April 2011 at the American College of Cardiology meeting, BGMD reported that a nested case control study from the PROVE-IT-TIMI 22 study suggested elevated galectin-3 levels in acute coronary syndrome (ACS) patients can be used as a marker for predicting risk of developing heart failure. The analysis evaluated 100 patients hospitalized at Brigham & Women's Hospital and Harvard Medical School for new or worsening heart failure after ACS. All subjects were matched 1:1 with controls by age, sex, ACS type and randomized treatment. All patients in the study were randomized to intensive vs. moderate statin therapy. The study was published in the November 2011 issue of the journal *Clinical Chemistry*.

### Framingham Heart Study

In March 2009, the Framingham Heart Study launched its Systems Approach to Biomarker Research in Cardiovascular Disease (SABRe CVD) to create new blood-based tests to identify people at high risk of heart disease and stroke. BGMD will contribute to the program through a 5-year agreement with the NHLBI, which oversees the Framingham cohort. The agreement calls for BGMD to assist in the screening of up to 1,000 biomarkers from frozen blood samples collected from 7,000 patients. The results will be compared with results from imaging studies and other tests to identify biomarkers associated with heart disease and metabolic syndrome. All data will be made publicly available through Database for Genotype and Phenotype (dbGAP). We expect results from a study using the cohort to screen for heart failure risk based on galectin-3 levels to be presented at ACC meeting in March 2012.

## OVERCOMING A WALL OF SKEPTICISM ABOUT VASCULAR BIOMARKERS

We believe the history of vascular biomarkers adding clinical utility beyond traditional clinical risk factors has been checkered at best. While most vascular biomarkers are focused on coronary disease, we believe the prevailing skepticism creates a higher bar for heart failure tests such as galcetin-3.

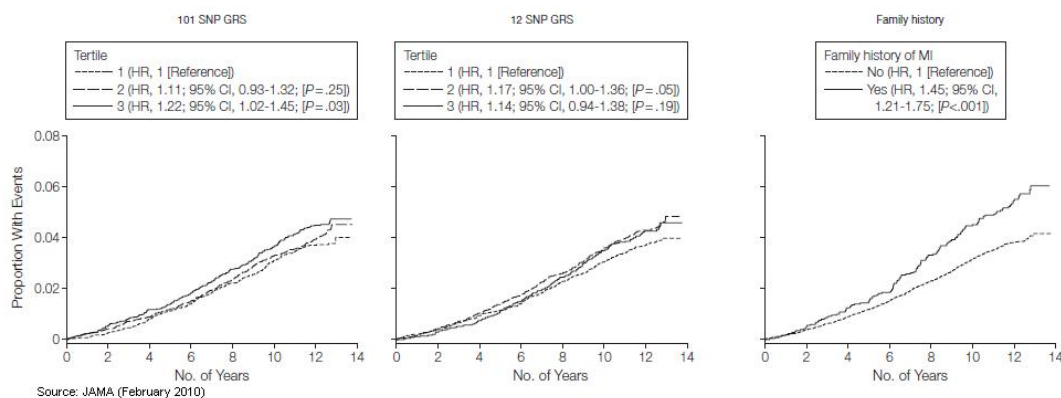
Over the past two years several studies have suggested current biomarkers offer limited clinical utility for predicting MACE (major adverse cardiovascular events). Among the most notable was a February 2010 study published in *JAMA* that reviewed data from 19,313 Caucasian women enrolled in the Women's Genome Health Study.

Blood samples were analyzed for cholesterol, C-reactive protein, triglycerides and other plasma biomarkers. One cohort was evaluated for 12 SNPs linked to cardiovascular disease and another cohort looked at 101 markers linked to phenotypes such as blood pressure or cholesterol. A third cohort evaluated family history and traditional plasma markers.

After 12.3 years of follow up and 777 cardiovascular events, traditional patient history and plasma markers were a more powerful predictor of heart disease than either set of genetic markers. Adding genetic information to traditional clinical risk factors provided no incremental clinical utility.

We'd note that traditional clinical markers offer less predictive value in heart failure than in coronary artery disease but the *JAMA* article and other studies with similar findings suggest the bar for demonstrating clinical utility of biomarkers - and potentially for reimbursement - may be rising.

**Table 14.**



## AMIPREDICT

AMIPredict is a panel of 7 protein biomarkers that have shown promise in improving risk assessment for acute atherothrombosis (commonly known as vulnerable plaque) versus the current clinical risk scores. BGMD believes the potential market in the U.S. could include all men over age 50 (43.3 million) and women over age 55 (39.8 million).

The clinical value for a test such as AMIPredict is based on several large population studies demonstrating traditional clinical markers offer relatively poor risk stratification with 75% of coronary events occurring in people defined as low or intermediate risk by clinical metrics. Based on these findings, the company began working with Duke University School of Medicine in 2006 to identify new blood-based markers for risk of atherothrombosis. Additionally, in February 2008, the company announced an agreement with the Copenhagen

General Population Study to validate markers for the rupture of atherosclerotic plaque and myocardial infarction. The studies were conducted as part of the HRP Initiative.

The initial screening work by Duke and BGMD was combined with 750 clinical samples from the Copenhagen Heart Study (CPH) to complete the biomarker discovery phase of development. In 2009, a series of biomarker discovery studies based on the CPH cohort and matched controls screened over 1,000 analytes to identify proteins, multi-protein panels and algorithms associated with increased risk.

These findings were evaluated in a pilot study of 252 healthy subjects who experienced a heart attack within 4 years of entering the CPH study and 499 healthy matched controls who did not experience a heart attack in the first four years. In May 2011, the company completed a second independent pilot study evaluating blood samples from 315 subjects who experienced a heart attack within four years compared to 632 matched controls. Both studies demonstrated increased power to detect high risk patients compared to clinical markers such as total cholesterol, HDL cholesterol and hypertension.

### **HRP Initiative**

Unstable plaque has been shown to be more closely associated with cardiovascular events than traditional LDL cholesterol markers - unstable plaque can rupture leading to thrombosis. The High Risk Plaque (HRP) was initiated in 2006 to identify new markers for atherothrombotic cardiovascular disease such as heart attack and stroke. The initial design called for 6 partners to pay \$5M each spread over four years. BGMD has received over \$25M in funding for the program through sponsors including Abbott, AstraZeneca, Merck, Philips and Takeda. Humana agreed to recruit volunteers from its insurance membership in Chicago and South Florida, which contributed to accelerated patient enrollment in the project. In terms of future activity, \$631,000 at September 30, 2011 was identified as restricted cash on BGMD's balance sheet to be used solely to fund research for the HRP program. The company will own any inventions and data that are conceived in the conduct of the HRP initiative with a royalty-free license issued to each participant in the program. There are no current plans for additional funding commitments or development plans by HRP members.

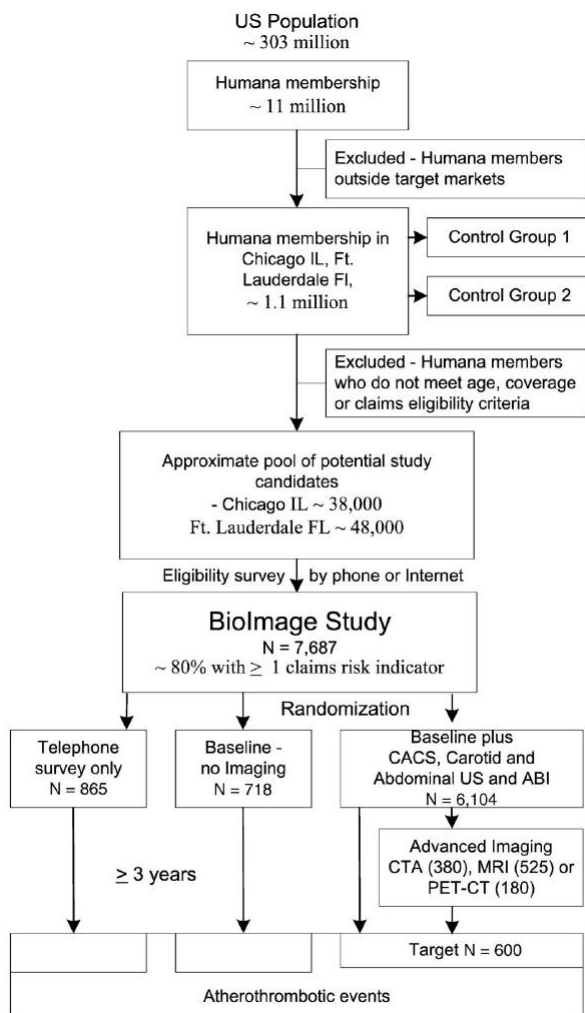
### **Biolmage Cohort to Serve as Clinical Validation Study for AMIPredict**

In June 2009, the HRP Initiative completed enrollment of 6,822 patients (males ages 55-80 and females ages 60-80) in its first screening study, known as the Biolmage Study. All participants submitted to a physical exam and provided a blood samples to screen for potential biomarkers. This information will be compared to results from imaging procedures to identify correlation between biomarkers and the imaging data from ultrasound of the carotid arteries and a CT-scan to measure coronary calcification. BGMD retains rights to use samples collected in the Biolmage study and to the data for its product discovery and development studies.

We expect results of the Biolmage AMIPredict validation study to be presented in 1Q12 and to serve as the basis for a regulatory filing of AMIPredict.



Table 15.



Source: American Heart Journal (July 2010)

## LIPIDDX

BGMD and Merck are in the discovery research phase of the LipidDx blood-based protein assay for detecting lipid disorders. The program seeks to optimize a test that both provides prognostic information on lipid disorders and offers an assessment of the contribution of lipid disorders to risk of cardiovascular disease. In January 2010, the company licensed rights to certain intellectual property for lipid biomarkers from Merck. BGMD screened roughly 1,000 samples provided by Merck against a validated assay for the undisclosed biomarker.

BGMD hopes to launch an Elisa version of the test in 2012 but has provided little disclosure about the program.

## **SMA**

---

In September 2007, BGMD and the Spinal Muscular Atrophy Foundation launched a collaboration to identify new blood-based biomarkers to predict response to therapies for spinal muscular atrophy (SMA). The autosomal recessive genetic disorder results in destruction of nerve cells in the spinal cord and respiratory problems. The SMA Foundation estimates there are 50,000 SMA patients in the United States, Europe and Japan, including 9,000 in the United States. The disease is diagnosed in newborns with an incidence rate of 1 in 10,000 live births. Life expectancy for SMA Type I and Type II varies but is around 2 years. All SMA patients have a missing or impaired copy of the SMN1 gene. A second gene, SMN2, can produce the same protein but at much lower levels than SMN1. Therapeutic strategies for treating SMA are focused on boosting SMN protein production from either SMN1 or SMN2 gene.

## **LTBS BIOMARKER DISCOVERY STUDIES**

---

In October 2005, the company and the FDA's National Center for Toxicological Research (NCTR) initiated the Liver Toxicology Biomarker Study (LTBS) to discover biomarkers of hepatotoxicity. Initial toxicity studies began in 2007 with additional corporate support from Applied Biosystems (mass spectrometry platform) and funding from Pfizer, Johnson & Johnson, Mitsubishi, Orion, UCB, Sankyo Co. and Eisai. Each of the 7 pharmaceutical sponsors contributed \$350,000 to the program in return for certain intellectual property rights. Total revenue to BGMD totaled \$2.5M. The agreement expired in 2008 and no additional studies are planned. The LTBS study is part of the FDA's Critical Path initiative to reduce the cost of drug development.

## **REIMBURSEMENT**

---

In November 2011 BGMD received an analyte-specific CPT code for measuring galectin-3 in plasma or serum. Following a meeting in July 2012 to assess clinical utility, reimbursement levels will be set and the code will become active in the 2013 Clinical Laboratory Fee Schedule.

As mentioned in our investment thesis, BGMD is seeking to crosswalk reimbursement to the same reimbursement level as NT-proBNP, which is reimbursed at about \$48. We'd note that crosswalking to BNP reimbursement has been a common and successful strategy over the past five years for other cardiovascular tests including myeloperoxidase (MPO) testing for risk of atherosclerosis.

Importantly, the company's diagnostic equipment partners for galectin-3 are responsible for collection of reimbursement with BGMD receiving a fee payable by the equipment vendor.

## **COMMERCIAL AND PRODUCT DEVELOPMENT PARTNERSHIPS**

---

BGMD's business model relies on maintaining a broad network of collaborations for both content development and commercialization of its diagnostic tests. For commercialization, the company relies on LabCorp for selling activity of the galectin-3 Elisa test and Abbott, Alere, bioMérieux and Siemens to sell automated versions of the test. BGMD has worked with a range of academic institutions and industry-driven collaborative research projects for the development of biomarker content. Current and former partners include ACS Biomarker, AstraZeneca, Boston Scientific, Cordex Pharma, Lipid Nutrition BV, Humana, HDL, GSK, MD Anderson, Mitsubishi Pharma, Multiple Sclerosis Research Center of New York (MSRCNY), Philips and the TB Alliance. In our view, the ACS agreement is the only collaboration with material future economic commitments.

**ACS**

In March 2007, the company licensed rights for intellectual property to develop galectin-3 as a diagnostic from ACS Biomarker B.V. The agreement was amended in May 2007 to include specific language regarding commercialization of a second marker, thrombospondin-2, and a cardiovascular multivariate biomarker test for the early confirmation of a heart attack. In addition to the intellectual property, BGMD sublicensed rights to certain peptides for use in diagnosing atherothrombotic vascular disease. BGMD also received a limited right of first negotiation to additional intellectual property from ACS. BGMD paid an upfront fee of \$750,000 and we estimate the company is required to pay a mid-to-high single digit royalty on future sales of galectin-3 tests.

**Abbott**

In November 2009, the company announced an agreement with Abbott to commercialize the galectin-3 test for Abbott's i1000SR and i2000SR instruments and the i-STAT point-of-care system. Under terms of the agreement with Abbott, BGMD is allowed to license its galectin-3 automated assay to up to 4 other companies for the first five years following commercial launch of the first product from Abbott. If any future licensee receives terms materially more favorable on an automated test, Abbott is entitled to receive the more favorable terms. Abbott also has a right to rebates and an option to discontinue sales if average selling price falls below certain undisclosed thresholds. In 2010, BGMD expanded the relationship to include a license to run AMIPredict on the Abbott Architect Immunochemistry Diagnostics Platform.

**Alere**

In April 2010, Inverness Medical Innovations (now Alere) agreed to develop the galectin-3 test for the Triage Meter Pro point-of-care platform. We expect Alere to file for regulatory approval of its automated test in 1H12 and pay a fee to BGMD of \$10-\$15 per test analyzed.

**AstraZeneca**

In February 2004, the company entered an agreement with AstraZeneca to apply systems biology to predictive toxicology. Additionally, BGMD received plasma samples from the CORONA study evaluating potential benefits of the statin Crestor in heart failure patients. BGMD conducted galectin-3 testing on the samples to identify a subset of patients that appeared to demonstrate a benefit from Crestor. Data from the CORONA study has been used in discussions with payers regarding galectin-3 and may be included in future regulatory filings for galectin-3.

**bioMérieux**

BioMérieux is one of four companies with a license to sell galectin-3 on an automated platform. The bioMérieux galectin-3 test will run on the VIDAS/miniVIDAS platform, which is placed in Europe and emerging markets such as South America. We believe the terms are substantially similar to the other galectin-3 licenses and require bioMérieux to pay BGMD a license fee of \$10-\$15 per test.

**Boston Scientific**

In March 2011, BGMD entered an agreement with Boston Scientific to study the role of galectin-3 as an aid in screening for cardiac-resynchronization therapy (CRT) using patient data from the MADIT-CRT study. BGMD will work on identifying other biomarkers that correlate to CRT treatment response. The companies hope the data will provide more insight on expected disease progression. We expect galectin-3 data from the MADIT-CRT study to be published in 2012.

**Cordex Pharma**

In March 2009, BGMD announced a partnership with Cordex Pharma to use galectin-3 as a biomarker for clinical response in a Phase II study of CDP-1050 in heart failure patients. CDP-1050 attempts to inhibit reactive oxygen radical production while restoring nitric oxide levels through targeting of the ryanodine receptor. Terms of the license were not disclosed and the status of CDP-1050 development is unclear.

**Lipid Nutrition BV**

In April 2006, BGMD announced a partnership with Lipid Nutrition BV and the Erasmus University Medical Center to identify biomarkers for early screening of diabetes. The first 3 years were funded through a 1 million Euro grant from the Dutch governmental organization Senter Novem. Lipid Nutrition will obtain royalty-bearing rights for nutritional products, its parent, Dnage, will obtain similar rights for pharmaceutical products and BGMD will obtain rights for biomarkers. DNage was acquired by Pharming.

**GlaxoSmithKline (GSK)**

In January 2004, BGMD signed a research agreement with GSK to apply its expertise in systems biology to metabolic diseases. Financial terms were not disclosed and to the best of our knowledge the collaboration is no longer active.

**HDL**

Health Diagnostic Laboratory (HDL) is a testing laboratory focused on specialty testing for cardiovascular disease and metabolic disorders. In March 2011, HDL agreed to sell BGMD's Elisa galectin-3 test. Terms were not disclosed but BGMD has indicated partners for the Elisa test pay the company a fee that we estimate at \$8-\$10 per test.

**Humana**

The company has been working with Humana since 2007 on biomarker discovery research for response to various therapeutic products. Currently, the companies are collaborating to evaluate potential biomarkers of response to TNF-alpha drugs such as Enbrel, Remicade and Humira used in the treatment of autoimmune diseases. Terms of the agreement call for Humana to recruit patients from its health insurance membership for potential inclusion in discovery research. Humana has also contributed patients for BGMD's clinical development programs for cardiovascular disease. BGMD believes this recruitment structure will accelerate enrollment and provide a more accurate assessment of the overall population than evaluating samples gathered from drug clinical trials. BGMD will conduct all biomarker discovery work and make certain undisclosed payments to Humana for any diagnostic tests incorporating findings from these biomarker studies.

**MD Anderson**

In March 2007, BGMD and MD Anderson launched a research collaboration to identify new blood-based protein and metabolite biomarkers for breast cancer. Clinical samples would be provided by MD Anderson and BGMD would provide its biomarker discovery technology. The status of this program is not disclosed.

**Mitsubishi Pharma**

In March 2006, the company began working with Mitsubishi Pharma to identify biomarkers for muscle toxicity. BGMD agreed to screen certain lipid lowering agents with its toxicology platform to identify biomarkers impacting skeletal muscle. The companies will jointly own any IP related to the partnership. The status of this program is not disclosed.

**MSRCNY**

The Multiple Sclerosis Research Center of New York (MSRCNY) and BGMD entered an agreement in 2007 to discover new blood-based biomarkers for multiple sclerosis disease activity and biomarkers of response to certain therapies. Terms call for BGMD to make undisclosed payments in exchange for clinical samples and support services. The status of this program is not disclosed.

**Philips**

In August 2006, BGMD and Philips announced an agreement to develop molecular imaging and point-of-care diagnostics. BGMD contributed its expertise in identifying biomarker sets associated with disease stage, progression and treatment. The partnership will focus on cardiovascular disease and oncology. Philips also acquired a minority stake in BGMD.

**Siemens**

In January 2011, BGMD entered an agreement with Siemens Healthcare Diagnostics to develop a galectin-3 test for Siemens' automated immunoassay platforms. Siemens will be responsible for developing the assay.

**TB Alliance**

In February 2006, BGMD announced a partnership with the TB Alliance to identify biomarkers for drug efficacy in the treatment of tuberculosis. The partners, in conjunction with Colorado State University, conducted a six-month animal study. The current status of this program is not disclosed.



## IP

---

Intellectual property is a central component of BGMD's content-driven business model. The company has a non-exclusive license to two issued U.S. patents and their foreign counterparts related to methods for discovering biomarkers. As of November 1, 2010, the company had 20 pending patent applications with the USPTO, PCT and foreign counterparts. The central patent pertaining to galectin-3 test for heart failure is U.S. Patent Application No. 10/575,745 (licensed from ACS Biomarker), which received a notice of allowance on October 1, 2010. Based on the notice date, BGMD should have patent protection at least through 2025. The company and its partners have also filed 9 related patent applications in the United States and in foreign jurisdictions. These patent applications cover a specific method and for detecting galectin-3 and the related kit, and methods for clinical evaluation of therapies based on galectin-3 measurements.

## LABORATORY FACILITIES

---

BGMD intends to outsource commercial manufacturing of galectin-3 and other products under development. The galectin-3 Elisa test is manufactured by a sole third party contract manufacturer, Corgenix Medical Corp., for the U.S., Europe and other markets. All biomarker discovery analysis and diagnostic test development is conducted at the company's 22,000 square foot facility in Waltham, Massachusetts. In November 2010, the company received a 483 letter from FDA citing variances or deficiencies in: 1) documentation of procedures for a stability study (remedied by repeating study at Corgenix), 2) documentation and implementation of corrective and preventative action procedures and 3) documentation and implementation of training programs for its staff. We do not expect any of these issues to impact continued sales the galectin-3 Elisa assay. Automated versions of the galectin-3 assay will be manufactured by the licensee and conducted at reference laboratories and hospitals with installed analytical systems. BGMD has not disclosed a commercial or distribution strategy for AMIPredict.

## SALES INFRASTRUCTURE

---

The company plans to retain primary marketing responsibilities in promoting clinical adoption of galectin-3 through physician education, interaction with payers and recruitment of thought leaders to communicate the clinical value of galectin-3 testing. In addition to the announced agreements with Abbott, Alere, bioMérieux and Siemens, the company retains the right to assign a license to one additional analytical equipment vendor.

In May 2010, the company signed a distribution agreement with LabCorp for the manual Elisa galectin-3 test for at least the first 3 years of launch. Kordia N.V. is responsible for distributing and promoting the Elisa galectin-3 test in Europe. LabCorp also has a commercial license to sell the Elisa test in Canada and the United Arab Emirates. Economics of the LabCorp agreement call for BGMD to receive a fixed payment for each manual test kit. LabCorp is entitled to rebates if test volumes for automated versions of the test exceed certain undisclosed thresholds. Holders of the license to automated versions of the test are required to supply kits to LabCorp. In recent months BGMD has signed agreements with HDL and other laboratories to promote the Elisa assay and build awareness of galectin-3.

## CAPITAL STRUCTURE

---

From 2000 through February 2011 the company was funded through venture capital, government grants and research partnerships. The only disclosed private financing round was a \$40M Series D venture financing in July 2008 with participation from Legg Mason Capital Management, GE Asset Management, SMALLCAP World Fund, Flagship Ventures, Gilde Healthcare Partners, Humana, and Stelios Papadopoulos. These funds and entities represented the majority of BGMD's equity prior to the IPO and continue to be large shareholders of the company.

In February 2011, BGMD raised \$36.6M from an initial public offering of 5.8 million shares at \$7.00 per share. BGMD has 19.3 million shares outstanding on a diluted basis, excluding anti-dilutive options and warrants underlying 4.5 million shares.

On September 30, 2011 the company had \$28.0M in cash and \$0.0M in debt. Lastly, as of December 31, 2010, BGMD had gross NOLS for federal income taxes totaling \$68.3M.

## MODELING ASSUMPTIONS

**Sales.** We assume BGMD recognizes \$4.50 per Elisa galectin-3 test and \$13.50 per test with automated design sold by partners. For the remainder of 2011, we expect test volumes to trend higher based on increased traction from partner HDL but expect reported revenues to remain de minimis until the launch of the first automated version of galectin-3 in 4Q12. Our galectin-3 test volume forecast is 3,500 for 2011 and 12,688 for 2012.

License revenue is related primarily to continued payments from partners in the HRP program. Our model calls for modest future revenue recognition from the program and other research collaborations to total about \$0.6M annually.

We do not expect any revenues from AMIPredict until 2013.

**COGS.** Cost of goods is primarily related to test kit production and reagent for the Elisa galectin-3 assay, royalties to ACS (our estimate is 7-10%) for intellectual property pertaining to galectin-3 and activity under the HRP research partnership. We estimate cost of goods for Elisa approach 50%. However, with the launch of automated designs for galectin-3 in 4Q12 BGMD will have almost no direct cost and should recognize incremental gross margin of 90%. Additionally, the LabCorp agreement requires BGMD to pay a royalty on any sales of automated versions of galectin-3 for the first three years of launch. Once this agreement expires, our model calls for BGMD to recognize a 200 basis point improvement in gross margin to 92%.

**SG&A.** We expect a 31% Y-O-Y increase in SG&A expenses to \$10.6M in 2011 primarily due to costs of reporting as a publicly traded company and increased spending on the marketing of galectin-3. Our model calls for BGMD to add about 20 marketing and medical liaison personnel following the launch of the first automated galectin-3 platform in 4Q12, which should add about \$2.5M annually to BGMD's selling expenses.

**R&D.** Our forecast calls for R&D spending to increase 26% to \$8.2M for 2011 as BGMD invests in validation studies for AMIPredict and use of galectin-3 as a biomarker for heart failure risk. Our 2012 forecast assumes BGMD initiates additional post-approval studies to demonstrate the clinical utility of galectin-3 and AMIPredict resulting in full year expenses of \$8.8M.

**EPS.** We expect BGMD to record EPS of (\$1.02) and (\$0.99) for 2011 and 2012, respectively. Our cash burn rate for 2012 is \$21.0M

**Share Count.** While BGMD believes its current cash balance of \$28.0M is sufficient to fund operations through 2012, our model assumes BGMD raises capital through the issuance of roughly 5 million shares in 2H12. Depending on commercial uptake of galectin-3 and AMIPredict and price of BGMD's common stock, we believe the 2012 financing may be sufficient to fund operations through profitability.

**Capital expenditures.** Capital expenditures should total \$0.2M in both 2011 and 2012.

## PRIMARY RISKS

---

We think the primary risks of an investment in BGMD shares include, but are not limited to:

**Intellectual Property.** The company's business model is based on identifying and commercializing tests based on proprietary biomarkers. BGMD has several filed and issued patents pertaining to the role of galectin-3 in diagnosing and staging heart failure patients and methods for developing diagnostic kits and tests based on galectin-3. There can be no assurance changes to U.S. patent law or interpretation will not adversely impact the company's future revenues.

**Regulatory.** Each of BGMD's IVD partners expect to submit a 510(k) application to the FDA for automated versions of the galectin-3 test. There can be no assurance validation studies and subsequent registration studies will be adequate to support 510(k) clearance of galectin-3 as an automated prognostic test for heart failure. Additionally, the predictive value of galectin-3 in assessing risk of heart failure following acute coronary injury is an important source of potential future market expansion. There can be no assurance galectin-3 will win FDA clearance in this indication. Additionally, the company may seek to launch its AMIPredict multivariate test as a laboratory developed test (LDT) under CLIA regulations. There can be no assurance that AMIPredict will receive a CLIA waiver or that the FDA will continue to exercise regulatory discretion over LDTs.

**Reimbursement.** Galectin-3 is not currently covered by most private insurance payers, Medicare or state health plans in Europe. In the U.S., clinicians and their patient can seek reimbursement through submission under miscellaneous codes on an out-of-network basis. BGMD has received a unique CPT code for galectin-3 and hopes to have the new code included in the 2013 clinical laboratory fee schedule. There can be no assurance Medicare or private payers will reimburse for the test or that reimbursement levels will be adequate to meet the terms of license agreements with IVD manufacturers or for BGMD to earn a profit. Additionally, the timing of future reimbursement coverage from both private payers, state health plans in Europe and Medicare is not certain.

**Partnership.** Abbott, Alere, bioMérieux, LabCorp and Siemens have licensed rights to sell galectin-3 tests both in the United States and certain ex-U.S. markets. There can be no assurance these partners can process the test in a commercially reasonable time period. Additionally, effective positioning of galectin-3 may require promotion to primary care doctors, which is outside of many of the partners' commercial focus and beyond the means of BGMD to address, in our view. There can be no assurance BGMD will identify an appropriate commercial partner to maximize the value of BGMD or that a partner will provide the required commitment of commercial resources.

**Financing.** The company believes current financial resources will fund the company through 2012. However, successful commercial launch of automated galectin-3 tests will require significant marketing expense and development of AMIPredict may require substantial direct research funding from BGMD. There can be no assurance BGMD will have access to private capital in the future on adequate terms, or at all.

## BGMD PERFORMS IN LINE WITH THE PMI INDEX

In January 2009, we constructed a basket of diagnostic products and services companies, referred to as the Personalized Medicine Index (PMI), to track the performance of the sector. The index includes the following nine companies: Celera Corporation (CRA), Clariant Inc. (CLRT), Genetic Technologies Limited (GENE), Genomic Health Inc. (GHDX, Neutral rated stock), Genoptics, Inc (GXDX), Myriad Genetics (MYGN, BUY rated stock), Nanosphere, Inc. (NSPH), Quiagen N.V. (QGEN) and Rosetta Genomics Limited (ROSG).

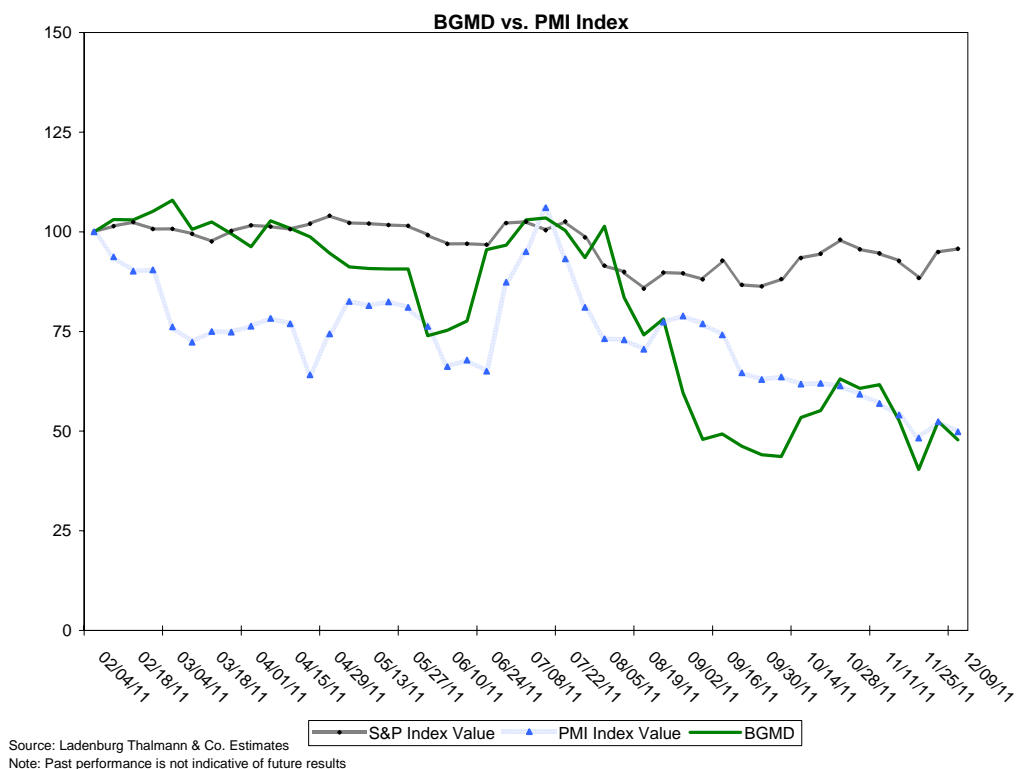
We defined the universe as companies with at least one marketed product or diagnostic-related service that is used by clinicians to make personalized medicine decisions. All stocks are publicly traded on a major U.S. stock exchange. The PMI is an equal weight index set to have a base index value of 100 on January 2, 2009. The divisor for the index is the aggregate value of the composite stocks on January 2, 2009 and scales the aggregate value to a lower order of magnitude.

For comparison, we also track the S&P 500 as an equal weight index using a similar methodology. As of December 20, 2011, three of the companies on the PMI have been acquired. These companies are Celera Corporation (CRA), Clariant Inc. (CLRT) and Genoptix, Inc (GXDX). We rebalance at the time of close for each acquisition. For disclosure information related to this index, please refer to Appendix A: General Disclaimer section.

Shares of BGMD began trading on February 4, 2011. For comparative purposes, we rebase our basket on February 4, 2011 for an apples-to-apples comparison of S&P 500 and PMI performance to BGMD's performance since the IPO.

Shares of BGMD have almost exactly in line with the rebased PMI and S&P index since then. Based on material news flow in over the next 12 months, we expect performance to diverge from the PMI over the next 12 months.

Table 16.



## MANAGEMENT

---

BGMD employed 38 fulltime employees as of December 31, 2010 including 24 engaged in research and development, 6 in sales and marketing functions and 8 in general and administrative functions. We expect the company to expand its marketing group following launch of an automated version of the galectin-3 test in 4Q12. Additionally, we expect the biomarker discovery group to expand modestly as BGMD maintains a high level of investment in identifying additional content.

**Chief Executive Officer:** Pieter Muntendam joined the company in 2004 as President and CEO. Previously he served as Director of the Biopharma Healthcare Practice at professional services group NetNumina Solutions, Inc. Much of Dr. Muntendam's professional experience is with large pharmaceutical companies including as a Vice President of Care Management at Glaxo Wellcome (now GlaxoSmithKline), Organon International Inc. and Johnson & Johnson. He was also a co-founder of two startups: health management group ProMedex Inc., which was sold to Landacorp, Inc., and the Vitivity Inc. subsidiary of Millennium Pharmaceuticals. Dr. Muntendam received his M.D. from Leiden University in the Netherlands.

**Senior Vice President, Biomarker Discovery:** Like CEO Pieter Muntendam, Neal Gordon has a mix of pharmaceutical and diagnostic products experience. He came to BGMD in 2009 from Epitome Biosystems where he served as President with oversight for market introduction of a line of multiplexed protein immunoassays. Other professional experience includes tenure at biotech group Antigenics Inc. (now Agenus Inc.) as Senior Vice President of Manufacturing Operations and as a senior scientist with life science tools group PerSeptive Biosystems (now part of Life Technologies). Dr. Gordon received a degree in chemical engineering from McGill University and a Ph.D. in biochemical engineering from Massachusetts Institute of Technology.

**Chief Financial Officer:** Mike Rogers joined BG Medicine in July 2009 as Executive Vice President, Chief Financial Officer and Treasurer. He has significant experience serving as CFO of several publicly traded healthcare companies including specialty pharmaceutical group Indevus Pharmaceuticals, which was sold to Endo Pharmaceuticals in 2009, healthcare information technology company Advanced Health Corp. and biotech AutoImmune, Inc. He also worked as an investment banker with Lehman Brothers and PaineWebber. Rogers received an M.B.A. from the Darden School at the University of Virginia and a B.A. from Union College.

**Chief Commercial Officer:** Stephen Miller joined BGMD in June 2011 with responsibility for managing the company's commercial operations. His recent experience includes sales positions at miRNA diagnostics startup Mira Dx, Inc. and 17 years with Athena Diagnostics. He also worked at Wyeth-Ayerst Laboratories as a pharmaceutical sales representative. Mr. Miller graduated from Miami University of Ohio.

**Vice President, Clinical and Regulatory Affairs:** Carol Adiletto has 25 years of diagnostic industry experience including positions with Inverness Medical Innovations (Now Alere) as Vice President Clinical & Regulatory Affairs with responsibility for the Cardiac Marker Division and as Director of Clinical Affairs at Johnson & Johnson's LifeScan division.

**Vice President, Medical Affairs & Senior Medical Officer:** Peter Gardiner's previous experience includes serving as Medical Director, Global Medical Affairs & Senior Medical Officer for Bristol-Myers Squibb's medical imaging division. Dr. Gardiner has also held senior positions with DuPont's Medical Imaging business, Gensia, Inc. and GD Searle & Co. He is also a member of the Royal College of Physicians.



Table 17.

BG Medicine Income Statement																
(in \$ millions except per share)	2010A	1Q11A	2Q11A	3Q11A	4Q11E	2011E	1Q12E	2Q12E	3Q12E	4Q12E	2012E	2013E	2014E	2015E	2016E	2017E
Galectin-3 sales	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.2	\$0.2	\$4.3	\$15.5	\$31.1	\$44.8	\$54.2
AMIPredict	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.7	1.7	3.8	7.5	11.5
HRP	0.0	0.8	0.2	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
License revenues	0.8	0.9	0.2	0.2	0.2	1.4	0.2	0.2	0.2	0.2	0.6	0.6	0.6	0.6	0.6	0.6
Total Revenue	\$0.8	\$0.9	\$0.2	\$0.2	\$0.2	\$1.4	\$0.2	\$0.2	\$0.2	\$0.3	\$0.8	\$5.6	\$17.7	\$35.5	\$52.9	\$66.3
COGS	0.8	0.2	0.2	0.1	0.1	0.5	0.1	0.1	0.1	0.1	0.4	0.7	1.8	3.2	3.9	4.6
Gross profit	\$0.0	\$0.7	\$0.0	\$0.1	\$0.1	\$0.9	\$0.1	\$0.1	\$0.1	\$0.2	\$0.5	\$4.9	\$15.9	\$32.3	\$49.0	\$61.6
SG&A	8.1	2.0	2.5	3.1	3.0	10.6	3.1	3.1	3.2	4.0	13.3	17.5	18.7	19.9	21.1	22.5
Research & development	6.5	1.7	2.4	1.9	2.2	8.2	2.2	2.2	2.2	2.2	8.8	9.6	10.4	11.2	12.0	12.4
Operating profit (loss)	(\$14.6)	(\$3.0)	(\$4.8)	(\$4.9)	(\$5.1)	(\$17.9)	(\$5.2)	(\$5.2)	(\$5.3)	(\$6.0)	(\$21.7)	(\$22.2)	(\$13.2)	\$1.2	\$15.9	\$26.8
Interest income (expense)	(2.6)	(0.1)	0.0	0.0	0.0	(0.1)	0.0	0.0	0.0	0.0	0.1	0.1	0.1	(0.0)	0.0	0.2
Taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	(9.7)
Net profit (loss)	(17.2)	(3.1)	(4.8)	(4.9)	(5.1)	(17.9)	(5.2)	(5.2)	(5.3)	(5.9)	(21.6)	(22.1)	(13.1)	1.2	15.9	17.3
Earnings (loss) per share	(\$5.78)	(\$0.26)	(\$0.25)	(\$0.25)	(\$0.26)	(\$1.02)	(\$0.27)	(\$0.27)	(\$0.22)	(\$0.24)	(\$0.99)	(\$0.91)	(\$0.54)	\$0.05	\$0.65	\$0.71
One-time gain (loss)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Accretion of redeemable convertible preferred stock	(\$0.35)	(\$0.01)	\$0.00	\$0.00	\$0.00	(\$0.01)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Net income (loss) as reported	(18.2)	(3.2)	(4.8)	(4.9)	(5.1)	(18.1)	(5.2)	(5.2)	(5.3)	(5.9)	(21.6)	(22.1)	(13.1)	1.2	15.9	17.3
Profit (loss) per share as reported	(\$6.13)	(\$0.27)	(\$0.25)	(\$0.25)	(\$0.26)	(\$1.03)	(\$0.27)	(\$0.27)	(\$0.22)	(\$0.24)	(\$0.99)	(\$0.91)	(\$0.54)	\$0.05	\$0.65	\$0.71
Weighted average common shares	3.0	12.2	19.2	19.3	19.3	17.5	19.3	19.3	24.3	24.3	21.8	24.3	24.3	24.3	24.3	24.3

Source: Company reports and Ladenburg Thalmann estimates

Table 18.

BG Medicine Balance Sheet						
(in \$ millions)	2Q10A	3Q10A	4Q10A	1Q11A	2Q11A	3Q11A
<b>Assets</b>						
Cash and short term investment	\$4.1	\$2.9	\$2.4	\$35.8	\$32.0	\$28.0
Accounts receivable	0.4	0.2	0.8	0.4	0.1	0.1
Inventories	0.0	0.0	0.0	0.0	0.2	0.3
Other	0.3	0.2	0.4	0.7	0.9	0.8
<b>Total current assets</b>	<b>\$4.8</b>	<b>\$3.2</b>	<b>\$3.6</b>	<b>\$36.9</b>	<b>\$33.1</b>	<b>\$29.2</b>
Property & equipment	\$0.8	\$0.7	\$0.6	\$0.5	\$0.4	\$0.3
Intangible assets	0.6	0.6	0.5	0.5	0.5	0.5
Other assets	1.3	1.5	2.3	0.0	0.0	0.0
<b>Total assets</b>	<b>\$7.5</b>	<b>\$6.0</b>	<b>\$7.0</b>	<b>\$38.0</b>	<b>\$34.0</b>	<b>\$30.0</b>
<b>Liabilities</b>						
Accounts payable	\$1.3	\$0.8	\$1.4	\$1.2	\$0.8	\$0.9
Other accrued liabilities	2.0	2.4	2.8	2.0	2.8	3.0
Deferred revenue	0.8	0.8	1.5	1.4	1.5	1.4
Current portion of long-term debt	2.7	4.5	6.4	0.0	0.0	0.0
<b>Total current liabilities</b>	<b>\$6.8</b>	<b>\$8.5</b>	<b>\$12.1</b>	<b>\$4.6</b>	<b>\$5.1</b>	<b>\$5.3</b>
Other	\$0.5	\$0.5	\$0.2	\$0.0	\$0.0	\$0.0
<b>Total liabilities</b>	<b>\$7.4</b>	<b>\$9.0</b>	<b>\$12.3</b>	<b>\$4.7</b>	<b>\$5.1</b>	<b>\$5.3</b>
<b>Shareholder equity</b>						
Paid-in capital	\$88.0	\$89.4	\$90.4	\$132.2	\$132.6	\$133.3
Common stock	0.0	0.0	0.0	0.0	0.0	0.0
Accumulated other comprehensive income	(0.0)	0.0	0.0	0.0	0.0	0.0
Accumulated deficit	(87.9)	(92.4)	(95.7)	(98.9)	(103.7)	(108.6)
<b>Total shareholder equity</b>	<b>\$0.1</b>	<b>(\$3.0)</b>	<b>(\$5.3)</b>	<b>\$33.4</b>	<b>\$28.9</b>	<b>\$24.7</b>

Source: Company reports

## APPENDIX A: IMPORTANT RESEARCH DISCLOSURES

### ANALYST CERTIFICATION

I, Kevin DeGeeter, attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

The research analyst(s) primarily responsible for the preparation of this research report have received compensation based upon various factors, including the firm's total revenues, a portion of which is generated by investment banking activities.

### COMPANY BACKGROUND

BG Medicine commercializes diagnostic tests based on content discovered by its biomarker discovery research group. The Waltham, MA-based company's lead program, a test for the galectin-3 biomarker, is FDA-cleared for use in staging of heart failure patients. The pipeline includes tests for predicting heart attack risk and for predicting risk of lipid disorders. BG Medicine sells its tests through commercial partners and has no plans for a significant direct sales effort.

### VALUATION METHODOLOGY

We currently rate BGMD shares at BUY with a price target of \$8.25 based on 26x multiple on our fully taxed 2017 EPS estimate of \$0.71 discounted back at a 20% cost of capital.

### RISKS

We think the primary risks of an investment in BGMD shares include, but are not limited to: Intellectual Property. The company's business model is based on identifying and commercializing tests based on proprietary biomarkers. BGMD has several filed and issued patents pertaining to the role of galectin-3 in diagnosing and staging heart failure patients and methods for developing diagnostic kits and tests based on galectin-3. There can be no assurance changes to U.S. patent law or interpretation will not adversely impact the company's future revenues. Regulatory. Each of BGMD's IVD partners expects to submit a 510(k) application to FDA for automated versions of the galectin-3 test. There can be no assurance validation studies and subsequent registration studies will be adequate to support 510(k) clearance of galectin-3 as an automated prognostic test for heart failure. Additionally, the predictive value of galectin-3 in assessing risk of heart failure following acute coronary injury is an important source of potential future market expansion. There can be no assurance galectin-3 will win FDA clearance in this indication. Additionally, the company may seek to launch its AMIPredict multivariate test as a laboratory developed test (LDT) under CLIA regulations. There can be no assurance that AMIPredict will receive a CLIA waiver or that FDA will continue to exercise regulatory discretion over LDTs. Reimbursement. Galectin-3 is not currently covered by most private insurance payers, Medicare or state health plans in Europe. In the U.S., clinicians and their patient can seek reimbursement through submission under miscellaneous codes on an out-of-network basis. BGMD has received a unique CPT code for galectin-3 and hopes to have the new code included in the 2013 clinical laboratory fee schedule. There can be no assurance Medicare or private payers will reimburse for the test or that reimbursement levels will be adequate to meet the terms of license agreements with IVD manufacturers or for BGMD to earn a profit. Additionally, the timing of future reimbursement coverage from both private payers, state health plans in Europe and Medicare is not certain. Partnership. Abbott, Alere, bioMérieux, LabCorp and Siemens have licensed rights to sell galectin-3 tests both in the United States and certain ex-U.S. markets. There can be no assurance these partners can process the test in a commercially reasonable time period. Additionally, effective positioning of galectin-3 may require promotion to primary care doctors, which is outside of many of the partners' commercial focus and beyond the means of BGMD to address, in our view. There can be no assurance BGMD will identify an appropriate commercial partner to maximize the value of BGMD or that a partner will provide the required commitment of commercial resources. Financing. The company believes current financial resources will fund the company through 2012. However, successful commercial launch of automated galectin-3 tests will require significant marketing expense and development of AMIPredict may require substantial direct research funding from BGMD. There can be no assurance BGMD will have access to private capital in the future on adequate terms, or at all.

### STOCK RATING DEFINITIONS

Buy: The stock's return is expected to exceed 12.5% over the next twelve months.

Neutral: The stock's return is expected to be plus or minus 12.5% over the next twelve months.

Sell: The stock's return is expected to be negative 12.5% or more over the next twelve months.

Investment Ratings are determined by the ranges described above at the time of initiation of coverage, a change in risk, or a change in target price. At other times, the expected returns may fall outside of these ranges because of price movement and/or volatility. Such interim deviations from specified ranges will be permitted but will become subject to review.

### RATINGS DISPERSION AND BANKING RELATIONSHIPS (as of 11/30/11)

Buy	76%	(30% are banking clients)
Neutral	24%	(11% are banking clients)
Sell	0%	( 0% are banking clients)

**PERSONALIZED MEDICINE STOCKS UNDER AUTHOR ANALYST COVERAGE (“The Universe”)**

BG Medicine (BGMD), Exact Sciences (EXAS), Genetic Technologies (GENE), Genomic Health (GHDX), Myriad Genetics (MYGN), NeoGenomics (NGNM), Neoprobe (NEOP), OPKO Health (OPK), Response Genetics (RGDX), Sequenom (SQNM), SeraCare Life Sciences (SRLS) and Vermillion (VRML).

**COMPANY SPECIFIC DISCLOSURES**

With the exception of Neoprobe Corp. (NEOP) and Opko Health, Inc. (OPK), Ladenburg Thalmann & Co. Inc. makes a market in all of the stocks listed in the Universe. Ladenburg Thalmann & Co. Inc. acted as a co-manager in a securities offering for Opko Health, Inc. (OPK) and acted in an advisory capacity on a private securities transaction for Genetic Technologies, LTD. (GENE) in the last 12 months. Ladenburg Thalmann and Co. received compensation related to investment banking services from Opko Health, Inc. (OPK) and Genetic Technologies, LTD. (GENE) in the last 12 months. Ladenburg Thalmann & Co. Inc. expects to receive or intends to seek compensation for investment banking services during the next 3 months for all companies listed in the Universe. Neither the Analyst, nor members of the Analyst's household own any securities issued by any company in the Universe or other companies mentioned in this report. A member of the Board Of Directors of Sequenom Inc. has an affiliation with members of the Board of Directors of companies in which the Chairman of Ladenburg Thalmann Financial Services Inc, the parent company of Ladenburg Thalmann & Co. Inc. has a beneficial interest. Genomic Health Inc. (GHDX) and Teva Pharmaceuticals Industries (TEVA) have joint distribution interests. The Chairman of Ladenburg Thalmann Financial Services Inc. is also Chairman of Teva. The Chairman of the Board and Controlling shareholder of Ladenburg Thalmann Financial Services Inc., the parent company of Ladenburg Thalmann & Co. Inc. is the Chairman of the Board, CEO and Director and Controlling shareholder of Opko Health Inc. Members of the Board of Directors of OPK have a non-investment banking securities related relationship with Ladenburg Thalmann & Co. Inc.

**OTHER COMPANIES MENTIONED:** Abbott Labs (ABT, Not Rated, \$54.86), Agenesis Inc. (AGEN, Not Rated, \$2.27), Alere (ALR, Not Rated, \$22.78), AstraZeneca (AZN, Not Rated, \$45.51), Autolimmune Inc. (AIMM, Not Rated, \$0.01), Boston Scientific (BSX, Not Rated, \$5.15), Bristol-Myers Squibb (BMY, Not Rated, \$35.03), Cordex Pharma (CDXP, Not Rated, \$0.03), Corgenix Medical Group (CONX, Not Rated, \$0.14), Daiichi Sankyo (DSKYF, Not Rated, \$18.36), Du Pont El De Nemours (DD, Not Rated, \$45.01), Endo Pharmaceuticals (ENDO, Not Rated, \$34.78), Eisai (ESALY, Not Rated, \$40.07), General Electric (GE, Not Rated, \$17.28), GlaxoSmithKline (GSK, Not Rated, \$45.23), Humana (HUM, Not Rated, \$86.63), Johnson & Johnson (JNJ, Not Rated, \$64.52), LabCorp (LH, Not Rated, \$84.24), Lehman Brothers (LEHMQ, Not Rated, \$0.02), Legg Mason (LM, Not Rated, \$23.94), Life Technologies (LIFE, Not Rated, \$39.84), Merck (MRK, Not Rated, \$37.07), Mitsubishi (MTU, Not Rated, \$4.22), Pfizer (PFE, Not Rated, \$21.46), Pharming (PHGUF, Not Rated, \$0.09), Philips (PHG, Not Rated, \$20.15), Siemens (SI, Not Rated, \$95.01) and UCB (UCBJF, Not Rated, \$40.92).

**GENERAL DISCLAIMERS**

Information and opinions presented in this report have been obtained or derived from sources believed by Ladenburg Thalmann & Co. Inc. to be reliable. The opinions, estimates and projections contained in this report are those of Ladenburg Thalmann as of the date of this report and are subject to change without notice. Any reference to the subject Company's or other third party website is provided for informational purposes only. Ladenburg Thalmann & Co. Inc. does not endorse such websites and does not guarantee the accuracy of the content of those websites.

Ladenburg Thalmann & Co. Inc. accepts no liability for loss arising from the use of the material presented in this report, except that this exclusion of liability does not apply to the extent that such liability arises under specific statutes or regulations applicable to Ladenburg Thalmann & Co. Inc. This report is not to be relied upon in substitution for the exercise of independent judgment. Ladenburg Thalmann & Co. Inc. may have issued, and may in the future issue, other reports that are inconsistent with, and reach different conclusions from, the information presented in this report. Those reports reflect the different assumptions, views and analytical methods of the analysts who prepared them and Ladenburg Thalmann & Co. Inc. is under no obligation to ensure that such other reports are brought to the attention of any recipient of this report.

Some companies that Ladenburg Thalmann & Co. Inc. follows are emerging growth companies whose securities typically involve a higher degree of risk and more volatility than the securities of more established companies. The securities discussed in Ladenburg Thalmann & Co. Inc. research reports may not be suitable for some investors. Investors must make their own determination as to the appropriateness of an investment in any securities referred to herein, based on their specific investment objectives, financial status and risk tolerance.

The historical performance results represented in this report do not reflect the deduction of transaction and other charges, the incurrence of which would decrease the historical performance results listed. This information is provided for comparison purposes only. The S+P 500 is a market capitalization-weighted index of 500 widely based stocks often used as a proxy for the U.S. stock market. The historical performance results of the S+P 500 (and those of all other indices) do not reflect the deduction of transaction and other charges, the incurrence of which would decrease the historical performance results listed. The information is provided for comparison purposes only. In addition, comparisons to peers/indices have limitations and material characteristics that may differ from other indices. Indices may also contain securities or types of securities that are not comparable. Because of these differences, peers/indices should not be relied upon as an accurate measure of comparison.

The Personalized Medical Index (“PMI”) is an index which tracks a basket of diagnostic products and service companies. The index is comprised of the following nine companies: Celera Corporation (CRA), Clariant Inc. (CLRT), Genetic Technologies Limited (GENE),

Genomic Health Inc. (GHDX), Genoptics, Inc (GXDX), Myriad Genetics (MYGN), Nanosphere, Inc. (NSPH), Quiagen N.V. (QGEN) and Rosetta Genomics Limited (ROSG). Companies were selected for inclusion if they have at least one marketed product or diagnostic-related service used by clinicians to make personalized medicine decisions. The index tracks the weekly performance of the preceding stocks is updated weekly from Reuters data. The index represents only prices of the underlying stocks and not dividends paid. The Index's value is determined by taking the aggregate sum of the closing prices of the constituent stocks and dividing it by a common divisor. The divisor for the index is the aggregate value of the composite stocks on January 2, 2009, which gives the Index a base index value of 100 on January 2, 2009. The Index is an equal weight index. The index's constituents were determined as of February 26, 2010 and the index's value prior to that date was calculated based on those constituents historical share price performance. Reference to the time period prior to that date is for informational purposes only. As of June 28, 2011, three of the companies on the PMI have been acquired. These companies are Celera Corporation (CRA), Clariant Inc. (CLRT) and Genoptix, Inc (GXDX). We rebalance at the time of close for each acquisition. Investors cannot trade an index and the index is unmanaged and does not reflect the impact of fees. An investor's performance may differ substantially for the performance of an index. Any index is provided for informational purposes only and does not constitute an offer to sell or the solicitation of any offer to buy any securities mentioned herein. In considering the prior performance information contained herein, investors should bear in mind that past performance is no guarantee of future results and there can be no assurance that the companies represented in the Index will achieve comparable results. Comparisons to indices (including but not limited to the S&P 500) have limitations because indices have volatility and other material characteristics that may differ from a particular investment or strategy. Actual results may be materially lower than those estimated. At any point in time, Ladenburg Thalmann & Co. Inc. will make a market in some of the companies represented in the index and maintain research coverage and have investment banking relationship(s) as well with some of the companies represented. Additional information is available upon request. This information has been obtained or derived from sources believed to be reliable.

Investing in low priced securities is speculative and carries a high degree of risk. You should independently investigate and understand all risks before making any investment. The markets for small cap stocks are highly speculative and this level of risk may not be appropriate for all investors. Some of the companies listed may be subject to the "Penny Stock Rule". Under this rule, the SEC has defined a "penny stock" to be any equity security which has a market price of less than \$5.00 share, subject to certain exemptions. Such exemptions include an equity listed security listed on NASDAQ and an equity security issued by an issuer which has (i) net tangible assets of at least \$2,000,000, if such issuer has been in continuous operational for three (3) years; (ii) net tangible assets of at least \$5,000,000, if such issuer has been in continuous operation for less than three (3) years; or (iii) average revenue of at least \$6,000,000 for the preceding three (3) years. Unless such exemption is available, regulations require delivery of a risk disclosure document explaining the penny stock market and the risks associated therewith prior to any transaction involving a penny stock. For stock not quoted on NASDAQ or at any time that the company has less than \$2,000,000 in net tangible assets, the trading in the common stock is covered under Rule 15c-9 under the Securities Exchange Act of 1934 for non-NASDAQ and non-exchange listed securities. Under such rule, broker-dealers who recommend covered securities to persons other than established customers and accredited investors must make a written suitability determination for the purchaser and receive the purchaser's written agreement to a transaction prior to sale. Some securities may not be cleared for sale in all states or other jurisdictions and LTCO assumes no responsibility to apprise you of individual states or jurisdictions' regulatory restrictions. Stocks in the microcap segment of market have risks that are not as common in other segments of market. These risks include, but are not limited to, liquidity risk, which can lead to higher volatility and low trade volume, company specific risks that contribute to lower valuation, higher probability of financial default and distress.

Past performance should not be taken as an indication or guarantee of future performance, and no representation or warranty, express or implied, is made regarding future performance. The price, value of and income from any of the securities mentioned in this report can fall as well as rise. The value of securities is subject to exchange rate fluctuation that may have a positive or adverse effect on the price or income of such securities. Investors in securities such as ADRs, the values of which are influenced by currency volatility, effectively assume this risk. Securities recommended, offered or sold by Ladenburg Thalmann & Co. Inc. (1) are not insured by the Federal Deposit Insurance Company; (2) are not deposits or other obligations of any insured depository institution; and (3) are subject to investment risks, including the possible loss of some or all of principal invested. Indeed, in the case of some investments, the potential losses may exceed the amount of initial investment and, in such circumstances; you may be required to pay more money to support these losses.

The information and material presented in this report are provided to you for information purposes only and are not to be used or considered as an offer or the solicitation of an offer to sell or to buy any securities mentioned herein. This publication is confidential for the information of the addressee only and may not be reproduced in whole or in part, copies circulated, or disclosed to another party, without the prior written consent of Ladenburg Thalmann & Co. Inc.

Member: NYSE, NYSE Amex, FINRA all other principal exchanges, and SIPC

*Additional Information Available Upon Request*

© 2011 - Ladenburg Thalmann & Co. Inc. All Rights Reserved.