BG MEDICINE, INC.

FORM 10-K
(Annual Report)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2015 or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File Number: 001-33827

BG MEDICINE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**04-3506204**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
303 Wyman Street, Suite 300 Waltham, Massachusetts	**02451**
(Address of principal executive offices)	(Zip Code)

(781) 890-1199
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Exchange Act: None

Securities registered pursuant to Section 12(g) of the Exchange Act: Common Stock, $0.001 par value per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☐
Non-accelerated filer ☐ [Do not check if a smaller reporting company] Smaller reporting company ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold as of June 30, 2015 was approximately $15,578,339.

As of March 15, 2016, the registrant had 11,319,475 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the Registrant's Definitive Proxy Statement for the 2016 Annual Meeting of Stockholders.

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PART I

Item 1. BUSINESS

Unless otherwise indicated herein, the terms "we", "our", "us", or "the Company" refer to BG Medicine, Inc. and its subsidiary.

We are commercializing diagnostic products that may be used to help guide the care and management of patients who suffer from heart failure and related disorders.

Our BGM Galectin-3 ® Test is our first U.S. Food and Drug Administration, or FDA, cleared and CE Marked diagnostic product. The BGM Galectin-3 ® Test is an *in vitro* diagnostic device that employs a manual micro-titer platform to quantitatively measure galectin-3 levels in blood plasma or serum for use as an aid in assessing the prognosis of chronic heart failure in conjunction with clinical evaluation. The BGM Galectin-3 ® Test is currently available as a blood test in the United States and the European Union, or EU.

We have entered into licensing agreements with leading diagnostic instrument manufacturers to develop and commercialize galectin-3 assays to be performed on automated platforms that have been incorporated into routine practice in laboratories throughout the world. On December 23, 2014, the FDA granted 510(k) clearance for Abbott Laboratories' (Abbott) ARCHITECT ® Galectin-3 assay, the first FDA cleared automated blood test for Galectin-3. In July 2015, we announced that the ARCHITECT ® Galectin-3 assay is available in the United States. This is the first automated test for galectin-3 to be introduced for commercial use in the United States. The ARCHITECT ® Galectin-3 assay is performed using the Abbott ARCHITECT ® automated immunoassay analyzer and is being commercialized through an agreement between us and Abbott.

We have evolved from a research and development company to a commercial diagnostics company. Our initial transition to a commercial organization began with the FDA 510(k) clearance of our first diagnostic product, the BGM Galectin-3 Test, in November 2010. The first stage of transition was substantially completed in the first half of 2013 with the elimination of research and development activities no longer core to our commercial strategy. The second stage of transition was initiated in anticipation of the U.S. introduction of automated testing for galectin-3 and the commencement of commercialization activities by our automated partners. In order to reduce operating expenses and extend our cash runway in anticipation of the commercial launch of automated testing for galectin-3, we implemented a reduction in our workforce on September 11, 2014. In so doing, we primarily eliminated our sales and marketing organizations and removed certain positions in other function areas, while preserving some senior management and other critical roles to support the clinical and commercial adoption of galectin-3 testing by providing support to the marketing and selling efforts of our automated partners. We expect that the majority of revenues currently generated from the sale of our BGM Galectin-3 Test kits will be diminished over time and we expect that any future revenues will be primarily derived from product fees that are generated from the sale of automated tests by Abbott (and our other automated partners when and if their automated tests become available). We also expect that our revenue going forward will depend on the extent to which Abbott (and our other automated partners when and if their automated tests become available) is successful in gaining clinical adoption of their automated test for galectin-3.

Given the significant cost and resource demands of being a public company, we have determined that it is advisable to terminate the registration of our common stock under the Securities Exchange Act of 1934, as amended, or the Exchange Act. We anticipate filing a Form 15 with the Securities and Exchange Commission, or SEC, to effect the deregistration in April 2016. After careful consideration, the Board of Directors decided to deregister based on its belief that the savings we will achieve as a result of deregistration, particularly on costs related to the preparation and filing of SEC reports and compliance with Sarbanes-Oxley obligations, will benefit stockholders, and such benefits will outweigh any advantages of continuing as an SEC reporting company. Upon the filing of the Form 15, our obligation to file periodic and current reports with the SEC, including Forms 10-K, 10-Q, and 8-K, will be suspended.

Recent Developments

On July 8, 2015, we effected a 1-for-4 reverse stock split of our common stock. All previously reported common stock share amounts in the accompanying financial statements and related notes have been retroactively adjusted

to reflect the reverse stock split and unless otherwise indicated in this report, all share and per share figures in this report have been adjusted to reflect the reverse stock split.

Since September 11, 2014, we have implemented a reduction of approximately 77% of our workforce, or 17 people, which we refer to as the Restructuring, leaving five employees. We took this step in order to reduce our operating expenses and extend our cash runway in anticipation of the commercial launch of automated versions of our galectin-3 test. The automated galectin-3 tests are being developed and commercialized by our diagnostic instrument manufacturing partners and will be performed on the partners' automated platforms. The Restructuring primarily eliminated our sales and marketing organization and removed certain positions in other functional areas, while preserving some senior management and other critical roles to support the clinical and commercial adoption of galectin-3 testing by providing support to the marketing and selling efforts of our automated partners.

On July 14, 2015, we issued and sold 1,176,262 shares of our newly designated Series A Preferred Stock, $0.001 par value per share, or our Series A Preferred Stock, in a private placement to our principal stockholders at a purchase price of $1.7003 per share for aggregate gross cash proceeds of approximately $2.0 million. In addition, the $500,000 in aggregate principal amount of our senior secured convertible promissory notes, plus accrued but unpaid interest, that we previously issued to our principal stockholders on May 12, 2015 converted into 298,181 shares of Series A Preferred Stock. As of December 31, 2015, we had issued an aggregate of 1,474,443 shares of Series A Preferred Stock.

In June 2015, we entered into a sublease agreement with a third party for the office space we lease located at 880 Winter Street, Waltham, Massachusetts. The term of the sublease is from June 1, 2015 through December 31, 2018 covering the balance of the underlying lease term. We have obtained office space on a short term rental basis and expect to generate annualized savings of approximately $240,000. On February 10, 2012, we entered into a secured term loan facility, and a term loan in the aggregate principal amount of $10.0 million was funded upon the closing of the transaction. On July 14, 2015, we paid off all of our outstanding obligations under the term loan. The security interest granted by us to the lenders in our assets in connection with the loan facility was also terminated at the time of the payoff.

In August 2015, we closed on an underwritten public offering of (i) 2,315,654 Series A units, each consisting of one share of common stock and one half of a warrant to purchase one share of common stock, at a purchase price of $1.00 per Series A unit, and (ii) 184,346 Series B units, in lieu of Series A units, at a purchase price of $1.00 per Series B unit to those purchasers whose purchase of additional Series A units in the offering would result in the purchaser beneficially owning more than 9.99% of the Company's outstanding common stock following the completion of the offering. Each Series B unit consists of one fully pre-funded warrant to purchase one share of common stock and one half of a warrant to purchase one share of common stock. The $1.00 exercise price per share of the pre-funded warrant was paid to the Company on the closing date and, consequently, no additional consideration shall be required to be paid by the holder to effect any exercise of the pre-funded warrant. The warrants (other than the fully pre-funded warrants) will have an exercise price of $1.00 per share. The net offering proceeds received by the Company, after deducting discounts and commissions and expenses incurred with the offering were approximately $2.0 million.

Our common stock was listed on The NASDAQ Capital Market until September 15, 2015, when it was suspended for failure to comply with The NASDAQ Capital Market continued listing standards. On September 16, 2015, our common stock began trading on the OTC Markets' OTCQB market tier under the trading symbol "BGMD."

On December 23, 2014, the FDA granted 510(k) clearance for Abbott Laboratories' (Abbott) ARCHITECT ® Galectin-3 assay for use in conjunction with clinical evaluation as an aid in assessing the prognosis of patients diagnosed with chronic heart failure. The ARCHITECT ® Galectin-3 assay is the first FDA cleared automated blood test for galectin-3 and, as such, is the first automated test for galectin-3 to be introduced for clinical use in the U.S. The clearance was obtained based on a 510(k) submission made to the FDA in February 2014, on behalf of Abbott, by Fujirebio Diagnostics, Incorporated, or Fujirebio. On May 8, 2015, in anticipation of the U.S. market launch of the ARCHITECT ® Galectin-3 assay we amended our license and development agreement with Abbott due to market dynamic considerations since the Galectin-3 assay first began development in 2009. On

July 6, 2015, we announced that the ARCHITECT ® Galectin-3 assay is available for purchase from Abbott in the United States. On November 24, 2015, we further amended our license and distribution agreement with Abbott, in regard to product fees paid to us by Abbott for galectin-3 tests sold by Abbott to reference laboratories, while retaining the previously negotiated product fees for the other customer segments. In consideration for the amendment, Abbott agreed to make an initial payment of $500,000 to us on November 30, 2015 and a second payment of up to $500,000 payable to us, by June 30, 2016, subject to achievement of certain commercial milestones. We expect that this modification to the agreement will expedite the transition from manual to automated testing for galectin-3. We expect that the majority of revenues currently generated from the sale of our BGM Galectin-3 Test kits will be diminished over time and we expect that any future revenues will be primarily derived from product fees that are generated from the sale of automated tests by Abbott (and our other automated partners when and if their automated tests become available). We also expect that our revenue going forward will depend on the extent to which Abbott (and our other automated partners when and if their automated tests become available) is successful in gaining clinical adoption of their automated test for galectin-3.

On March 31, 2015, we filed for premarket 510(k) notification with the FDA in order to obtain regulatory clearance to market our BGM Galectin-3 Test in the United States for a new indication for use, as an aid in the assessment of near-term risk of fatal cardiovascular events in older adults who have no prior history of coronary heart disease, cerebrovascular disease, or vascular disease. In August 2015, we received a request for additional information from the FDA, including information regarding the intended use of our test for this new indication, our clinical validation study and additional statistical analyses. We submitted our response to the FDA in November 2015. On December 17, 2015, we conducted a follow up discussion with the FDA regarding our November 2015 response. On December 18, 2015, following that additional dialogue with the FDA, we concluded that demonstrating the clinical utility of our test for this proposed new indication would require a broadening of the defined indication to include aiding in the assessment of the near-term risk of both fatal and non-fatal cardiovascular events in our study population and, as a result, a new 510(k) submission. Accordingly, we submitted to the FDA a notice of withdrawal of the 510(k) notification that we submitted on March 31, 2015. We are evaluating what additional data, studies and analyses would be required to support a new submission and a broader indication for use.

We believe that our existing cash will be sufficient to fund our operations into July 2016. To date, our primary sources of liquidity have included our cash balances, sales of our equity securities, our term loan, product revenue from sales of our BGM Galectin-3 Test, and service revenue from the HRP initiative. Until we generate significant revenues from product sales and/or product fees generated by sales of automated tests made by our automated partners to reach cash breakeven, we will need to raise additional funds to finance our operations beyond July 2016. We may not be able to obtain adequate financing to do so when necessary, and the terms of any financing, if any, may not be advantageous to us and any financings may result in dilution to our stockholders. As of December 31, 2015, we had $1.5 million of cash and working capital of $771,000. As of March 25, 2016, we had cash totaling $1.0 million.

Our BGM Galectin-3 Test

Our BGM Galectin-3 Test is our first FDA cleared and CE Marked diagnostic product. It is an *in vitro* diagnostic device that quantitatively measures galectin-3 in serum or plasma by enzyme linked immunosorbent assay (ELISA) on a microtiter plate platform. Heart failure patients with elevated galectin-3 levels as measured using our BGM Galectin-3 Test have been found to be at significantly greater risk of adverse outcomes, including death or hospitalization. Measurement of this protein biomarker is intended to be used in conjunction with clinical evaluation.

Galectins are a family of proteins that appear to play important roles in inflammation, immunity and cancer. Galectin-3, a member of this family of proteins, appears to be a key protein mediator of fibrosis, scarring and tissue repair and has been implicated in fibrosis in the heart, human atherosclerotic lesions, liver, kidney and lung. Elevated galectin-3 levels have been associated with adverse outcomes in heart failure, cardiovascular disease, chronic renal disease, pulmonary disease, liver disease and cancer.

In animal experiments, administration of galectin-3 to the heart led to the development of cardiac fibrosis, or stiffening, in the heart muscle, a process that is often referred to as cardiac remodeling. In these animal studies, adverse remodeling reduced the heart's ability to pump normally, causing the animals to develop heart failure. This link between galectin-3 and cardiac remodeling is significant and suggests that galectin-3 may be a useful biomarker for adverse cardiac remodeling, an important determinant of the clinical outcome of patients suffering from heart failure.

We have obtained an exclusive worldwide license to certain galectin-3 rights that relate to the association of this protein biomarker with heart failure. We have also filed several of our own patent applications related to galectin-3.

Our BGM Galectin-3 Test is currently available as a blood test in the United States and the EU. The following table summarizes the current indications for use and commercial status of our BGM Galectin-3 Test:

Test / Disease Area	Indications	Regulatory and Commercial Status
BGM Galectin-3 Test	An aid in assessing the prognosis of chronic heart failure	- Marketed in the U.S. and Europe - FDA 510(k) cleared November 2010 - CE Mark obtained October 2009
	An aid in assessing the prognosis of acute heart failure	- Marketed in Europe - CE Mark obtained October 2009
	An aid to identify adults at elevated risk of developing heart failure	- Marketed in Europe - CE Mark obtained May 2012

Automated Testing For Galectin-3

Overview

We believe that automation of our galectin-3 test will broaden its acceptance by laboratory customers and, as a result, accelerate its clinical adoption. To that end, we have entered into licensing and commercialization agreements with four leading diagnostic instrument manufacturers to develop and commercialize automated instrument versions of our galectin-3 test. We have entered into worldwide license, development and commercialization agreements with Abbott Laboratories, or Abbott, bioMérieux SA, or bioMérieux, Siemens Healthcare Diagnostics Inc., or Siemens, and Alere Inc., or Alere. These diagnostic instrument manufacturers account for a significant percentage of the automated laboratory testing instruments that are used throughout the world. The installed customer base of these automated partners reflects all major segments of the diagnostics market, including hospital laboratories, national reference laboratories, regional laboratories and others.

Progress to Date

On December 23, 2014, the FDA granted 510(k) clearance for Abbott's ARCHITECT ® Galectin-3 assay for use in conjunction with clinical evaluation as an aid in assessing the prognosis of patients diagnosed with chronic heart failure. The ARCHITECT ® Galectin-3 assay is the first FDA cleared automated blood test for galectin-3 and, as such, is the first automated test for galectin-3 to be introduced for clinical use in the U.S. The clearance was obtained based on a 510(k) submission made to the FDA in February 2014, on behalf of Abbott, by Fujirebio Diagnostics, Incorporated, or Fujirebio. On May 8, 2015, in anticipation of the U.S. market launch of the ARCHITECT ® Galectin-3 assay, we amended our license and development agreement with Abbott due to market

dynamic considerations since the Galectin-3 assay first began development in 2009. On July 6, 2015, we announced that the ARCHITECT ® Galectin-3 assay is available for purchase from Abbott in the United States. On November 24, 2015, we amended our license and distribution agreement with Abbott, in regard to product fees paid to us by Abbott for galectin-3 tests sold by Abbott to reference laboratories, while retaining the previously negotiated product fees for the other customer segments. In consideration for the amendment, Abbott agreed to make an initial payment of $500,000 to us on November 30, 2015 and a second payment of up to $500,000 payable to us, by June 30, 2016, subject to achievement of certain commercial milestones. We expect that this modification to the agreement will expedite the transition from manual to automated testing for galectin-3. As a result, the majority of revenues currently generated from sales of manual test kits are expected to be diminished over time and we expect that any future revenues will be primarily derived from product fees that are generated from the sale of automated tests by Abbott (and our other automated partners when and if their automated tests become available). We expect that our revenue going forward will depend on the extent to which Abbott (and our other automated partners when and if their automated tests become available) is successful in gaining clinical adoption of their automated test for galectin-3.

In January 2013, bioMérieux obtained a CE Mark for its VIDAS ® Galectin-3 assay and initiated its commercial launch in the EU. The VIDAS ® Galectin-3 assay was developed by bioMérieux for the quantitative measurement of galectin-3 levels in blood using the bioMérieux VIDAS ® automated and multiparametric immunoassay testing system. In April 2013, Abbott obtained a CE mark for its ARCHITECT ® Galectin-3 assay and initiated its commercial launch in the EU.

Recognition of Galectin-3 Testing in U.S. Guideline for the Management of Heart Failure

In June 2013, galectin-3 testing was recognized for the first time in the 2013 American College of Cardiology Foundation and the American Heart Association Guideline for the Management of Heart Failure. The ACCF/AHA Guideline is designed to assist clinicians in selecting the best management strategy for individual patients and provides expert analysis of data on prevention, diagnosis, risk stratification, and treatment. Galectin-3 testing has been assigned a Level of Evidence of ‘A’, multiple populations evaluated, and a Class of Recommendation corresponding to ‘May Be Considered’ for the purpose of additive risk stratification of acute heart failure patients, and a Level of Evidence of ‘B’, limited populations evaluated, and a Class of Recommendation of ‘May Be Considered’ for risk stratification of ambulatory heart failure patients. The guideline further notes that testing for galectin-3 is predictive of risk of adverse outcomes in heart failure, including hospitalization, and is additive to BNP and NT-proBNP testing for heart failure patient risk stratification. Writing committees are charged with regularly reviewing and evaluating all available evidence to develop balanced, patient-centric recommendations for clinical practice. The guidelines for heart failure management were last revised in 2009.

Reimbursement for Galectin-3 Testing

Approximately 70% of heart failure patients in the United States are of Medicare age. Therefore, reimbursement by Medicare is important to our laboratory customers. In the United States, for the 2014 calendar year, the Centers for Medicare and Medicaid Services, or CMS, published a 2014 Medicare national limitation amount for the galectin-3 blood test (analyte-specific CPT ® Code 82777) at the amount of a crosswalked test (analyte-specific CPT ® Code 84244) whose 2014 national limitation amount was $30.01. This national limitation replaced the galectin-3 blood test’s national limitation amount of $17.80 that was effective in 2013. In 2015, the national limitation amount for the galectin-3 blood test was reduced to $29.93 and applied across the U.S., except in Ohio and West Virginia where rates of $23.93 and $26.33, respectively, applied. In 2016, the national limitation amount for the galectin-3 blood test was increased to $29.96 and applies across the U.S., except in Ohio and West Virginia where rates were increased to $23.95 and $26.36, respectively. In Europe, reimbursement is covered under the hospital budgeting process and typically applies to testing performed during emergency room visits and on hospital in-patients.

Market Opportunity for Galectin-3 Testing in Heart Failure

Heart Failure

Heart failure is a condition caused by a combination of diseases or factors that damage or overwork the heart muscle, thereby limiting its ability to efficiently pump blood. Heart failure may lead to serious complications and is a leading cause of death. The most common cause of heart failure is coronary artery disease, including heart attack and unstable angina. Heart failure is associated with other predisposing factors, such as high blood pressure, diabetes and defects of the heart valves or heart muscle. Patients with heart failure typically exhibit non-specific signs and symptoms such as swollen legs or ankles and shortness of breath or weight gain. Heart failure may lead to declining function and, even, failure of other body organs, such as the kidney, lungs, and liver. Although the condition is usually progressive, the rate of progression varies markedly from no noticeable deterioration over multiple years to rapid progression and death in just weeks or months.

Heart Failure in the United States – According to the American Heart Association, over 5 million Americans currently suffer from heart failure and by 2030, the number of Americans suffering from heart failure is expected to increase to over 8 million. The Heart Failure Society of America estimates that between 400,000 and 700,000 new cases of heart failure are diagnosed each year in the United States. According to the Centers for Disease Control, nearly 309,000 Americans died from heart failure related causes in 2014, a significant increase from about 290,000 in 2000. The American Heart Association estimates that annual direct and indirect costs associated with heart failure in the United States are approximately $32 billion.

Once diagnosed, the overall mortality, or rate of death, associated with heart failure is high, with an estimated 20% dying within the first year of diagnosis and an estimated 50% dying within the first five years of diagnosis. In the United States, treatment of heart failure patients is associated with a high rate of hospitalization and ambulatory care visits, with an estimated 1.3 million hospitalizations and an estimated 1.8 million physician office visits per year for patients with a primary diagnosis of heart failure. Unplanned re-hospitalization of heart failure patients is known to have a significant impact on the utilization of health care resources. A recent review of Medicare claims data for re-hospitalization showed that patients with a discharge diagnosis of heart failure had a 30-day re-hospitalization rate of approximately 25%. Heart failure is the number one cause of early re-hospitalization among Medicare patients in the United States.

Heart Failure in Europe – The European Society of Cardiology estimates that among the 51 countries it represents, there are at least 15 million individuals diagnosed with heart failure. Survival is poor, with reported 5-year survival rates of 35% in the Netherlands and 41% in Sweden. A study in the UK reported a 10-year survival rate of 27%.

Clinical Utility and Benefits of Galectin-3 Testing for Patients with Heart Failure

Approximately 30% to 50% of heart failure patients are found to have elevated blood plasma or serum levels of galectin-3. Clinical studies have demonstrated that patients with elevated levels of galectin-3 experience a significantly higher rate of adverse outcomes, including mortality, or hospitalization. We believe that the measurement of the protein biomarker galectin-3 in patients with heart failure may facilitate decisions that are made regarding the intensity, locale, and nature of a heart failure patient's ongoing care.

Our Commercial Strategy

We believe that the introduction of automated testing for galectin-3 will increase the adoption of galectin-3 testing. We believe that laboratory adoption of automated testing for galectin-3 will improve access to testing, shorten turn-around-time for receipt of test results, minimize objections related to the more labor intensive manual micro-titer plate testing method and, accelerate clinical adoption of galectin-3 testing. As a result, since its United States market introduction in July of 2015, we have focused on supporting the commercialization of automated testing for galectin-3.

In order to reduce operating expenses and extend our cash runway in anticipation of the commercial launch of automated testing for galectin-3, we implemented a reduction in our workforce on September 11, 2014. In so doing, we primarily eliminated our sales and marketing organizations and removed certain positions in other functional areas, while preserving some senior management and other critical roles to support the clinical and commercial adoption of automated galectin-3 testing.

Our Product Pipeline

New Clinical Claims and Indications for the BGM Galectin-3 Test

On March 31, 2015, we filed for premarket 510(k) notification with the FDA in order to obtain regulatory clearance to market our BGM Galectin-3 Test in the United States for a new indication for use, as an aid in the assessment of near-term risk of fatal cardiovascular events in older adults who have no prior history of coronary heart disease, cerebrovascular disease, or vascular disease. In August 2015, we received a request for additional information from the FDA, including information regarding the intended use of our test for this new indication, our clinical validation study and additional statistical analyses. We submitted our response to the FDA in November 2015. On December 17, 2015, we conducted a follow up discussion with the FDA regarding our November 2015 response. On December 18, 2015, following that additional dialogue with the FDA, we concluded that demonstrating the clinical utility of our test for this proposed new indication would require a broadening of the defined indication to include aiding in the assessment of the near-term risk of both fatal and non-fatal cardiovascular events in our study population and, as a result, a new 510(k) submission. Accordingly, we submitted to the FDA a notice of withdrawal of the 510(k) notification that we submitted on March 31, 2015. We are evaluating what additional data, studies and analyses would be required to support a new submission and a broader indication for use. Subject to obtaining substantial additional financing, we expect to pursue new clinical claims and indications for the BGM Galectin-3 Test in assessing heart failure, as well as, in related disorders. Expansion of the product label to include new clinical claims and indications for use will require additional clinical studies and clearance, or approval, by regulatory bodies, such as the FDA, and inclusion in our CE Mark for use in the EU. Our ability to engage in these activities would require us to obtain substantial additional financing.

CardioSCORE ™ Test

Our CardioSCORE test is a multi-analyte biomarker-based blood test that was designed as an aid in the assessment of near-term risk for significant atherothrombotic cardiovascular events, such as heart attack and ischemic stroke. In December 2012, we obtained a CE Mark for the CardioSCORE test, which will enable us to market the test in Europe and other countries that recognize CE Mark. In December 2011, we filed for premarket 510(k) notification with the FDA in order to obtain regulatory clearance to market the CardioSCORE test in the United States. In response to this submission, the FDA requested that we engage an independent committee of physicians to conduct a medical review and adjudication of clinical endpoints reported in the submission. Due to the time involved in responding to this request, we withdrew the 510(k) on August 8, 2012. Our medical review also included the assessment of sample stability and the evaluation of other technical issues raised by the FDA. The adjudication process was completed in 2013 and yielded results that are broadly in line with what would be expected in a U.S.-based epidemiological cohort of this composition.

In light of our efforts to reduce our operating expenses and to extend our cash runway, we have redirected our limited resources to provide support to the commercialization of galectin-3 testing by our automated partners and are not actively engaged in development or commercialization activities related to CardioSCORE.

BioImage Study Patient Cohort and Banked Specimens

We have exclusive rights to diagnostic inventions arising from our analysis of a proprietary observational and community-based cohort of over 6,800 individuals who have been followed since 2009. Baseline blood serum, plasma, DNA, and RNA samples collected from all participants have been stored and are available for our analysis. In addition, insurance claims data, including information regarding diagnoses, procedures, and therapies

related to over 1,200 non-fatal cardiovascular events that were experienced by participants in the cohort over the more than four years since follow-up was initiated is available to us for data mining. We believe that this asset may provide us with a unique and proprietary platform from which we may validate and develop new diagnostic products.

Clinical Laboratory Supply Agreements for Sale of Our BGM Galectin-3 Test Kits

Sales of our BGM Galectin-3 Test kits are typically accomplished through written supply and pricing agreements under which we agree to supply BGM Galectin-3 Test kits, at a specified price, to specialty, national reference, regional reference, hospital and research laboratories with the expectation that the contracting laboratory will offer galectin-3 testing services to their customers as part of their standard testing menu. These include long term agreements that we have entered into with Health Diagnostic Laboratory, Inc., a United States based specialty laboratory, and Laboratory Corporation of America, a United States based national reference laboratory:

True Health Diagnostics (formerly Health Diagnostic Laboratory, Inc.)

In March 2011, we entered into a supply agreement with Health Diagnostic Laboratory, Inc., or HDL, pursuant to which HDL agreed to purchase BGM Galectin-3 Test kits from us and to offer galectin-3 testing services to physicians in the United States. On June 7, 2015, HDL, the largest customer of our BGM Galectin-3 ® Test (manual micro-titer platform) with sales that represented approximately 83% and 75% of our product revenues for the fiscal year ended December 31, 2014 and December 31, 2013, respectively, filed a voluntary petition for bankruptcy protection under Chapter 11 in the United States Bankruptcy Court for the Eastern District of Virginia, Richmond Division. With court approval, HDL continued to operate its business, to purchase tests kits from us in the ordinary course and agreed to accelerated payment terms and a limitation on amounts owed to us on such new orders. Shipments of galectin-3 test kits to HDL resumed on June 15, 2015 at volumes that were initially comparable to those that had been shipped immediately prior to the June 7, 2015 bankruptcy filing, but, subsequently declined beginning in the third quarter of 2015. In accordance with the post-bankruptcy accelerated payment terms, we received timely payment from HDL for kit shipments that we made to them after June 15, 2015. On September 11, 2015, True Health Diagnostics announced the acquisition of HDL, in a court-supervised auction, pursuant to a court approved plan of liquidation or reorganization. True Health Diagnostics declined to assume our supply agreement with HDL, which expired in March of 2016, but has continued to purchase BGM Galectin-3 Test kits from us and to offer galectin-3 testing services to physicians in the United States. On February 11, 2016, HDL filed its Amended Disclosure Statement, seeking solicitation in favor of its Second Amended Plan of Liquidation, or the Plan. The court approved Disclosure Statement summarized HDL's proposed Plan, which provides that all allowed administrative expense claims will be paid in full and that all allowed general unsecured claims will be paid their pro rata portion of funds in a liquidating trust. A hearing to consider confirmation of the Plan was held on March 29, 2016. To the extent the Plan is confirmed and our administrative expense claim is allowed, we will receive a full distribution on account of such claim from HDL in the amount of $83,356.52, however, it is uncertain when HDL will make such distribution. Further, to the extent the Plan is confirmed, it is, as yet, uncertain what distribution, if any, will be made to us on account of our general unsecured claim we asserted in the amount of $171,641.08, with respect to the accounts receivable balance and to offset our provision for doubtful accounts of $151,000 on account of allowed claims related to the sale of BGM Galectin-3 Test kits to HDL prior to their filing for bankruptcy protection under Chapter 11. HDL, now True Health Diagnostics, accounted for 71% of our product revenues for the fiscal year ended December 31, 2015.

Laboratory Corporation of America

In May 2010, we entered into a license and supply agreement with Laboratory Corporation of America, or LabCorp, pursuant to which LabCorp agreed to make our BGM Galectin-3 Test available to physicians in the United States. Under the terms of the agreement, we granted LabCorp and its affiliates a semi-exclusive worldwide license under our patent rights related to galectin-3 to market, offer for sale and otherwise commercialize galectin-3 testing services using our BGM Galectin-3 Test. The license was semi-exclusive in the United States through the third year following the commercial launch of the BGM Galectin-3 Test. The current license and supply agreement expired on May 10, 2015. We have provided LabCorp with updated pricing for 2016 but we do not expect to derive significant additional revenue, if any, from sales to LabCorp.

Development and Commercialization Agreements to Automate Galectin-3 Testing

Abbott, Alere, bioMérieux and Siemens

In November 2009, we entered into a strategic collaboration with Abbott Laboratories, to develop and commercialize galectin-3 assay kits and related control kits and calibrators, or Galectin-3 Products, for purposes of this agreement, utilizing our galectin-3 technology and patent rights, for use on Abbott's Architect ® Immunochemistry Diagnostics Platform, or the Abbott Architect, and other Abbott diagnostic instruments. In March 2010, we entered into a second strategic collaboration agreement with Alere to develop an automated version of our galectin-3 test for use on Alere's Triage ® line of instruments. In May 2010, we entered into a third strategic collaboration agreement with bioMérieux to develop an automated version of our galectin-3 test for use on bioMérieux's VIDAS ® automated testing platform. In December 2010, we entered into a fourth strategic collaboration agreement with Siemens to develop an automated version of our galectin-3 test on Siemens's systems. We refer to Abbott, Alere, bioMérieux and Siemens as our automated partners.

As part of these collaborations, we entered into a non-exclusive license and distribution agreement with each automated partner, which we refer to as our automated partner agreements, pursuant to which we provided each automated partner and its affiliates with a non-exclusive, worldwide license under our patent rights related to galectin-3 to commercialize Galectin-3 Products for use on each automated partner's respective automated instrument platform.

Under the automated partner agreements, each automated partner is prohibited from sublicensing its rights to commercialize our Galectin-3 Products and, except for the Galectin-3 Products described above, is prohibited from developing galectin-3 assays covered by our patent rights. We have the right to enter into a total of five licenses of our patent rights related to galectin-3 for the commercialization of Galectin-3 Products through the expiration of the five-year period following the date on which Abbott made its first commercial sale of Galectin-3 Products, which occurred in April 2013, and we may enter into unlimited additional licenses thereafter. Under these agreements, our automated partners are responsible for developing and commercializing the tests and we are responsible for furthering clinical awareness and developing the market for galectin-3 testing. Also under these agreements, each automated partner will pay us a product access fee and a marketing service fee for each Galectin-3 Product it sells.

Upon commercial introduction of the automated tests by our partners, royalties on sales of their automated galectin-3 tests will be due to us. The agreements contain provisions that, under certain circumstances, entitle our partners to reduce the royalty amounts payable to us on the sales of their tests in amounts that are subject to negotiation by us and our respective partners. In some cases, our partners' rights to reduce the royalty amounts are triggered by the CMS payment rate described above under "- Reimbursement for Galectin-3 Testing" or the average selling prices in other regions that are below certain agreed-upon thresholds. The CMS national payment limit for galectin-3 testing for the 2016 calendar year is currently below the agreed-upon CMS payment rate thresholds in certain of these agreements. Accordingly, a new royalty amount could be negotiated with the partners.

Each automated partner is required to use its commercially reasonable efforts to promote, market, sell and distribute the Galectin-3 Products worldwide. We are required to use our commercially reasonable efforts to pursue certain clinical development objectives, perform certain marketing services in the United States and certain foreign countries, and develop and implement a reimbursement strategy for galectin-3 assays in those countries.

Unless terminated earlier, each automated partner agreement will expire on the expiration date of the last-to-expire patent in our patent rights related to galectin-3. In the case of each automated partner agreement, we or our automated partner may terminate the agreement upon 60 days written notice of a material breach of the agreement that is not cured within such 60 days, and, in the case of each automated partner agreement, each automated partner may terminate its agreement with us upon 30-days written notice upon the occurrence of certain events, including if the Galectin-3 Products fail to meet certain product claims, performance requirements or manufacturing requirements, the automated partners become aware of possible third-party patent infringement of our patent rights relating to galectin-3, the Galectin-3 Products negatively impact other assay or system

performance parameters that cannot be resolved, the predicate device does not receive regulatory approval in the United States or galectin-3 is either not accepted by, or a new marker showing superior clinical utility is adopted by, the physician community.

In January 2013, bioMérieux obtained a CE Mark for its VIDAS ® Galectin-3 assay and initiated its commercial launch in the EU. The VIDAS ® Galectin-3 assay was developed by bioMérieux for the quantitative measurement of galectin-3 levels in blood using the bioMérieux VIDAS ® automated and multiparametric immunoassay testing system.

In April 2013, Abbott obtained a CE mark for its ARCHITECT ® Galectin-3 assay and initiated its commercial launch in the EU. On December 23, 2014, the FDA granted 510(k) clearance for Abbott's ARCHITECT ® Galectin-3 assay for use in conjunction with clinical evaluation as an aid in assessing the prognosis of patients diagnosed with chronic heart failure. The ARCHITECT ® Galectin-3 assay is the first FDA cleared automated blood test for galectin-3 and, as such, is the first automated test for galectin-3 to be introduced for clinical use in the U.S. The clearance was obtained based on a 510(k) submission made to the FDA in February 2014, on behalf of Abbott, by Fujirebio Diagnostics, Incorporated, or Fujirebio. On May 8, 2015, in anticipation of the U.S. market launch of the ARCHITECT ® Galectin-3 assay we amended our license and development agreement with Abbott due to market dynamic considerations since the Galectin-3 assay first began development in 2009. On July 6, 2015, we announced that the ARCHITECT ® Galectin-3 assay is available for purchase from Abbott in the United States. On November 24, 2015, we further amended our license and distribution agreement with Abbott, in regard to product fees paid to us by Abbott for galectin-3 tests sold by Abbott to reference laboratories, while retaining the previously negotiated product fees for the other customer segments. In consideration for the amendment, Abbott agreed to make an initial payment of $500,000 to us on November 30, 2015 and a second payment of up to $500,000 payable to us, by June 30, 2016, subject to achievement of certain commercial milestones. We expect that this modification to the agreement will expedite the transition from manual to automated testing for galectin-3. We expect that the majority of revenues currently generated from the sale of our BGM Galectin-3 Test kits will be diminished over time and we expect that any future revenues will be primarily derived from product fees that are generated from the sale of automated tests by Abbott (and our other automated partners when and if their automated tests become available). We also expect that our revenue going forward will depend on the extent to which Abbott (and our other automated partners when and if their automated tests become available) is successful in gaining clinical adoption of their automated test for galectin-3.

Our Technology In-Licenses from Third Parties

ACS Biomarker

We have exclusively licensed from ACS Biomarker B.V., or ACS Biomarker, a portion of the intellectual property rights covering our galectin-3 tests. In May 2007, we entered into an initial biomarker product license and collaboration agreement with ACS Biomarker and in July 2012, we entered into a sublicense agreement with ACS Biomarker, which superseded the initial agreement in its entirety. Pursuant to the agreement, ACS Biomarker granted to us an exclusive, worldwide sublicense to develop and commercialize two proprietary cardiovascular biomarkers for congestive heart failure, galectin-3 and thrombospondin-2. Each of these biomarkers is licensed by ACS Biomarker from the University of Maastricht. The agreement permits us to sublicense the rights that ACS Biomarker granted to us to third parties.

Under the terms of the agreement, we implemented a plan to develop and commercialize products derived from the licensed biomarkers. As consideration for the sublicenses, we were required to pay ACS Biomarker an upfront payment and are required to make milestone payments and royalty prepayments to the extent that we achieve specified development and regulatory milestones. Additionally, we are obligated to pay ACS Biomarker royalties on any net sales, together with a percentage of any sublicense revenue, from our galectin-3 tests and any other products that we develop using the licensed intellectual property. As of December 31, 2015, we have paid to ACS Biomarker a total of approximately $1.0 million in up-front, milestone and royalty prepayments.

The term of the agreement extends from its effective date until the last date on which a claim on the licensed IP remains issued and unexpired, unless terminated earlier pursuant to the terms of the agreement. Either party may terminate the agreement upon written notice if the other party fails to perform a material obligation under the

agreement, or upon the occurrence of certain bankruptcy events involving the other party. The licenses granted by ACS Biomarker to us will expire immediately upon any such termination, but certain other obligations, including those related to payment of royalties, indemnification and confidentiality, shall survive.

Our Other Research Collaboration

HRP Initiative

In 2006, we initiated the High-Risk Plaque, or HRP, initiative for atherothrombotic cardiovascular disease. The HRP initiative consisted of a series of pre-competitive, multi-party research and development projects, which was administered and coordinated by us pursuant to participation agreements with Abbott; AstraZeneca plc, or AstraZeneca; Merck & Co., Inc., or Merck; Koninklijke Philips N.V., or Philips; and Takeda Pharmaceutical Company Limited, or Takeda. Since the inception of the HRP initiative, these participating companies supported the research and development projects by providing approximately $26.6 million in funding. The overall goals of the HRP initiative was to advance the understanding, recognition and management of atherothrombotic cardiovascular disease, to provide a roadmap for the development and registration of screening, diagnostic and therapeutic interventions for high-risk plaque and to promote the use of these interventions by patients, pharmaceutical companies and third-party payers.

The HRP initiative was governed by a joint steering committee, or JSC, which was comprised of designees from the participating companies, and was led by a scientific program board consisting of academic experts in the cardiovascular field, which advised the JSC and assisted in the design of the research protocols. The JSC was responsible for overseeing the conduct and progress of the HRP initiative, including finalizing and approving program activities, program and activity budgets, external communications, patent filings, third-party licensing and commercialization of data and rights under the HRP initiative. We will own certain inventions and data that were conceived in the conduct of the HRP initiative, including those that arise from our data mining and analysis of a proprietary patient cohort and specimen repository that was developed as part of this initiative. We agreed to grant each participating company a non-exclusive, perpetual, royalty-free license to all such inventions and data for any and all uses. Each participation agreement expired upon the earlier of the completion of the HRP initiative or the fifth anniversary of such agreement, unless otherwise terminated by the parties.

Among other research projects, the HRP initiative contributed to what we believe are important advances in the identification of patients at risk for major atherothrombotic events, including data derived from studies that validated our CardioSCORE and BGM Galectin-3 test, as aids in the assessment of near-term risk of fatal cardiovascular events, and a novel three-dimensional vascular ultrasound technique. The three-dimensional vascular ultrasound technique is being pursued by companies other than BG Medicine.

The HRP initiative met the goals we set out to accomplish and we are no longer initiating new research projects in the initiative. All revenue for the HRP initiative has been recorded as of December 31, 2013.

Intellectual Property

The focus of our work is the commercialization of novel diagnostic tests based on biomarkers. Through our research and development efforts, we have developed expertise in proprietary methods using experimental design, biological sample preparation, high throughput biomolecular data and statistical analysis, clinical study design and statistical analysis, and specialized bioinformatics methods to interpret data sets. We seek to protect these methods as trade secrets and, in some cases, by filing patent applications.

We seek to protect the diagnostic tests that we have developed primarily through patents. The patentability of test methods and products based on biomarkers is well-established in most countries. Because we use an empirical as well as a hypothesis-driven approach to biomarker discovery, we may measure many different molecules in each biological specimen. Thus, we may be able to identify multiple biomarkers and biomarker combinations that are associated with a clinical outcome of interest. We believe that this may enhance our ability to obtain patents for

diagnostic tests based on our discoveries. However, due to technological changes that may affect our proposed products or judicial interpretation of the scope of our patents, our proposed products might not, now or in the future, be adequately covered by our patents.

As of February 29, 2016, we had six issued U.S. patents and five pending patent applications filed with the U.S. Patent and Trademark Office, or USPTO. A portion of the intellectual property that we own or license relates to our galectin-3 test. This intellectual property includes U.S. Patent Nos. 7,888,137 and 8,084,276, exclusively licensed from ACS Biomarker B.V. and six corresponding patent applications pending in the United States and abroad, as well as issued patents in Europe, Australia, Canada, China, Hong Kong, and Japan. U.S. Patent No. 7,888,137 is scheduled to expire in November 2026 and U.S. Patent No. 8,084,276 is scheduled to expire in September 2024. We own a U.S. patent application and corresponding foreign patents and patent applications relating to a specific method and kit for detecting galectin-3. Any patent issuing from this U.S. application could expire as early as 2029. In addition, we own one issued U.S. patent and corresponding foreign patents and patent applications related to methods for clinical evaluation of subjects based on galectin-3 measurements. A portion of the intellectual property that we own relates to our CardioSCORE test. This intellectual property includes U.S. Patent Application No. 12/946,470, an issued patent in Europe and an issued patent in Japan, and U.S. Patent Application No. 13/765,366 and one corresponding patent application abroad. Any patent issuing from the earliest-filed U.S. application could expire as early as 2030. For the diagnostic tests that we develop based on our biomarker discoveries, we expect to rely primarily on patent protection. Several of our patent applications are in an early stage of prosecution, and we cannot assure you that any of the pending patent applications will result in patents being issued. In addition, due to technological changes that may affect our proposed products or judicial interpretation of the scope of our patents, our proposed products might not, now or in the future, be adequately covered by our patents.

In addition to our internal diagnostic product development efforts, for which we plan to seek to obtain exclusive ownership rights, we expect to obtain certain ownership rights to intellectual property conceived in the conduct of the HRP initiative, a study of atherothrombotic cardiovascular disease that we initiated, and from our research, development and commercialization collaboration with other initiatives or collaborations that we may undertake.

We maintain a policy of requiring our employees and consultants to execute confidentiality and invention assignment agreements upon commencement of their relationships with us. These agreements are designed both to enable us to protect and maintain the confidentiality of our trade secret information by prohibiting unauthorized disclosure or use of our technology, and to secure title to technology developed by us or on our behalf so that it may be protected through patent filings or other means.

Manufacturing

Since 2009, we have been operating under an exclusive development and manufacturing agreement with Corgenix Medical Corporation, pursuant to which Corgenix will manufacture the BGM Galectin-3 Test for distribution in the United States, Europe and elsewhere. Corgenix develops, manufactures, distributes and markets in vitro diagnostic products based on ELISA technology using the microtiter format. Corgenix is the sole manufacturer of our BGM Galectin-3 Test. As part of our development and commercialization activities, we and Corgenix are required to comply with the FDA's quality system regulation, or QSR, and other regulations which cover, among other things, the methods and documentation for the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. The FDA monitors compliance with QSR through periodic inspections.

Competition

We believe that our cardiovascular diagnostic tests address significant unmet medical needs, improve patient outcomes and contain health care costs. We believe that we compete primarily on the basis of the value of the quantitative information our cardiovascular diagnostics provide and the clinical validation of our BGM Galectin-3 Test's ability to aid in the prognosis of patients with chronic heart failure. We also compete by leveraging

industry leaders in diagnostic instrument platform manufacturers and reference laboratory providers as we seek to provide comprehensive worldwide access to our BGM Galectin-3 test in outpatient and inpatient settings, along a continuum extending from physician offices, clinics, hospital emergency rooms, intensive care units and central labs to commercial reference labs.

We face competition from a number of companies in the commercialization of diagnostic products for cardiovascular disease. Established diagnostics companies, such as Abbott Diagnostics, Alere, Beckman Coulter, bioMérieux, General Electric, Mitsubishi, Ortho Clinical Diagnostics, Philips , Roche Diagnostics and Siemens offer cardiovascular disease tests to complement their legacy routine testing businesses. In addition, commercial laboratories with extensive service networks for diagnostic tests, such as LabCorp and Quest Diagnostics, have expanded or acquired testing capabilities to include more specialized cardiovascular testing. Specialized cardiovascular CLIA laboratories such as Atherotech, Berkeley Heart Lab (now part of Quest Diagnostics), Bioreference Lab (now part of OPKO Health), Boston Heart Diagnostics (formerly Boston Heart Lab and now part of Eurofins), Cardio DX, Cleveland HeartLab, Liposcience (now part of LabCorp), and True Health Diagnostics (formerly Health Diagnostic Laboratory) have expanded their presence and product menu in the cardiovascular market and some have developed their own tests or panels.

We have identified a number of recent entrants to the field with competing technologies and approaches in cardiovascular diagnostics. Companies that may compete with us in the cardiovascular diagnostics market, include Athena Diagnostics (now part of Quest Diagnostics), Atherotech, Berkeley Heart Lab, Critical Diagnostics, Bioreference Lab (now part of OPKO Health), Dako (now part of Agilent Technologies), diaDexus, Myriad Genetics, Singulex and True Health Diagnostics (formerly HDL).

We have identified a number of companies who manufacture and sell reagent products, including test kits for galectin-3 that have been developed for research use only, and who compete with us for sales to research laboratories. These research use only reagents are not currently cleared or approved for use as clinical diagnostic products, and, therefore, are only suitable for research studies. Companies that may compete with us in the research market include BioVendor, DRG International, eBioscience, IBL, Kamiya, R&D Systems and Thermo Fisher Scientific.

Regulatory

Our BGM Galectin-3 Test is our first FDA cleared and CE Marked diagnostic product. The test received 510(k) regulatory clearance from the FDA in November 2010 and obtained CE Mark in the European Union in October 2009.

On December 23, 2014, the FDA granted 510(k) clearance for Abbott's ARCHITECT ® Galectin-3 assay, the first FDA cleared automated blood test for galectin-3. The clearance was obtained based on a 510(k) submission made to the FDA in February 2014, on behalf of Abbott, by Fujirebio Diagnostics, Incorporated, or Fujirebio. On July 6, 2015, we announced that the ARCHITECT ® Galectin-3 assay is available for purchase from Abbott in the United States.

On March 31, 2015, we submitted a premarket 510(k) notification with the FDA requesting regulatory clearance to market our BGM Galectin-3 Test in the United States for a new indication for use, as an aid in the assessment of near-term risk of fatal cardiovascular events in older adults who have no prior history of coronary heart disease, cerebrovascular disease, or vascular disease. In August 2015, we received a request for additional information from the FDA, including information regarding the intended use of our test for this new indication, our clinical validation study and additional statistical analyses. We submitted our response to the FDA in November 2015. On December 17, 2015, we had a follow up discussion with the FDA regarding our November 2015 response. On December 18, 2015, following that additional discussion with the FDA, we concluded that demonstrating the clinical utility of our test for this proposed new indication would require a broadening of the defined indication to include aiding in the assessment of the near-term risk of both fatal and non-fatal cardiovascular events in our study population and, as a result, would require a new 510(k) submission.

Accordingly, we submitted to the FDA a notice of withdrawal of the 510(k) notification that we submitted on March 31, 2015. We are evaluating what additional data, studies and analyses would be required to support a new submission and a broader indication for use if we choose to resubmit this proposed indication for use to the FDA.

Subject to obtaining substantial additional financing, we expect to pursue new clinical claims and indications for the BGM Galectin-3 Test in assessing heart failure, as well as, in related disorders. Expansion of the product label to include new clinical claims and indications for use will require additional clinical studies and clearance, or approval, by regulatory bodies, such as the FDA, and to expand the scope of our current CE Mark for use in the EU. Our ability to engage in these activities would require us to obtain substantial additional financing.

In December 2012, we obtained a CE Mark for the CardioSCORE test, which permits us to market the test in Europe and other countries that recognize or require the CE Mark. However, as a result of our decision to focus our efforts on increasing the adoption and sales of our galectin-3 test, we have decided to redirect our resources from a launch of the CardioSCORE test in Europe to support our galectin-3 efforts. In December 2011, we submitted a premarket 510(k) notification to the FDA to request regulatory clearance to market the CardioSCORE test in the United States as an aid in the assessment of near-term risk for significant cardiovascular events, such as heart attack and stroke. In response to this submission, FDA requested that we engage an independent committee of physicians to conduct a medical review and adjudication of clinical endpoints reported in the submission. Due to the time involved in responding to this request, we withdrew the 510(k) on August 8, 2012. Our medical review included the assessment of sample stability and the evaluation of other technical issues raised by the FDA. The adjudication process was completed in 2013. In light of our efforts to reduce our operating expenses and to extend our cash runway, we have redirected our limited resources to provide support to the commercial introduction of galectin-3 testing by our automated partners and are not actively engaged in development or commercialization activities related to CardioSCORE.

The FDA recommends that sponsors like us interact with the agency early and often in the development of diagnostic products. We intend to follow this recommendation in an effort to manage development risks and facilitate the regulatory process. In light of the importance of the U.S. market for our potential products, and because of the opportunity to seek and receive early FDA input on development programs, we will prioritize U.S. regulatory plans and submissions over other jurisdictions. In addition, we intend to identify opportunities to prepare and file submissions in compliance with EU-Directive 98/79/EC and other applicable standards and national reimbursement rules. We plan to prioritize European Union Member States based on market size, regulatory approvals and other considerations.

Our current and planned business is subject to extensive and frequently changing laws and regulations in the United States, the European Union, and elsewhere that we may do business.

U.S. Regulations

Food and Drug Administration

In the United States, in vitro diagnostics are regulated by the FDA as medical devices. There are two principal regulatory pathways to receive authorization to market in vitro diagnostics, a 510(k) premarket notification and a premarket approval application, or PMA. The FDA makes a risk-based determination as to which pathway a particular in vitro diagnostic is eligible. In addition, since July 2012 with the enactment of the Food and Drug Administration Safety and Innovation Act, or FDASIA, a *de novo* pathway is directly available for certain low to moderate risk devices that would not qualify for the 510(k) notification pathway due to lack of a predicate device. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. Medical devices are classified into one of three classes on the basis of their level of risk and the controls deemed by the FDA to be necessary to reasonably assure their safety and effectiveness. Class I devices are subject to “general controls”, including establishment registration, device listing, labeling, reporting and recordkeeping, and adherence to the FDA’s quality system regulations, which are device-specific good manufacturing practices. Class II devices are

subject to the general controls and also special controls, including guidance documents, performance standards, and postmarket surveillance. Class III devices are subject to most of the previously identified requirements as well as to premarket approval. Most Class I devices are exempt from the requirement for premarket notification to the FDA; most Class II devices require the submission and clearance of a 510(k) premarket notification to the FDA prior to commercial marketing; and Class III devices require submission and approval of a PMA. Device manufacturers and PMA holders are also subject to numerous postmarketing requirements.

The FDA can require the submission of clinical data to support 510(k) clearance, *de novo* reclassification, or a PMA. Clinical studies undertaken in the United States are subject to FDA requirements applicable to investigational device exemptions, or IDEs, institutional review boards, or IRBs, review and approval, and informed consent of the study subjects.

Clinical Trials of Devices

Clinical trials for a medical device must be conducted in accordance with FDA requirements, including informed consent from study participants, review and approval by an IRB at each institution where a trial will be conducted, financial disclosure by clinical investigators, and listing of appropriate studies on ClinicalTrials.gov. Additionally, FDA approval of an IDE application must be obtained in order to conduct a clinical trial of "significant risk" devices, which are devices that present a potential for serious risk to the health, safety, or welfare of a subject, including devices that are of substantial importance in diagnosing or treating disease, or preventing impairment of human health. Sponsors of clinical trials are responsible for monitoring the studies, and for recordkeeping and reporting. The FDA may prevent clinical trials from moving forward, and may suspend or terminate trials once initiated. The FDA may inspect sponsor records, clinical investigators, and clinical sites involved in clinical trials. The FDA may take enforcement action for non-compliance with any of these requirements.

510(k) Premarket Notification

A 510(k) notification requires the sponsor to demonstrate that a medical device is substantially equivalent to another marketed device, termed a "predicate device", that is legally marketed in the United States and for which a PMA was not required. A device is substantially equivalent to a predicate device if it has the same intended use and same technological characteristics as the predicate or has the same intended use but different technological characteristics, where the information submitted to the FDA does not raise new questions of safety or effectiveness and demonstrates that the device is at least as safe and effective as the legally marketed predicate device.

The FDA's performance goal review time for a 510(k) notification is 90 days from the date of receipt. In practice, however, the review process often takes significantly longer. After its initial review, the FDA may require additional information, including clinical data, in order to make a decision regarding the claims of substantial equivalence. Clinical studies of in vitro diagnostic products are typically designed with the primary objective of obtaining analytical or clinical performance data. If the FDA believes that the device is not substantially equivalent to a predicate device, it will issue a "Not Substantially Equivalent" letter and designate the device as a Class III device, which will require the submission and approval of a PMA before the new device may be marketed. Under certain circumstances, the sponsor may submit a *de novo* petition to the FDA to reclassify the new device as a Class I or Class II device.

If a predicate device does not exist, the FDA may make a risk-based determination that the device is eligible for *de novo* reclassification and premarket review instead of requiring a PMA. The *de novo* process is similar to clearance of the 510(k) premarket notification, and typically requires the submission of clinical data to support the reclassification. A *de novo* petition can be submitted either prior to the submission of a 510(k) when no predicate device can be identified, or after the FDA determines that a new device is "not substantially equivalent" due to lack of an appropriate predicate device. Under the FDASIA, the FDA may "decline to undertake a classification" if the FDA either (1) identifies a legally marketed predicate device that would be appropriate for a

510(k), or (2) determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed. The statute directs the FDA to classify the device within 120 days following receipt of the *de novo* application.

Premarket Approval

The PMA process is more complex, costly and time consuming than the 510(k) process. A PMA must be supported by manufacturing data, preclinical data, and more detailed and comprehensive scientific evidence, including clinical data, to demonstrate the safety and efficacy of the medical device for its intended purpose. If the device is determined to present a "significant risk," the sponsor may not begin a clinical trial until it submits an application for an investigational device exemption, or IDE, to the FDA and obtains approval from the FDA to begin the trial.

After the PMA is submitted, the FDA has 45 days to make a threshold determination that the PMA is sufficiently complete to permit a substantive review. If the PMA is deemed not sufficiently complete, the FDA will issue a "refuse to file" determination. If the PMA is complete, the FDA will file the PMA and begin a substantive review of the application. The FDA is subject to a performance goal review time for a PMA that is 180 days from the date of filing, although in practice the total review time is longer. Questions from the FDA, requests for additional data, additional testing and submissions by the applicant, and referral to an advisory committee may delay the process considerably. Indeed, the total process may take several years and there is no guarantee that the PMA will ever be approved. Even if approved, the FDA may limit the indication for which the device may be marketed. The FDA may also request additional clinical studies or registries as a condition of approval or even after the PMA is approved. Any changes to the medical device may require a supplemental PMA to be submitted and approved. In addition, annual reports and other reports are required.

Requirements Applicable to Marketed Devices

The FDA Quality System Regulations, or QSRs, impose requirements for design control and validation, management review, complaint handling and investigation, labeling control, servicing and recordkeeping, among others. The FDA also regulates device imports and exports. Manufacturers are required to submit medical device reports for deaths or serious injuries associated with the use of their devices, and for malfunctions that could cause or contribute to a death or serious injury. The FDA also requires reporting of certain corrections or removals of devices. Labeling and promotional activities are subject to regulation by the FDA, and certain device advertising is subject to regulation by the Federal Trade Commission.

Laboratory Developed Tests

Although the FDA has claimed for many years that it has the statutory authority to regulate laboratory-developed tests, or LDTs, as medical devices, the agency has generally exercised enforcement discretion toward them. LDTs are tests that are developed, validated, and offered as testing services by a clinical laboratory, and these tests are regulated under the Clinical Laboratory Improvement Act, or CLIA. The FDA has stated that it will take enforcement action against any specific LDT if necessary to protect the public health. In addition, under FDA regulations applicable to analyte-specific reagents, or ASRs, a laboratory using an ASR in its LDT is required to indicate in its test report that the test has not been cleared or approved by the FDA. The FDA has also issued several draft guidance documents, such as those regarding products labeled "Research Use Only," or RUO, and In Vitro Diagnostic Multivariate Index Assays, or IVDMIAs, which may affect the regulation of clinical laboratory tests if finalized.

In recent years, the FDA has indicated that it is reconsidering its policy of enforcement discretion and reviewing the regulatory requirements that it will apply to LDTs. In recent years, however, the FDA has stated it intends to end its policy of general enforcement discretion and regulate certain LDTs as medical devices. To this end, on October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory

Developed Tests (LDTs)", respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The FDA has indicated that it does not intend to modify its policy of enforcement discretion until the draft guidance documents are finalized. It is unclear at this time when, or if, the draft guidance documents will be finalized, and even then, the new regulatory requirements are proposed to be phased-in consistent with the schedule set forth in the guidance (in as little as 12 months after the draft guidance is finalized for certain high-priority LDTs). Nevertheless, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time. LDTs with the same intended use as a cleared or approved companion diagnostic are defined in FDA's draft guidance as "high-risk LDTs (Class III medical devices)" for which premarket review would be first to occur.

CLIA and State Clinical Laboratory Laws

The FDA is responsible for the complexity categorization of commercially marketed in vitro diagnostic, or IVD, tests under CLIA, placing them into one of three categories based upon the potential risk to public health in reporting erroneous results. The categories were devised on the basis of the complexity of the test, and include waived tests, tests of moderate complexity, and tests of high complexity.

The Center for Medicare and Medicaid Services, or CMS, regulates clinical laboratories under CLIA. Laboratories that perform testing on human specimens for the purpose of providing information for diagnosis, prevention or treatment of disease or assessment of health are subject to CLIA, which imposes quality standards for laboratory testing to ensure the accuracy, reliability and timeliness of patient test results.

Laboratories performing moderate- or high-complexity testing must meet various CLIA requirements applicable to personnel, operations, establishment and verification of performance specifications, proficiency testing, patient test management, quality control, and quality assurance. CLIA certified laboratories are typically subject to survey and inspection every two years to assess compliance with program standards. Sanctions can be applied against a laboratory that is found to be out of compliance with CLIA requirements, including, among others, suspension, limitation, or revocation of a CLIA certificate.

Laboratories may also seek accreditation by the College of American Pathologists, or CAP. CAP is an independent, non-governmental organization approved by CMS to inspect laboratories to determine compliance with CLIA requirements. The CAP Laboratory Accreditation Program is an internationally recognized program that utilizes teams of practicing laboratory professionals as inspectors, and accreditation by CAP can often be used to meet CLIA or state certification requirements.

In addition to CLIA, States also have laws that apply to clinical laboratories, including state licensing laws. Some states impose requirements that are more stringent than CLIA requirements. State laws may also require detailed review of a laboratory's technical procedures or scientific validation of laboratory tests.

Environmental, Health and Safety for Clinical Laboratories

Clinical laboratories are subject to federal and state laws and regulations related to the protection of the environment, health and safety of employees, the handling of medical specimens, and medical waste. For example, the federal Occupational Safety and Health Administration, or OSHA, has established standards for the protection of health care employees, including requirements to protect workers from blood-borne pathogens, such as HIV and hepatitis B and C. Some biological materials and laboratory supplies are classified as hazardous materials and are subject to applicable regulations of the Department of Transportation, the United States Postal Service, the Public Health Service, and the International Air Transport Association. In addition, state laws regulate the disposal of medical waste and hazardous waste.

HIPAA and Other Privacy and Data Security Laws

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, established for the first time comprehensive federal protections for the privacy and security of health information. HIPAA standards apply to

three types of organizations, or "Covered Entities": health plans, health care clearing houses, and health care providers which conduct certain health care transactions electronically. HIPAA's Privacy rule requires Covered Entities to implement policies and procedures regulating uses and disclosures of protected health information, granting individuals certain rights with respect to their protected health information and complying with a variety of administrative requirements such as training and progressive discipline in response to violations. HIPAA's Security standards require Covered Entities and individuals or organizations providing services to Covered Entities involving the use or disclosure of protected health information, or Business Associates, to have in place administrative, physical, and technical standards to guard against the misuse of protected health information.

HIPAA was amended in 2009 by the Health Information Technology for Economic and Clinical Health Act, or HITECH, provisions of the American Recovery and Reinvestment Act. HITECH strengthened and expanded HIPAA and increased penalties for violations. Among other changes, HITECH requires Covered Entities and Business Associates to report breaches of unsecured protected health information to affected individuals and to the federal government and in some cases to local or national media outlets. Under HITECH, Business Associates are directly liable for compliance with applicable HIPAA requirements and both Covered Entities and Business Associates are subject to audit by the federal government and enforcement by state Attorneys General, who were given authority to enforce HIPAA under HITECH. Additionally, some state laws impose privacy protections more stringent than HIPAA and data security requirements applicable to information beyond health care information. These state laws create an additional level of enforcement and may require additional reporting in the event of breach. Most of the institutions and physicians from which we obtain biological specimens and patient level data that we use in our research and validation work are Covered Entities and must obtain proper authorization from their patients for the subsequent use of those samples and associated clinical information. While we are not presently subject to HIPAA, we will be obligated to comply with HIPAA if we begin billing electronically for tests that we conduct. Additionally, if we provide clinical laboratory testing services or enter into specific kinds of relationships with a Covered Entity or a Business Associate of a Covered Entity, we may incur HIPAA compliance obligations. HIPAA governs the availability of samples and associated patient data, so we must carefully structure research and development activities to ensure that HIPAA will permit participation by our covered entity collaborators.

Beyond HIPAA, our activities must comply with all applicable privacy and data security laws. For example, there are international privacy laws that impose restrictions on the access, use, and disclosure of health information from outside of the United States. All of these laws may impact our business. Many of them overlap and apply simultaneously making compliance a difficult and complex endeavor. Our failure to comply with these privacy and security laws or a breach of protected health information or personal data could cause significant financial or reputational harm to our company. If we engage in activities that make us a Covered Entity or Business Associate for HIPAA purposes, we will have to implement a comprehensive HIPAA compliance program. Additionally, significant changes in the laws restricting our ability to obtain tissue samples and associated patient information or our failure to comply with existing law could significantly impact our business and our future business plans.

European Regulations

Article 168 of the Treaty on the Functioning of the European Union, or TFEU, requires a high level of human health protection to be ensured in the definition and implementation of all European Union policies and activities. European Union action, which complements national policies, must be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. On the basis of article 168(4)(a) of the TFEU, the European Legislator is required to contribute to the achievements of these objectives through adopting measures setting high standards of quality and safety for organs and substances of human origin, blood and blood derivatives, as well as for medicinal products and medical devices.

In the European Union, IVD medical devices are regulated under EU-Directive 98/79/EC, or the IVD Directive, which is implemented by national provisions. The IVD Directive is currently under revision. A new Regulation – applicable directly in all Member States without need for implementation – may be adopted in the near term. The

proposed regulation is substantially different than the current IVD Directive, and contains significant changes that are anticipated to be stricter and costlier to manufacturers. It is believed that device manufacturers will have between three and five years (until between 2019 and 2021) to meet the new requirements.

The IVD Directive requires that medical devices meet the essential requirements set out in Annex I to the IVD Directive. These requirements include the safety and efficacy of the devices. According to the IVD Directive, the Member States presume compliance with these essential requirements in respect of devices which are in conformity with the relevant national standards transposing the harmonized standards of which the reference numbers have been published in the Official Journal of the European Communities. These harmonized standards include ISO 13485:2012, the quality standard for medical device manufacturers. In addition, specific requirements can be laid down in Common Technical Specifications adopted by the European Commission.

For devices for performance evaluation (including clinical investigation), the manufacturer is required to prepare a statement containing: (i) an evaluation plan stating the purpose, scientific, technical or medical grounds, scope of the evaluation, (ii) the list of laboratories taking part in the evaluation study, (iii) the starting date and scheduled duration for the evaluation, and (iv) a statement that the device conforms to the requirements of the IVD Directive, apart from those specifically itemized in the statement, and a statement that every precaution has been taken to protect the health and safety of the patient, user, and other persons. Individual Member States may also subject certain types of investigations to a review by an Ethics Committee and authorization by their competent authorities. The proposed new regime introduces an authorization requirement by the Member States' competent authorities for interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the clinical studies. For IVD devices, these clinical evidence requirements will be proportional to the assigned risk class of a device.

IVD medical devices, other than devices for performance evaluation, must bear the CE marking of conformity when they are placed on the market. The CE mark is a declaration by the manufacturer that the product meets all the appropriate provisions of the relevant legislation implementing the relevant European Directive. The manufacturer must follow a conformity assessment procedure to obtain this CE marking. The manufacturer must also prepare an EC Declaration of Conformity before placing the IVD on the market. For certain IVD medical devices, a review by an independent body, or notified body, is necessary. Experts estimate that, whereas approximately 20% of IVD medical devices currently require notified body approval to obtain the CE marking in accordance with the IVD Directive, as many as 80% of IVD medical devices will require notified body review and approval under the proposed regulation.

Each European Member State must adopt its own laws, regulations and administrative provisions necessary to implement the IVD Directive. Member States may not create any obstacle to the placing on the market or the putting into service within their territory of devices bearing the CE marking according to the conformity assessment procedures, except for purposes of pricing and reimbursement procedures.

Advertising of medical devices is regulated separately by each individual European Member State. While some Member States only impose requirements on the content of advertising, some others require prior approval by the authorities, at least for some categories of IVD medical devices.

EU rules governing the donation, procurement, testing, processing, preservation, storage and distribution of cells and tissues that are not medicinal products are contained in Directive 2004/23/EC. A company in the European Union that conducts such activities must be licensed and is subject to inspection by regulatory authorities. Such company must implement appropriate quality systems and maintain appropriate records to ensure that cells and tissues can be traced from the donor to the recipient and vice versa. There are also requirements to report serious adverse events and reactions linked to the quality and safety of cells and tissues. Individual EU Member States are free to further restrict the export, collection, and use of such bodily material.

Moreover, in the European Union, the protection of individuals with regard to the processing of personal data is regulated under EU-Directive 95/46/EC on Data Protection, or the DP Directive (which also is in the process of

being replaced by a stricter Regulation). If specimens, such as blood plasma and urine, taken from patients relate to an identified or identifiable natural person, the data derived from such specimens fall within the scope of the DP Directive. Member States prohibit the processing of personal data concerning health, unless (i) explicit consent has been obtained; (ii) the processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health care services; or (iii) the health data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy. In addition, EU Member States may allow for the processing of health data for research purposes, subject to possible conditions.

Billing and Reimbursement

United States

In the United States, diagnostic tests may be paid for by several sources, including third-party payers such as insurance companies, managed care organizations or government health programs such as Medicare and Medicaid, and patients. Each of these payers may have different billing requirements. Currently, we do not bill any third-party payer for the galectin-3 test or any other test.

Coding

Clinical laboratory tests are typically billed to payers using the Healthcare Common Procedure Coding System, or HCPCS, and the Current Procedural Terminology, or CPT, coding systems. CPT codes are incorporated in the HCPCS as Level I HCPCS codes and typically result in a predetermined payment for a specific in vitro diagnostic test. The CPT set of codes is copyrighted and maintained by the American Medical Association, or AMA. The AMA publishes the CPT Code, which is a listing of descriptive terms and identifying codes for items and services provided in outpatient settings. The purpose of the CPT Code is to provide a uniform language that accurately describes medical, surgical, and diagnostic services, and it is used by CMS and private insurers for reimbursement.

If a new laboratory test does not fall under an existing CPT code, it may require a new code for reimbursement purposes. The process for seeking a test-specific code for such a new test is lengthy and typically takes from one to two years to complete. While the AMA's decision is pending, billing may be done under an existing, non-specific CPT code. A manufacturer or provider may decide not to request assignment of a CPT code and instead use an existing, non-specific code for reimbursement purposes. However, use of such codes may result in more frequent denials and/or requests for supporting clinical documentation from the third-party payer and in lower reimbursement rates, which may vary based on geographical location.

A manufacturer of an in vitro diagnostic kit or a provider of laboratory services may request establishment of a Category I CPT code for a new product. Assignment of a specific CPT code ensures routine processing and payment for a diagnostic test by both private and government third-party payers. In October 2011, the AMA CPT ® Editorial Panel accepted our request to establish a Category 1 code for galectin-3 in the pathology and laboratory/chemistry section of CPT and established a new analyte-specific code, 82777. In November 2012, CMS, in the Final Determination for the Medicare Clinical Laboratory Fee Schedule for 2013, assigned a payment rate for the galectin-3 blood test under CPT code 82777, effective January 1, 2013. In December 2013, after further consideration based on additional information provided by BG Medicine, CMS agreed that its original decision to crosswalk galectin-3 to existing test code 83520 should be revised. CMS published the final determination of the 2014 Medicare national limitation amount for the Company's galectin-3 blood test (analyte-specific CPT ® Code 82777) at the amount of a crosswalked test (analyte-specific CPT ® Code 84244) whose 2014 national limitation amount was $30.01. This national limitation amount replaced the galectin-3 blood test's national limitation amount of $17.80 that was effective in 2013. Crosswalking is used when a new test code is comparable to an existing test code, multiple existing test codes, or a portion of an existing test code on the Clinical Laboratory Fee Schedule, or CLFS. Under this methodology, the new test code is assigned the local fee

schedule amounts and the national limitation amount of the existing test, with payment made at the lesser of the local fee schedule amount or the national limitation amount. In 2015, the national limitation amount for the galectin-3 blood test was reduced to $29.93, which applied across the U.S., except in Ohio and West Virginia where rates of $23.93 and $26.33, respectively, applied. In 2016, the national limitation amount for the galectin-3 blood test was increased to $29.96, which applies across the U.S., except in Ohio and West Virginia, where rates were increased to $23.95 and $26.36, respectively.

Coverage Decisions

When deciding whether to pay for a particular diagnostic test, third-party payers generally consider whether the test is a covered benefit under the relevant plan and, if so, whether it is reasonable and necessary for the diagnosis or treatment of illness and injury. Coverage determinations often are influenced by current standards of practice and clinical data, particular at the local level. CMS, which is the government agency responsible for overseeing the Medicare program, has the authority to make coverage determinations on a national basis, but most Medicare coverage decisions are made at the local level by contractors that administer the Medicare program in specified geographic areas. Private and government third-party payers have separate processes for making coverage determinations, and private third-party payers may or may not follow Medicare's coverage decisions. If a third-party payer has a coverage determination in place for a particular diagnostic test, billing for that test must comply with the established policy. Otherwise, the third-party payer makes payment decisions on a case-by-case basis.

Payment

Payment for covered diagnostic tests is determined based on various methodologies, including prospective payment systems and fee schedules. In addition, private third-party payers may negotiate contractual rates with participating providers or set rates as a percentage of the billed charge. Diagnostic tests furnished to Medicare inpatients generally are included in the bundled payment made to the hospital under Medicare's Inpatient Prospective Payment System. Payment for diagnostic tests furnished to Medicare beneficiaries in most other circumstances is based on the CLFS under which a payment amount is assigned to each covered CPT code. The law requires fee schedule amounts to be adjusted annually by the percentage increase in the consumer price index, or CPI, for the prior year, but Congress has frequently frozen the payment rates.

European Union

In the European Union, the reimbursement mechanisms used by private and public health insurers vary by Member State. For the public systems, reimbursement is determined by guidelines established by the legislator or responsible national authority. As elsewhere, inclusion in reimbursement catalogues focuses on the medical usefulness, need, quality and economic benefits to patients and the health care system. Acceptance for reimbursement comes with cost, use and often volume restrictions, which can vary by Member State.

Employees

As of March 15, 2016 we employed five full-time employees, of whom three had advanced degrees. None of our employees are represented by a labor union. Since September 11, 2014, we implemented a reduction of approximately 77% of our workforce, or 17 people, leaving five employees. For more information about our employees, see "- Recent Developments" and "Item 1A – Risk Factors – Following our reduction in force since September 2014, which resulted in the elimination of approximately 77% of our headcount, we may not be able to retain our remaining employees."

Company History and Available Information

We were incorporated in Delaware in February 2000 and later that year chose the name Beyond Genomics, Inc. In October 2004, we changed our name to BG Medicine, Inc. We maintain our operations at 303 Wyman Street, Suite 300, Waltham, Massachusetts 02451 (formerly 880 Winter Street, Suite 210, Waltham, Massachusetts

02451), and our phone number is (781) 890-1199. Our Internet website address is www.bg-medicine.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act are available free of charge through the investor relations page of our internet website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission.

Item 1A. RISK FACTORS

The risks and uncertainties described below are those that we currently believe may materially affect us. If any of the following risks actually occur, they may materially harm our business, our financial condition and our results of operations.

Risks Related to Our Financial Position

We need immediate additional funding to continue our operations and support our capital expenditures, which may not be available to us. Without modifications to our existing payment obligations or receipt of additional funding, our existing cash and other sources of liquidity may only be sufficient to fund our limited operations through July 2016. If we do not receive adequate financing or engage in a strategic transaction on acceptable terms before our available cash necessary to sustain our ongoing operations is depleted, we will likely cease operations and liquidate our assets and our common stock stockholders will likely lose their entire investment in us.

Our business does not generate the cash necessary to finance our operations and has consumed substantial amounts of cash to date. We incurred net losses of $8.1 million in 2014 and $5.3 million in 2015. We expect to continue to incur losses and use cash during 2016 and beyond. Our cash utilization generally depends on the extent to which our automated partners are successful in developing and commercializing their automated versions of our tests, as well as the costs, timing and outcomes of our efforts to support the marketing and selling efforts of our automated partners, among several other factors.

Without modifications to our existing payment obligations or receipt of additional funding, we will require additional capital to continue our operations beyond July 2016. At December 31, 2015, we had cash totaling $1.5 million. At March 25, 2016, we had cash totaling $1.0 million. During the year ended December 31, 2015, we incurred a net loss totaling $5.3 million and used cash in operating activities totaling $3.7 million.

Our near-term capital needs depend on many factors, including:

- our ability to continue to carefully manage our costs;
- the amount and timing of revenue received from sales of our galectin-3 test on the Abbott ARCHITECT ® and other automated platforms;
- the amount and timing of investment required to support the commercialization efforts of Abbott and our other our automated partners; and
- our success in promptly identifying alternative sources of financing or establishing a strategic alternative that is in our stockholders' best interests.

As of the date of this report and since September 11, 2014, we have implemented a reduction of approximately 77% of our workforce, or 17 people, leaving five employees. We took these steps in order to reduce our operating expenses and extend our cash runway in anticipation of the commercial launch of automated versions of our galectin-3 test.

On November 13, 2014, we announced that we had retained Stifel Nicolaus & Company, Incorporated, an investment banking firm, to assist us in reviewing and evaluating strategic alternatives. We engaged in that formal process during the ten months that followed our announcement and we terminated our formal engagement with Stifel during the third quarter of 2015.

If we are unable to obtain adequate financing or engage in a strategic transaction on acceptable terms, we will be required to implement further cost reduction strategies. These reductions would significantly impact activities related to the commercialization of the BGM Galectin-3 Test and the development of additional indications for the BGM Galectin-3 Test and other pipeline products, and would result in significant harm to our business, financial condition and results of operations.

If we do not receive adequate financing or engage in a strategic transaction on acceptable terms before our available cash necessary to sustain our ongoing operations is depleted, we will likely be forced to wind down our operations, either through liquidation, voluntary or involuntary bankruptcy or a sale of our assets. Upon liquidation, including deemed liquidations pursuant to a merger, consolidation or a sale of all or substantially all of our assets, the holders of our Series A Preferred Stock will be entitled to be paid first out of any proceeds in an amount per share equal to the price at which shares of Series A Preferred Stock were sold in the Series A Preferred Stock financing, plus all accrued but unpaid dividends on each share of Series A Preferred Stock, and prior to payment of any amounts on our common stock. Thereafter, the holders of Series A Preferred Stock will also share pro rata on an as converted to common stock basis in payments made to the holders of our common stock. Accordingly, the holders of the Series A Preferred Stock will be entitled to receive the proceeds out of any sale or liquidation of the Company before any such proceeds are paid to holders of our common stock and then share in any proceeds paid to holders of our common stock. As a result, only the sale or liquidation proceeds in excess of the liquidation preference plus accrued but unpaid dividends would be available for distribution to holders of our common stock. Therefore, if we wind down our operations for any reason, it is likely that our common stockholders will lose their entire investment in us.

There is substantial doubt concerning our ability to continue as a going concern.

Our financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We expect to incur further losses in the commercialization of our cardiovascular diagnostic test and the operations of our business and have been dependent on funding our operations through the issuance and sale of equity securities. These circumstances raise substantial doubt about our ability to continue as a going concern. As a result of this uncertainty and the substantial doubt about our ability to continue as a going concern as of December 31, 2015, the Reports of Independent Registered Public Accounting Firms included immediately prior to the Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K include a going concern explanatory paragraph. Management's plans include focusing on increasing revenue by seeking new arrangements with commercial distribution partners and the reduction of expenditures. However, no assurance can be given at this time as to whether we will be able to achieve these objectives. Our financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

The impact and results of our exploration of strategic alternatives are uncertain and may not be successful.

On November 13, 2014, we announced that we had retained Stifel Nicolaus & Company, Incorporated, an investment banking firm, to assist us in reviewing and evaluating strategic alternatives. We engaged in that formal process during the ten months that followed our announcement and we terminated our formal engagement with Stifel during the third quarter of 2015. Without the benefit of an outside financial advisor, however, we continue to explore possible strategic alternatives including joint ventures, strategic partnerships or alliances, or merger or sale of the Company or other possible transactions.

There can be no assurance that this exploration process will result in any initiatives, agreements or transactions that will enhance stockholder value. Further, any strategic transaction that is completed ultimately may not deliver the anticipated benefits or enhance stockholder value.

In addition, there is uncertainty regarding the length and/or complexity of the strategic-alternative exploration process. We also expect that the process will continue to distract the attention of our management from operating and growing our business and may impair our relationships with our customers, partners and employees. It is also possible that we will incur significant expenses pursuing one or more transactions unsuccessfully. We do not currently intend to disclose further developments with respect to this process, unless and until our board of directors approves a specific transaction or otherwise concludes its review of strategic alternatives.

Due in part to our limited financial resources, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable indications for our product candidates, and/or we may be unable to pursue the indications that we would like to pursue.

We have limited technical, managerial and financial resources to determine the indications on which we should focus the development efforts related to our product candidates. Due to our limited available financial resources and staffing, we have had to curtail development programs for our CardioSCORE test and certain additional indications for our galectin-3 test and activities that might otherwise have led to more rapid progress of our product candidates through the regulatory and development processes.

Furthermore, we cannot assure you that we will be able to retain or regain adequate staffing levels to run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish. The decisions to allocate our research, management and financial resources toward particular indications for our product candidates may not lead to the development of viable commercial products and may divert resources from better opportunities. Similarly, our decisions to delay or terminate certain development programs may also cause us to miss valuable opportunities.

We intend to deregister our securities under the Exchange Act. Deregistration will result in less disclosure about us and may negatively affect our ability to raise additional funds, the ability of our stockholders to sell our securities and the liquidity and trading prices of our common stock.

On March 25, 2016, our Board of Directors voted to voluntarily deregister our common stock under the Exchange Act and become a non-reporting company. In connection therewith, the Board of Directors approved the filing with the SEC of a Form 15 to voluntarily deregister our securities under Section 12(g) of the Exchange Act and suspend our reporting obligations under Section 15(d) of the Exchange Act. We expect to file the Form 15 in April 2016. We expect that our obligations to file periodic reports, such as Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, will be suspended immediately upon the filing of the Form 15 with the SEC, and our proxy statement, Section 16 and other Section 12(g) reporting responsibilities will terminate effective 90 days after the filing of the Form 15. We are eligible to deregister under the Exchange Act because our common stock is held by fewer than 300 stockholders of record. Following deregistration, we do not expect to publish periodic financial information or furnish such information to our stockholders except as may be required by applicable laws. As a result of the foregoing factors, deregistration will result in less disclosure about us and may negatively affect our ability to raise additional funds, the ability of our stockholders to sell our securities and the liquidity and trading prices of our common stock.

Risks Related to Our Business and Strategy

We are an early stage commercial company with a history of losses resulting from our research and development and early commercialization efforts, we expect to incur losses for at least the next several years, and we may never achieve profitability.

We have incurred substantial net losses since our inception in February 2000. For the years ended December 31, 2015, 2014 and 2013, we incurred net losses of $5.3 million, $8.1 million and $15.8 million, respectively. Our accumulated deficit was approximately $166.3 million at December 31, 2015. We expect to continue to incur net losses for 2016 and beyond. We will need to generate significant revenue from product sales and product fees to achieve profitability.

Historically, we have generated limited revenue from our biomarker discovery and analysis services agreements. Our current sources of revenues include product sales of our BGM Galectin-3 Test kits, partnership revenues related to modifications made to our license and distribution agreements or for achievement of specified commercial milestones, and product fees generated from the sale of automated tests for galectin-3 by our automated partners.

We are in the process of commercializing our first product and, to date, have generated a limited amount of product revenue. Our BGM Galectin-3 Test, received clearance from the U.S. Food and Drug Administration, or FDA, in late 2010 as an aid in assessing the prognosis of patients suffering from chronic heart failure, and is commercially available in the United States. Our BGM Galectin-3 Test is also available in Europe under a CE Mark as an aid in assessing the prognosis of acute and chronic heart failure and as an aid in identifying individuals in the general population who are risk of developing heart failure. Our BGM Galectin-3 Test is being marketed in the United States through specialty, national, regional and hospital laboratories.

Automated tests for galectin-3 developed by Abbott and bioMérieux are available in Europe under a CE Mark as an aid in assessing the prognosis of chronic heart failure. The Abbott ARCHITECT automated galectin-3 test received 510(k) clearance from the FDA on December 23, 2014 as an aid in assessing the prognosis of chronic heart failure and in July 2015 became commercially available in the United States. On May 8, 2015, in anticipation of the U.S. market launch of the ARCHITECT ® Galectin-3 assay we amended our license and development agreement with Abbott due to market dynamic considerations since the Galectin-3 assay first began development in 2009. On July 6, 2015, we announced that the ARCHITECT ® Galectin-3 assay is available for purchase from Abbott in the United States. This is the first automated test for galectin-3 to be introduced for commercial use in the United States. On November 24, 2015, we further amended our license and distribution agreement with Abbott, in regard to product fees paid to us by Abbott for galectin-3 tests sold by Abbott to reference laboratories, while retaining the previously negotiated product fees for the other customer segments. In consideration for the amendment, Abbott agreed to make an initial payment of $500,000 to us on November 30, 2015 and a second payment of up to $500,000 payable to us, by June 30, 2016, subject to achievement of certain commercial milestones. We expect that this modification to the agreement will expedite the transition from manual to automated testing for galectin-3. As a result, the majority of revenues currently generated from sales of manual test kits are expected to be diminished over time and we expect that any future revenues will be primarily derived from product fees that are generated from the sale of automated tests by Abbott (and our other automated partners when and if their automated tests become available). However, there can be no assurance that we will generate increased product fees from the sale of automated tests. We will need to generate significant product revenue to achieve profitability.

Even as we seek to increase our sales of our BGM Galectin-3 Test, increase product revenue from the sale of automated tests by Abbott, and launch additional automated versions of our galectin-3 test, we expect our losses to continue as a result of manufacturing, sales and marketing support of our automated partners, and other ongoing expenses. These losses, among other things, have had and will continue to have an adverse effect on our working capital, total assets and stockholders' equity. Because of the numerous risks and uncertainties associated with our commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and then maintain profitability, our business, financial condition and results of operations will be negatively affected and the market value of our common stock will decline.

If we are unsuccessful in the execution of our commercial strategy, our business, financial condition, results of operations and prospects will be materially adversely affected.

We have implemented a commercial strategy that is intended to generate revenues through the widespread market adoption of our BGM Galectin-3 Test and automated galectin-3 testing. In support of this strategy, we have supported clinical research studies that have been designed to provide evidence of the clinical utility of our products, to further differentiate our products and to otherwise support the commercial introduction of our BGM Galectin-3 Test, automated galectin-3 testing and future products in our pipeline. We are unable to give any assurance that we will be successful in executing our commercial strategy or that we will be successful in providing evidence of clinical utility of our products, differentiating our products or otherwise supporting our products in the manner, timeframe or under the cost parameters we anticipate, if at all. Even if we execute this strategy as planned, we may not yield the increased revenues and market growth that we anticipate. Our failure to be commercially successful in implementing our new commercialization strategy would materially adversely impact our business, financial condition, results of operations and prospects.

Our business is dependent on our ability to successfully commercialize novel diagnostic tests. If we fail to develop and commercialize these products, we may be unable to execute our business plan.

Historically, we have generated revenues from initiatives, collaborations and biomarker discovery and analysis services agreements with pharmaceutical companies and health care organizations. Our current business strategy, however, focuses on commercializing diagnostic tests that incorporate biomarkers that we in-license and/or identify through data mining and outsourced laboratory analysis of specific patient cohorts and specimen repositories. Beginning in November 2012, we have shifted our focus from early stage biomarker discovery toward a more commercially-oriented role in which we have generated and supported studies that have been designed to provide evidence of clinical utility, further differentiate and support the BGM Galectin-3 Test and future products in our pipeline. We expect that our commercial strategy will continue to increasingly rely on the success of our automated partners to commercialize automated versions of the galectin-3 test. We do not expect to receive future revenue from performing biomarker discovery and analysis services for third parties. The success of our business will depend on our ability to commercialize diagnostic tests based on the products in our current pipeline, as well as others that we may in-license in the future, and the ability of our automated partners to commercialize automated versions of our galectin-3 test.

Prior to commercializing our diagnostic tests, we are required to undertake time-consuming and costly development activities, sometimes including clinical studies, and to obtain regulatory clearance or approval, for which the outcome is uncertain. We have limited experience in developing and commercializing diagnostic tests and there are considerable risks involved in these activities. The science and methods that we are employing are innovative and complex, and any product development program in which we may engage in the future may not ultimately yield diagnostic tests for commercialization. Products that appear promising in early development may fail to be validated in subsequent studies, and even if we achieve positive results, we may still fail to obtain the necessary regulatory clearances or approvals. Few research and development projects result in commercial products, and perceived viability in early clinical studies often is not replicated in later studies. At any point, we may abandon development of a product candidate, or we may be required to expend considerable resources obtaining additional clinical and nonclinical data, which would adversely impact the timing for generating potential revenue from those product candidates. If our development programs yield fewer commercial products than we expect, we may be unable to execute our business plan, and our business, financial condition and results of operations may be adversely affected.

We expect that our commercial strategy will increasingly rely on the success of our automated partners to develop and commercialize automated versions of the galectin-3 test. If our automated partners fail to perform or prioritize their collaborations or terminate their agreements with us, our ability to substantially increase customer acceptance and clinical adoption of our galectin-3 test will be undermined.

Although, to date, the micro-titer plate version of the BGM Galectin-3 Test has been the primary focus of our commercialization strategy, we believe that the introduction of automated testing for galectin-3 will improve access to testing, shorten turn-around time to receive testing data, minimize objections related to the more labor intensive micro-titer plate testing method and, as a result, accelerate adoption of galectin-3 testing. To this end, we have partnered with four leading diagnostic instrument manufacturers to develop automated versions of our galectin-3 test. We also expect that the introduction of automated testing for galectin-3 will result in broader customer acceptance and clinical adoption of galectin-3 testing because the four automated partners maintain broad access to major segments of the diagnostics market, including hospital laboratories, private laboratories, reference laboratories and physician office laboratories, due to the widespread coverage of their installed bases.

Automated tests for galectin-3 developed by Abbott and bioMérieux are available in Europe under a CE Mark as an aid in assessing the prognosis of chronic heart failure. The Abbott ARCHITECT ® automated galectin-3 test received 510(k) clearance from the FDA on December 23, 2014 as an aid in assessing the prognosis of chronic heart failure. On May 8, 2015, in anticipation of the U.S. market launch of the ARCHITECT ® Galectin-3 assay we amended our license and development agreement with Abbott due to market dynamic considerations since the Galectin-3 assay first began development in 2009. On July 6, 2015, we announced that the ARCHITECT ® Galectin-3 assay is available for purchase from Abbott in the United States. This is the first automated test for galectin-3 to

be introduced for commercial use in the United States. On November 24, 2015, we further amended our license and distribution agreement with Abbott, in regard to product fees paid to us by Abbott for galectin-3 tests sold by Abbott to reference laboratories, while retaining the previously negotiated product fees for the other customer segments. In consideration for the amendment, Abbott agreed to make an initial payment of $500,000 to us on November 30, 2015 and a second payment of up to $500,000 payable to us, by June 30, 2016, subject to achievement of certain commercial milestones. We expect that this modification to the agreement will expedite the transition from manual to automated testing for galectin-3. As a result, the majority of revenues currently generated from sales of manual test kits are expected to be diminished over time and we expect that any future revenues will be primarily derived from product fees that are generated from the sale of automated tests by Abbott (and our other automated partners when and if their automated tests become available). However, there can be no assurance that we will generate increased product fees from the sale of automated tests. We will need to generate significant product revenue to achieve profitability.

Under the agreements, our partners are responsible for developing and commercializing the tests. Accordingly, we are dependent upon our automated partners to prioritize the development of their respective automated versions and the regulatory clearance of their automated versions. Our partners may experience difficulties and delays in other segments of their businesses that may negatively impact their ability to prioritize and commercialize the automated versions of our test. Our partners' delays, failures or unwillingness to prioritize or devote adequate resources to develop and obtain regulatory clearance for the automated versions of our galectin-3 test would result in a substantially smaller market opportunity for our galectin-3 testing business and would adversely impact our financial condition, results of operations and prospects.

We expect that our commercial strategy will increasingly rely on the success of our automated partners to develop and commercialize automated versions of the galectin-3 test. Our automated partners may be unable to develop and/or obtain regulatory clearance of galectin-3 tests that can be performed on their automated platforms, unable to gain market acceptance for their automated galectin-3 tests, unable to commercialize their galectin-3 tests or decide not to commercialize their automated galectin-3 tests.

We have entered into worldwide license, development and commercialization agreements with Abbott, bioMérieux, Siemens and Alere. Revenues generated from the sale of automated galectin-3 tests under these agreements have, thus far, been limited. To date, only bioMérieux and Abbott have launched galectin-3 tests developed for their automated platforms in Europe, under CE Mark and, on December 23, 2014, the FDA granted 510(k) clearance for Abbott Laboratories' ARCHITECT ® Galectin-3 assay, the first FDA cleared automated blood test for galectin-3. On May 8, 2015, in anticipation of the U.S. market launch of the ARCHITECT ® Galectin-3 assay we amended our license and development agreement with Abbott due to market dynamic considerations since the Galectin-3 assay first began development in 2009. U.S. market introduction of Abbott's ARCHITECT ® Galectin-3 automated assay was initiated in July of 2015. On November 24, 2015, we amended our License and Distribution Agreement with Abbott, in regard to product fees paid to us by Abbott for galectin-3 tests sold by Abbott to reference laboratories, while retaining the previously negotiated product fees for the other customer segments. In consideration for the amendment, Abbott agreed to make an initial payment of $500,000 to us on November 30, 2015 and a second payment of up to $500,000 payable to us, by June 30, 2016, subject to achievement of certain commercial milestones. We expect that this modification to the agreement will expedite the transition from manual to automated testing for galectin-3. As a result, the majority of revenues currently generated from sales of manual test kits are expected to be diminished over time and we expect that any future revenues will be primarily derived from product fees that are generated from the sale of automated tests by Abbott (and our other automated partners when and if their automated tests become available). However, there can be no assurance that we will generate increased product fees from the sale of automated tests. We will need to generate significant product revenue to achieve profitability.

Although we expect that our commercial strategy will increasingly rely on the success of our automated partners to develop and commercialize automated versions of the galectin-3 test, we are unable to give any assurance that our automated partners will be successful in gaining market acceptance of their automated tests for galectin-3. In addition, there are a variety of risks and uncertainties that may cause delays in, or prevent our automated partners from, successfully developing or obtaining CE Mark or regulatory clearance from the FDA for automated

versions of our galectin-3 test in the timeframes we expect, or at all. Delays may result from unanticipated problems in product development, an inability to obtain regulatory clearance or approval on a timely basis. Any material delays in our partners' receipt of regulatory clearance or approval for the automated versions of our galectin-3 test, or their failure to obtain such clearances or approvals at all, would have a material adverse effect on our business, financial condition and results of operations.

While we intend to leverage the commercial capabilities of our automated partners to promote the utility of our tests to clinicians, laboratory decision makers, payers, patients and other stakeholders, even if we are able to implement this strategy, we will be largely dependent on these third parties for the commercial success of our products. They may not deploy the resources we would like them to, and our revenue would then suffer. In addition, we could become embroiled in disputes with these parties regarding the terms of any agreements, their performance or intellectual property rights. Any dispute could disrupt the sales of our products and adversely affect our reputation and revenue. Failure of our strategy to leverage the expertise, marketing resources and installed base of our automated partners would have a material adverse effect on our future business, financial condition and results of operations.

The product fee provisions in the agreements with our partners for the automated versions of our galectin-3 test are subject to renegotiation and following renegotiation, the royalties payable to us may not be favorable to us.

The agreements we entered into with our partners who are developing and commercializing the automated versions of our galectin-3 test contain provisions that, under certain circumstances, entitle our partners to reduce the product fee amounts payable to us on the sales of their tests in amounts that are subject to negotiation by us and our respective partners. In some cases, our partners' rights to reduce the product fee amounts are triggered by the CMS payment rate being below certain agreed-upon thresholds and in other cases, our partners' rights to reduce the royalty amounts payable to us are triggered by the average selling prices for the tests in certain regions being below certain agreed-upon price thresholds. Effective January 1, 2014 the payment rate at which our BGM Galectin-3 Test is reimbursed by CMS was increased to $30.01 from $17.80 per test. In 2015, the national limitation amount for our BGM Galectin-3 Test was reduced to $29.93 and applied across the U.S., except in Ohio and West Virginia where rates of $23.93 and $26.33, respectively, applied. In 2016, the national limitation amount for our BGM Galectin-3 Test was increased to $29.96 and applies across the U.S., except in Ohio and West Virginia where rates of $23.95 and $26.36, respectively, apply. Even with the increase from 2013, the CMS payment rate for calendar years 2014, 2015 and 2016 are below the agreed-upon CMS payment rate thresholds in the agreements with certain of our automated partners. Accordingly, the current royalty amounts payable to us under these agreements are subject to reduction by our partners, in amounts to be negotiated by us and our respective partners. On May 8, 2015, in anticipation of the U.S. market launch of the ARCHITECT ® Galectin-3 assay we amended our license and development agreement with Abbott due to market dynamic considerations since the Galectin-3 assay first began development in 2009. On November 24, 2015, we further amended our license and distribution agreement with Abbott, in regard to product fees paid to us by Abbott for galectin-3 tests sold by Abbott to reference laboratories, while retaining the previously negotiated product fees for the other customer segments. There can be no assurance that in any future renegotiation of these product fee provisions we will be successful in negotiating new rates that will be favorable to us.

We may not be able to successfully commercialize our BGM Galectin-3 Test and our automated partners may not be able to successfully commercialize their automated tests for galectin-3 in the timeframes we expect, or at all.

Our first product, the BGM Galectin-3 Test, received clearance from the FDA in late 2010 and is commercially available throughout the United States as an aid in assessing the prognosis of patients suffering from chronic heart failure. In Europe, our BGM Galectin-3 Test is commercially available under a CE Mark as an aid in assessing the prognosis of patients suffering from acute and chronic heart failure and as an aid in identifying individuals in the general population who are at risk of developing heart failure. bioMérieux and Abbott have launched galectin-3 tests developed for their automated platforms in Europe, under CE Mark and, beginning in July of 2015, Abbott launched its automated ARCHITECT ® Galectin-3 assay in the United States. In the United States, our BGM Galectin-3 Test kits and the Abbott automated galectin-3 test are purchased by clinical, hospital and reference laboratories, clinical research organizations and pharmaceutical manufacturers. In Europe, our

BGM Galectin-3 Test kits and the bioMérieux and Abbott automated tests for galectin-3 are purchased by independent sales distributors, hospital and research laboratories, clinical research organizations and pharmaceutical manufacturers. We are unable to give any assurance that we will be successful in generating revenues from adoption of the BGM Galectin-3 Test or that our automated partners will be successful in generating revenues from adoption of their automated galectin-3 tests. Even if we are successful in generating revenue from the sale of the BGM Galectin-3 Test or our automated partners are successful in generating revenue from the sale of their automated galectin-3 tests, we may not generate the increased revenues and market growth that we anticipate. Our failure to generate revenue from the sale of the BGM Galectin-3 Test or product fees from the sale of automated tests for galectin-3 by our automated partners would materially adversely impact our business, financial condition, results of operations and prospects.

In pursuing our commercialization strategy for our BGM Galectin-3 Test for heart failure, we are particularly dependent upon True Health Diagnostics, formerly Health Diagnostic Laboratory, Inc., or HDL, which was responsible for approximately 71% of our BGM Galectin-3 Test kit sales in 2015. If True Health Diagnostics fails to purchase our galectin-3 tests at the same or greater levels as HDL purchased our tests during 2015, our results of operations could be materially adversely affected. Any disruption in True Health Diagnostic's operations or problems that otherwise adversely affect our business relationship with them could result in a delay or interruption of the sales volume of our galectin-3 test.

In March 2011, we entered into a supply agreement with HDL, pursuant to which HDL agreed to purchase BGM Galectin-3 Test kits from us and to offer galectin-3 testing services to physicians in the United States. On June 7, 2015, HDL, the largest customer of our BGM Galectin-3 ® Test (manual micro-titer plate platform) with sales that represented approximately 71%, 83% and 75% of our product revenues for the fiscal year ended December 31, 2015, December 31, 2014 and December 31, 2013, respectively, filed a voluntary petition for bankruptcy protection under Chapter 11 in the United States Bankruptcy Court for the Eastern District of Virginia, Richmond Division. Since HDL's bankruptcy filing, we have received substantially smaller and less frequent orders from HDL than we had received previously. In light of this filing, we provided a provision for doubtful accounts of $151,000 in the second quarter of 2015 for sales made to HDL totaling $254,995 prior to their June 7 th bankruptcy filing for which we had not yet received payment. With court approval, HDL continued to operate its business, to purchase tests kits from us in the ordinary course and agreed to accelerated payment terms and a limitation on amounts owed to the Company on such new orders. Shipments of galectin-3 test kits to HDL resumed on June 15, 2015 at volumes that were initially comparable to those that had been shipped immediately prior to the June 7, 2015 bankruptcy filing, but, subsequently declined beginning in the third quarter of 2015. In accordance with the post-bankruptcy accelerated payment terms, we received timely payment from HDL for kit shipments that we made to them after June 15, 2015. On September 11, 2015, True Health Diagnostics announced the acquisition of HDL, in a court-supervised auction, pursuant to a court approved plan of liquidation or reorganization. True Health Diagnostics declined to assume our supply agreement with HDL, which expired in March of 2016, but has continued to purchase BGM Galectin-3 Test kits from us and to offer galectin-3 testing services to physicians in the United States. Such orders from True Health Diagnostics, however, remain substantially smaller and less frequent than the orders we received previously from HDL. On February 11, 2016, HDL filed its Amended Disclosure Statement, seeking solicitation in favor of its Second Amended Plan of Liquidation, or the Plan. The court approved Disclosure Statement summarized HDL's proposed Plan, which provides that all allowed administrative expense claims will be paid in full and that all allowed general unsecured claims will be paid their pro rata portion of funds in a liquidating trust. A hearing to consider confirmation of the Plan was held on March 29, 2016. To the extent the Plan is confirmed and our administrative expense claim is allowed, we will receive a full distribution on account of such claim from HDL in the amount of $83,356.52, however, it is uncertain when HDL will make such distribution. Further, to the extent the Plan is confirmed, it is, as yet, uncertain what distribution, if any, will be made to us on account of our general unsecured claim to offset our provision for doubtful accounts on account of allowed claims related to the sale of BGM Galectin-3 Test kits to HDL prior to their filing for bankruptcy protection under Chapter 11. HDL, now True Health Diagnostics, accounted for 71% of our product revenues for the fiscal year ended December 31, 2015.

We may suffer significant losses as a result of any business interruptions experienced by True Health Diagnostics or if our relationship with them is otherwise adversely affected. Any prolonged disruption in their operations or problems that otherwise undermine our business relationship with them could have a significant negative impact

on our ability to execute on our commercialization strategy for our galectin-3 test in the United States and to maintain or increase the sales volume of our galectin-3 test. In addition, True Health Diagnostics is not obligated to continue to purchase BGM Galectin-3 Test kits as True Health Diagnostics declined to assume our supply agreement with HDL, which expired in March 2016.

Purchases of BGM Galectin-3 Test kits by research laboratories, clinical research organizations and pharmaceutical manufacturers who are employing the test for research purposes may fluctuate and impact sales volume of our galectin-3 test.

There is considerable interest in evaluating the measurement of galectin-3 as part of both heart failure and non-heart failure related preclinical and clinical research projects. Purchases of BGM Galectin-3 kits made by research laboratories, clinical research organizations and pharmaceutical manufacturers represent a potentially significant source of our revenue. However, sales related to test kit purchases made for research purposes may fluctuate significantly over time due to the fact that these purchases are typically buyer initiated, study specific and are dependent on the availability of research funding. In addition, low cost test kits containing research grade reagents that have not been cleared by regulatory authorities may be used for non-clinical testing of galectin-3 by some investigators. Accordingly, sales related to research applications of our BGM Galectin-3 Test kits may fluctuate widely over time and negatively impact on our ability to predict, maintain or increase the sales volume of our galectin-3 test.

We may not be able to provide evidence of clinical utility or to differentiate our galectin-3 testing through clinical research studies in the timeframes we expect, or at all.

We support clinical research studies performed by third party investigators that have been designed to provide evidence of the clinical utility of our galectin-3 testing and to differentiate its performance from other diagnostic products. The results of these studies are essential to our efforts to ensure customer acceptance and clinical adoption of galectin-3 testing. The results of these studies support our efforts to promote our BGM Galectin-3 Test and to educate potential customers. We may be unable to demonstrate that galectin-3 testing provides incremental benefits over currently available heart failure diagnostic tests sufficient to ensure adoption of our test in the timeframes we expect, or at all.

Furthermore, since we have limited technical, managerial and financial resources we may be unable to support clinical research studies that have been designed to provide evidence of the clinical utility of our BGM Galectin-3 Test and to differentiate its performance from other diagnostic products. Due to our limited technical, managerial and financial resources we have had to curtail certain clinical research activities that might otherwise have led to the development of additional evidence regarding the incremental benefits associated with galectin-3 testing.

We are unable to give any assurance that we will be successful in providing sufficient evidence of clinical utility of galectin-3 testing or differentiate from other diagnostic products in the manner, timeframe or under the cost parameters we anticipate, if at all. If we are unable to provide evidence of clinical utility and differentiate galectin-3 testing, we may not be able to generate the increased revenues and market growth that we anticipate. Our failure to generate revenue from the sale of the galectin-3 tests would materially adversely impact our business, financial condition, results of operations and prospects.

We may not be able to provide evidence of clinical utility or to differentiate our future pipeline products, including new indications for galectin-3 testing.

Our ability to successfully commercialize the future pipeline products that we may develop will depend on numerous factors, including whether health care providers believe that any other diagnostic tests that we successfully develop provide sufficient incremental clinical utility; whether the medical community accepts that our diagnostic products have sufficient sensitivity, specificity and predictive value to be meaningful in patient care and treatment decisions; and whether health insurers, government health programs and other third-party payers will cover and pay for our diagnostic tests and the amount that they will reimburse. These factors may

present obstacles to commercial acceptance of our diagnostic product candidates. To the extent these obstacles arise, we will need to devote substantial time and resources to overcome these obstacles, and we might not be successful. Failure to achieve widespread market acceptance of our diagnostic products would materially harm our business, financial condition and results of operations.

We are unable to give any assurance that we will be successful in providing sufficient evidence of clinical utility or any assurance that we will have adequate managerial, technical or financial resources to support the studies necessary to provide sufficient evidence of clinical utility of our future products including new indications for galectin-3 testing or differentiate from other diagnostic products in the manner, timeframe or cost parameters we anticipate, if at all. If we are unable to provide evidence of clinical utility and differentiate our future products including new indications for galectin-3 testing, we will not be able to generate the increased revenues and market growth that we seek. Our failure to generate revenue from the sale of current or future products including the BGM Galectin-3 Test would materially adversely impact our business, financial condition, results of operations and prospects.

We may not be able to successfully commercialize our BGM Galectin-3 Test and our automated partners may not be able to successfully commercialize their automated tests for galectin-3 because the clinical indications for use do not generate broad enough customer acceptance.

We believe that the measurement of the protein biomarker galectin-3 in patients with heart failure may facilitate treatment decisions that are made regarding the intensity, locale, and nature of a heart failure patient's ongoing care. We believe that results obtained from testing with our BGM Galectin-3 Test or automated tests for galectin-3 generated on the testing platforms developed by our automated partners may be used to aid in the assessment of prognosis, reduce hospital readmissions, and help identify patients who may require more intense and specialized care such as referral to a heart failure specialist, the need for advanced diagnostics and therapies, and the need for other specialized forms of monitoring. We cannot be certain that these or other indications for use will generate broad enough customer acceptance to yield the increased revenues and market growth that we seek from adoption of the BGM Galectin-3 Test or automated tests for galectin-3. Our failure to generate sufficiently broad customer acceptance and widespread market adoption of the BGM Galectin-3 Test and automated testing for galectin-3 would materially adversely impact our business, financial condition, results of operations and prospects.

If the marketplace does not accept our automated partners' automated tests for galectin-3 or our BGM Galectin-3 Test, we may be unable to generate sufficient revenue to sustain and grow our business.

Although we believe that our BGM Galectin-3 Test and automated tests for galectin-3 developed by our automated partners represent promising commercial opportunities, these products may never gain significant acceptance in the marketplace and therefore never generate substantial revenue or profits for us. As is the case with all novel biomarkers, we and our automated partners must establish markets for our diagnostic tests and build those markets through physician education and awareness programs. Our ability to market our products through physician education and awareness programs is currently limited as the result of our recent Restructuring, which eliminated our sales and marketing organization. Publication in peer reviewed journals of results from studies using our products will be an important consideration in the adoption by physicians of our products, but will be dependent on the interest of third party investigators, the funding and execution of well-designed clinical research studies, the nature of the results generated by these studies, and the extent to which third party investigators who perform these studies make the effort to communicate and publish the results of these studies. The process of publication in leading medical journals is subject to a peer review process. Peer reviewers may not consider the results of studies of our BGM Galectin-3 Test or automated tests for galectin-3 sufficiently novel or worthy of publication. Failure to have studies related to our BGM Galectin-3 Test or automated tests for galectin-3 published in peer reviewed journals may adversely affect adoption of our products.

Health insurers and other third-party payers may decide not to reimburse our diagnostic products or may provide inadequate reimbursement, which could jeopardize our commercial prospects.

In the United States, the regulatory process that allows diagnostic tests to be marketed is independent of any coverage determinations made by third-party payers. For new diagnostic tests, private and government payers

decide whether to cover the test, the reimbursement amount for a covered test and the specific conditions for reimbursement. Physicians may order diagnostic tests that are not reimbursed by third-party payers, but coverage determinations and reimbursement levels and conditions are critical to the commercial success of a diagnostic product.

Each third-party payer makes its own decision about which tests it will cover and how much it will pay, although many payers will follow the lead of Medicare. As a result, the coverage determination process is often a time-consuming and costly process that requires us to provide scientific and clinical support for the use of each of our products to each payer separately, with no assurance that approval will be obtained. If third-party payers decide not to cover our diagnostic tests or if they offer inadequate payment amounts, our ability to generate revenue from our diagnostic tests could be limited. Even if one or more third-party payers decide to reimburse for our tests, a third-party payer may stop or lower payment at any time, which could reduce revenue. We cannot predict whether third-party payers will cover our tests or offer adequate reimbursement. We also cannot predict the timing of such decisions. In addition, physicians or patients may decide not to order our tests if third-party payments are inadequate, especially if ordering the test could result in financial liability for the patient.

In the United States, the American Medical Association assigns specific CPT codes, which are a medical nomenclature used to report medical procedures and services under public and private health insurance plans. Once the CPT code is established, the CMS establishes reimbursement payment levels and coverage rules for Medicare, and private payers establish rates and coverage rules independently. Payment for diagnostic tests furnished to Medicare beneficiaries is made based on a fee schedule set by CMS that reflects its established reimbursement payment levels and coverage rules for Medicare.

Effective January 1, 2014, the payment rate at which the blood test for galectin-3 was reimbursed by CMS was increased to $30.01 from $17.80 per test. In addition, the 2014 national limitation amount was subject to a 2% sequestration applicable to Medicare services. In 2015, the national limitation amount for the blood test for galectin-3 was reduced to $29.93 and applied across the U.S., except in Ohio and West Virginia where rates of $23.93 and $26.33, respectively, applied. In 2016, the national limitation amount for the galectin-3 blood test was increased to $29.96, which applies across the U.S., except in Ohio and West Virginia where rates were increased to $23.95 and $26.36, respectively. Additionally, any or all of our diagnostic tests developed in the future may not be approved for reimbursement or may be approved at a level that limits our commercial success.

Reimbursement decisions in the European Union and in other jurisdictions outside of the United States vary by country and region and there can be no assurance that we will be successful in obtaining adequate reimbursement.

We expect to face intense competition, often from companies with greater resources and experience than us.

The clinical diagnostics industry is highly competitive and subject to rapid change. The industry continues to expand and evolve as an increasing number of competitors and potential competitors enter the market. Many of these competitors and potential competitors have substantially greater financial, technological, managerial and research and development resources and experience than we do. Some of these competitors and potential competitors have more experience than we do in the development of diagnostic products, including validation procedures and regulatory matters. In addition, our diagnostic products compete with product offerings from large and well-established companies that have greater marketing and sales experience and capabilities than we do. We are aware of other diagnostic tests under development, which, if successfully developed and commercialized, would compete with our products.

Our competitors, some of whom we collaborate with and rely on to commercialize our products, may include established diagnostics companies, such as Abbott Diagnostics, Alere, Beckman Coulter, bioMérieux, General Electric, Mitsubishi, Ortho Clinical Diagnostics, Philips, Roche Diagnostics and Siemens. In addition, national

commercial laboratories with extensive service networks for diagnostic tests, such as LabCorp and Quest Diagnostics, have expanded or acquired testing capabilities to include more specialized cardiovascular testing. Specialized cardiovascular CLIA laboratories such as Atherotech, Berkeley Heart Lab (now part of Quest Diagnostics), Bioreference Lab (now part of OPKO Health), Boston Heart Diagnostics (formerly Boston Heart Lab and now part of Eurofins), Cardio DX, Cleveland HeartLab, Liposcience (now part of LabCorp) and True Health Diagnostics (formerly Health Diagnostic Laboratory) have expanded their presence and product menu in the cardiovascular market and some have developed their own tests or panels. Companies that may compete with us in the cardiovascular diagnostics market include Athena Diagnostics (now part of Quest Diagnostics), Atherotech, Berkeley Heart Lab, Critical Diagnostics, Bioreference Lab (now part of OPKO Health), Dako (now part of Agilent Technologies), diaDexus, Myriad Genetics, Singulex and True Health Diagnostics (formerly HDL). Companies that may compete with us in the research market include BioVendor, DRG International, eBioscience, IBL, Kamiya, R&D Systems and Thermo Fisher Scientific.

We are dependent on third parties for the patient samples that are essential to the development and validation of our diagnostic tests.

To pursue our development and validation of our diagnostic tests, we need access, over time, to thousands of patient samples, including blood, blood plasma and serum, urine and other fluids. We do not have direct access to a supply of patient samples. As a result, we have made arrangements with third parties, such as academic medical centers, government programs and payers such as Humana that have given us access to a significant number of patient samples for the development and validation of our diagnostic tests. Most of the institutions and physicians from which we obtain biological specimens that we use in our research and validation work are "Covered Entities" under HIPAA. Under this law, these parties may have to obtain proper authorization from their patients, de-identify samples or take some other step to permit the subsequent use of those samples and associated clinical information. We are not presently a Covered Entity or a Business Associate of a Covered Entity subject to HIPAA, but we may become a Covered Entity or a Business Associate of a Covered Entity in the future. We may lose access to patient samples provided by such third parties, or have that access limited, because the third parties decrease the number of patient samples they provide, due to changes in privacy laws governing the use and disclosure of medical information or due to changes in the laws restricting our ability to obtain patient samples and associated information. In certain instances, we owe the party providing the samples for our research programs payments which may be related to the sales of products derived from those research programs. In addition, we may be forced to actively pursue patient samples from other sources for the diagnostic testing indications we pursue, which could be expensive and time consuming. If we fail to secure and maintain an adequate supply of patient samples, or if our existing supply arrangements are terminated or result in access to fewer samples than expected, our ability to pursue our development efforts may be slowed or halted, which could have a material adverse effect on our business, financial condition and results of operations. Additionally, if we engage in activities that make us a covered entity for HIPAA purposes, such as electronic billing of third party payers, we will have to implement a comprehensive HIPAA compliance program. HIPAA compliance is a costly and time consuming process. Failure to comply would have a material adverse effect on our business, financial condition and results of operations.

We are dependent on laboratory contractors for testing of patient samples that are essential to the development and validation of our diagnostic tests.

To pursue our development and validation of our diagnostic tests, we periodically need access to test results obtained from patient samples, including blood, blood plasma and serum, urine and other fluids. We do not operate a testing laboratory. As a result, we purchase testing services from third party laboratories, such as those associated with academic medical centers, hospitals and independent reference laboratories to perform testing on patient samples for the development and validation of our diagnostic tests. The testing laboratories are typically licensed, certified per the Clinical Laboratory Improvement Act (CLIA) and, often, also certified by the College of American Pathologists. All specimens and associated patient information are handled according to HIPAA and

other regulations associated with laboratory testing. Failure to access contracted laboratory services would have a material adverse effect on our ability to develop and validate our diagnostic tests.

Risks Related To Regulatory Approval and Other Government Regulations

The process of obtaining regulatory clearances or approvals to market medical devices, including in vitro diagnostic test kits, from the FDA and similar regulatory authorities outside of the United States can be costly and time-consuming.

In pursuing our strategy of commercializing our products worldwide, we face various regulatory schemes and requirements. Each regulatory agency may impose its own requirements and may refuse to grant approval or may require additional data before granting marketing approval even if marketing approval has been granted by other agencies. For example, in seeking clearance from the FDA for our galectin-3 test, we relied on samples from previously concluded studies sponsored by other parties to determine the clinical utility of our galectin-3 test, and we may do so for our other product candidates. While the FDA accepted such data in support of our galectin-3 test, and we believe it has accepted such data in other cases, the FDA may require us to conduct our own prospective studies to support future product clearances or approvals, which would make the development and validation of our product candidates more costly and time-consuming. There can be no assurance that such clearances or approvals will be granted on a timely basis or at all.

Although we have received FDA clearance for our BGM Galectin-3 Test for use as an aid in assessing the prognosis of patients diagnosed with chronic heart failure, we and our automated partners may not obtain regulatory clearance for additional indications that we and our automated partners may seek in the future.

In the United States, we may seek FDA clearance or approval for our products prior to their launch for clinical use, whether offered as a diagnostic kit or laboratory service. The FDA process can be lengthy and unpredictable. For example, for our first product, the BGM Galectin-3 Test for heart failure, we initially filed for premarket 510(k) notification with the FDA in March 2009. Upon review of our 510(k) filing, the FDA determined that our device was not substantially equivalent to the legally marketed device to which we claimed substantial equivalence and therefore denied clearance. The FDA indicated that additional clinical and other data were required in support of our filing, and we filed a new premarket 510(k) notification in December 2009, incorporating additional data. In February 2010, we received a letter from the FDA that requested additional clinical and statistical information to support our filing. After further contact with the FDA, we submitted our formal response to the FDA letter in August 2010. We received 510(k) clearance from the FDA in November 2010 for our BGM Galectin-3 Test as an aid in assessing the prognosis of patients diagnosed with chronic heart failure. In May 2012, we filed a premarket 510(k) notification with the FDA for use of the BGM Galectin-3 Test to aid in the identification of individuals who are healthy and asymptomatic at the time of testing, but, who are at increased risk for developing heart failure in the future. In July 2012, we received a letter from the FDA regarding this 510(k) filing in which FDA requested additional information, including information regarding our analytical validation and our clinical validation study, the Framingham Heart Study. We submitted our response to the FDA in November 2012, but based on our dialogue with the FDA, the nature of the additional information requested and the time required to address the FDA's questions regarding various matters including the age of the blood samples used to support our 510(k) filing, we allowed the 510(k) to expire on the January 23, 2013 deadline for submitting our response to the FDA.

On March 31, 2015, we filed for premarket 510(k) notification with the FDA in order to obtain regulatory clearance to market our BGM Galectin-3 Test in the United States for a new indication for use, as an aid in the assessment of near-term risk of fatal cardiovascular events in older adults who have no prior history of coronary heart disease, cerebrovascular disease, or vascular disease. In August 2015, we received a request for additional information from the FDA, including information regarding the intended use of our test for this new indication, our clinical validation study and additional statistical analyses. We submitted our response to the FDA in November 2015. On December 17, 2015, we conducted a follow up discussion with the FDA regarding our

November 2015 response. On December 18, 2015, following that additional dialogue with the FDA, we concluded that demonstrating the clinical utility of our test for this proposed new indication would require a broadening of the defined indication to include aiding in the assessment of the near-term risk of both fatal and non-fatal cardiovascular events in our study population and, as a result, a new 510(k) submission. Accordingly, we submitted to the FDA a notice of withdrawal of the 510(k) notification that we submitted on March 31, 2015. We are evaluating what additional data, studies and analyses would be required to support a new submission and a broader indication for use if we choose to resubmit this proposed indication for use to the FDA. There can be no assurance as to when we may be in a position to submit additional new premarket 510(k) notifications for this or other indications for our galectin-3 test to the FDA, if at all, nor can there be any assurance that we will receive 510(k) clearance from the FDA for this new or other new indications for use.

Subject to obtaining substantial additional financing, we expect to pursue new clinical claims and indications for the BGM Galectin-3 Test in assessing heart failure, as well as in related disorders. Expansion of the product label to include new clinical claims and indications for use will require additional clinical studies and clearance, or approval, by regulatory bodies, such as the FDA, and inclusion in our CE Mark for use in the EU. Our ability to engage in these activities would require us to obtain substantial additional financing. There can be no assurance as to if and when we may be in a position to submit additional new premarket 510(k) notifications for new indications for our galectin-3 test to the FDA, if at all, nor can there be any assurance that we will receive 510(k) clearance from the FDA for any new indications for use.

Although we have received FDA clearance for our BGM Galectin-3 Test for heart failure, our automated partners may not obtain regulatory clearance for their automated tests for galectin-3 when expected, if at all.

We believe that automation of our galectin-3 test will broaden its acceptance by laboratory customers and, as a result, accelerate its clinical adoption. To that end, we have entered into licensing and commercialization agreements with four leading diagnostic instrument manufacturers to develop and commercialize automated instrument versions of our galectin-3 test. Commercial introduction of the automated versions of our galectin-3 test will require FDA clearance or approval. On December 23, 2014, the FDA granted 510(k) clearance for Abbott Laboratories' (Abbott) ARCHITECT ® Galectin-3 assay, the first FDA cleared automated blood test for Galectin-3. There can be no assurances that our other automated partners will be successful in gaining FDA clearance.

Changes in regulatory review procedures, approval requirements or enactment of additional regulatory approval requirements in Europe may delay or prevent us from marketing our proposed products.

To market our products in Europe, we must obtain a CE Mark and may, in some cases, need marketing approval from the European Medicines Agency. In October 2009, we obtained a CE Mark in Europe for our first product, the BGM Galectin-3 Test for heart failure. In December 2012, we obtained a CE Mark in Europe for our second product, the CardioSCORE test. In addition, we have partnered with four leading diagnostic instrument manufacturers to develop automated tests for galectin-3. In January 2013, bioMérieux obtained a CE Mark in Europe. In April 2013, Abbott obtained a CE mark for its automated version of our galectin-3 test. To date, we have found the CE Mark process to be an efficient means to obtain regularly approval, thereby allowing for market entry for our products in Europe and in other countries that recognize CE Mark. If, however, the CE Mark process becomes more onerous, costly or time-consuming, we will need to re-evaluate our ex-U.S. commercialization strategy and invest more of our limited resources before even entering the market with our products.

Our CardioSCORE test has not been cleared by the FDA for sale in the United States.

We do not currently receive revenue from sales of our CardioSCORE test, which currently may only be marketed in Europe and other countries that recognize CE Mark. In December 2011, we filed a premarket 510(k) notification with the FDA in order to obtain regulatory clearance to market the CardioSCORE test in the

United States as an aid in the assessment of near-term risk for significant cardiovascular events, such as heart attack and stroke. In response to this filing, the FDA requested that we engage an independent committee of physicians to conduct a medical review and adjudication of clinical endpoints reported in the filing. Due to the time involved in responding to this request, we withdrew the 510(k) filing on August 8, 2012. Our medical review also included the assessment of sample stability and the evaluation of other technical issues raised by the FDA. The adjudication process is now complete. While we continue to explore potential opportunities to monetize CardioSCORE, we have redirected our resources to support our development and commercialization of galectin-3 testing. Currently, we are not actively engaged in development or commercialization activities related to CardioSCORE. There can be no assurance that we will receive significant revenue from sales of our CardioSCORE test in Europe, that we will succeed in otherwise monetizing CardioSCORE, that in the future we will file a premarket 510(k) notification with the FDA to obtain regulatory clearance to market the CardioSCORE test in the United States or that we will receive such clearance.

Our BGM Galectin-3 Test for heart failure and any future products cleared by the FDA will be subject to ongoing regulation by the FDA. Failure to comply with such regulation could cause a material adverse effect on our business, financial condition and results of operations.

After a device is placed on the market, numerous regulatory requirements apply. These include:

- compliance with the FDA's quality system regulation, or QSR;
- labeling regulations, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on marketing; and
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters;
- fines, injunctions, and civil penalties;
- recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusal to grant 510(k) clearance or PMAs of new products;
- withdrawal of 510(k) clearance or PMAs that are already granted; and
- criminal prosecution.

Being subject to any of these sanctions could adversely affect our business, financial condition and results of operations.

Even if we are successful in obtaining regulatory clearance or approval for our product candidates, we will be subject to regulations under additional federal and state laws.

If we develop diagnostic tests suitable for commercialization, and after receiving all necessary regulatory clearances and approvals, we will be subject to national, regional and local regulations. For example, in the United States, the regulations which we may be subject to include:

- the federal Food, Drug and Cosmetic Act and its related rules, regulations, guidance documents and other interpretations relating to the manufacture and marketing of medical products;
- the federal Medicare and Medicaid Anti-kickback Law, and state anti-kickback prohibitions;
- the federal physician self-referral prohibition, commonly known as the Stark Law, and the state equivalents;

- HIPAA;
- the various state laws governing patient privacy; and
- the federal civil and criminal False Claims Act.

The risk of our being found in violation of these laws and regulations is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations.

Any action brought against us for violation of these laws or regulations, even if we prevail, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines. We could also be required to refund any improperly received payments, and we could be required to further curtail our operations. Any of the foregoing consequences could seriously harm our business, financial condition and results of operations.

If we or our third-party manufacturer fail to comply with the FDA's quality system regulation, the development and manufacture of our products could be delayed or interrupted and our products may be subject to product recalls.

We and our contract manufacturers are required to comply with the FDA's QSR and other regulations which cover, among other things, the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. The FDA monitors compliance with QSR through periodic inspections. If the FDA determines that we or our contractors are not in compliance with applicable regulatory standards, we could be prevented or forced to delay the development or manufacture of our products, which could have a material adverse effect on our business, financial condition and results of operations. Moreover, any failure to maintain QSR compliance could force us to cease the development or manufacture of our products and subject us to other enforcement sanctions, including withdrawal of our products from the U.S. or foreign markets, and delay or interrupt the development or manufacture of additional products.

Health care reform measures could hinder or prevent our product candidates' commercial success.

The U.S. government and other governments have shown significant interest in pursuing health care reform. Any government-adopted reform measures could adversely impact the pricing of health care products, including our diagnostic products, and services in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third-party payers. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payers of health care services to contain or reduce health care costs may adversely affect our ability to set prices we believe are fair for any diagnostic products we may develop and commercialize. Changes in health care policy, such as the creation of broad limits for diagnostic products, could substantially interrupt the sale of future diagnostic tests, increase costs, divert management's attention and adversely affect our ability to generate revenues and achieve profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, relating to health care availability, methods of delivery or payment for diagnostic products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development or commercialization programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the U.S. government, new health care legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect our ability to sell any diagnostic products we may develop and commercialize profitably. Some of these proposed and implemented reforms could result in reduced reimbursement rates for our diagnostic products, which would adversely affect our business

strategy, operations and financial results. For example, in March 2010, President Obama signed into law a legislative overhaul of the U.S. health care system, known as the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010, or the PPACA, which may have far reaching consequences for life science companies like us. As a result of this legislation, substantial changes could be made to the current system for paying for health care in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services, drugs and devices. These structural changes could entail modifications to the existing system of private payers and government programs, such as Medicare and Medicaid, the creation of a government-sponsored health care insurance source, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the United States could impact the reimbursement for prescribed drugs, biopharmaceuticals, medical devices or our product candidates. If reimbursement for our approved product candidates, if any, is substantially less than we expect in the future, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted. In addition, certain members of Congress remain fixated on the repeal of some or all of PPACA, adding further uncertainty to the law's future impact on us.

Further federal and state proposals and health care reforms could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. Our results of operations could be materially adversely affected by the PPACA, by the Medicare prescription drug coverage legislation, by the possible effect of such current or future legislation on amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future.

Risks Related to Our Intellectual Property

If the combination of patents, trade secrets and contractual provisions that we rely on to protect our intellectual property proves inadequate, our ability to successfully commercialize our proposed products will be harmed and we may never be able to operate our business profitably.

Our success depends, in large part, on our ability to protect proprietary methods, discoveries and diagnostic tests that we develop under the patent and other intellectual property laws of the United States and other countries, so that we can seek to prevent others from unlawfully using our inventions and proprietary information. We rely on both patents and trade secrets to protect the proprietary aspects of our methods and discoveries. As of February 29, 2016, we have six issued U.S. patents and five pending patent applications filed with the USPTO. A portion of the intellectual property that we own or license relates to our galectin-3 test. This intellectual property includes U.S. Patent Nos. 7,888,137 and 8,084,276, exclusively licensed from ACS Biomarker B.V. and six corresponding patent applications pending in the United States and abroad, as well as issued patents in Europe, Australia, Canada, China, Hong Kong and Japan. U.S. Patent No. 7,888,137 is scheduled to expire in November 2026 and U.S. Patent No. 8,084,276 is scheduled to expire in September 2024. We own a U.S. patent application and corresponding foreign patents and patent applications relating to a specific method and kit for detecting galectin-3. Any patent issuing from this U.S. application could expire as early as 2029. In addition, we own one issued U.S. patent and corresponding foreign patents and patent applications related to methods for clinical evaluation of subjects based on galectin-3 measurements. A portion of the intellectual property that we own relates to our CardioSCORE test. This intellectual property includes U.S. Patent Application No. 12/946,470, an issued patent in Europe and an issued patent in Japan, and U.S. Patent Application No. 13/765,366 and one corresponding patent application abroad. Any patent issuing from the earliest-filed U.S. application could expire as early as 2030. For the diagnostic tests that we develop based on our biomarker discoveries, we expect to rely primarily on patent protection. Several of our patent applications are in an early stage of prosecution, and we cannot assure you that any of the pending patent applications will result in patents being issued. In addition, due to technological changes that may affect our proposed products or judicial interpretation of the scope of our patents, our proposed products might not, now or in the future, be adequately covered by our patents.

The patentability of molecular biomarkers and of test methods and products based on biomarkers is well-established in most countries. However, the issuance of any patent, including the patents for which we have applied, and the validity of the resulting patent rights depend upon a detailed interpretation of the specific patent claims and prior art, among other considerations, and generally is highly uncertain because of the complex legal and factual considerations it involves. In recent years, the United States Supreme Court has rendered several decisions in patent cases limiting the types of inventions for which patent protection is available and in particular, for claimed inventions directed to a law of nature, a natural phenomenon, or an abstract idea (collectively, the "judicial exceptions" to patent eligibility). For example, on March 20, 2012, the United States Supreme Court rendered its decision in Mayo Collaborative Services v. Prometheus Laboratories, Inc., in which the Court denied patent protection for patent claims covering methods that correlate the concentration of a well-known drug metabolite to the likely harm or ineffectiveness of the drug as a means of determining proper drug dosage. At issue was whether the claimed methods transformed unpatentable laws of nature into patent-eligible applications of those laws of nature. The Court held that the patent claims at issue effectively claim the underlying laws of nature themselves and thus ran afoul of the prohibition on patenting laws of nature, were not patent eligible and therefore, were determined to be invalid. In another example, on June 19, 2014, the United States Supreme Court reaffirmed in Alice Corporation Pty. Ltd. v. CLS Bank International that a patent claim directed to a judicial exception is invalid unless the claim recites additional elements that amount to "significantly more" than a law of nature, a natural phenomenon, or an abstract idea. As a result, unless the claims of our U.S. patents contain sufficient inventive content above and beyond the natural correlations underlying our claimed processes, we will not succeed in enforcing our U.S. patents. Similarly, unless the claims of our pending U.S. patent applications that involve natural correlations contain sufficient inventive content above and beyond those natural correlations, we may be unable to obtain issued U.S. patents based on those applications, which may preclude or limit the patent protection available for our diagnostic tests and therapeutic methods.

In addition, we cannot be certain that we hold the rights to the technology covered by pending patent applications or to other proprietary technology required for us to commercialize our current and proposed products. Rights in applications filed by us or our licensors may be affected adversely by patent applications filed by others which have not yet been published. For example, because certain U.S. patent applications are confidential until patents issue, such as applications filed prior to November 29, 2000, or applications filed after that date which will not be filed in foreign countries, third parties may have filed patent applications for technology covered by our pending patent applications without our being aware of those applications, and our patent applications may not have priority over those applications. For this and other reasons, we may be unable to secure desired patent rights, thereby losing desired exclusivity or co-exclusivity. It is also possible that one or more organizations will hold patent rights to which we will need a license. If those organizations refuse to grant us a license to such patent rights on reasonable terms, we will not be able to market our products.

If third parties assert that we have infringed their patents and proprietary rights or challenge the validity of our patents and proprietary rights, we may become involved in intellectual property disputes and litigation that would be costly, time consuming, and delay or prevent the development or commercialization of our current and proposed products.

Our ability to commercialize our current and proposed products depends on our ability to develop, manufacture, market and sell our current and proposed products without infringing the proprietary rights of third parties. Third parties may allege that our proposed products or our methods or discoveries infringe their intellectual property rights. Numerous U.S. and foreign patents and pending patent applications, which are owned by third parties, exist in fields that relate to our proposed products and our underlying methodologies and discoveries, including patents and patent applications claiming methods for the discovery of biomarkers or biomarker sets and assay systems and methods designed to exploit them clinically in drug discovery efforts or in selection of patients.

A third party may sue us for infringing its patent rights. Likewise, we may need to resort to litigation to enforce a patent issued or licensed to us or to determine the scope and validity of third-party proprietary rights. In addition, a third party may claim that we have improperly obtained or used its confidential or proprietary information. The

cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial, and the litigation would divert our management's attention from other aspects of our business. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

If we are found to infringe upon intellectual property rights of third parties, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties' patent rights. In addition to any damages we might have to pay, a court could require us to stop the infringing activity or obtain a license. Any license required under any patent may not be made available on commercially acceptable terms, if at all. In addition, such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some or all of our products, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Moreover, we expect that a number of our collaborations will provide that royalties payable to us for licenses to our intellectual property may be offset by amounts paid by our collaborators to third parties who have competing or superior intellectual property positions in the relevant fields, which could result in significant reductions in our revenue from products developed through collaborations.

Many of our employees were previously employed at universities or other biotechnology, pharmaceutical or diagnostic products companies, including our competitors or potential competitors. While we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have inadvertently or otherwise used or disclosed the former employer's intellectual property, trade secrets or other proprietary information. Litigation based on such allegations may be brought against us, and even if we are successful in defending ourselves, we could incur substantial costs and our management could be distracted. If we fail in defending such allegations, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel.

If we fail to comply with our obligations in the agreements under which we license development or commercialization rights to products or technology from third parties, we could lose license rights that are important to our business.

Several of our collaboration agreements provide for licenses to us of intellectual property or sharing of rights to intellectual property that is important to our business, and we may enter into additional agreements in the future that provide licenses to us of valuable technology. These licenses impose, and future licenses may impose, various commercialization milestones and other obligations on us, including the obligation to terminate our use of patented subject matter under certain contingencies. If a licensor becomes entitled to, and exercises, termination rights under a license, we would lose valuable rights and our ability to develop our products. We may need to license other intellectual property to commercialize future products. Our business may suffer if any current or future licenses terminate, if the licensors fail to abide by the terms of the license or fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid or if we are unable to enter into necessary licenses on acceptable terms.

If we are unable to protect our trade secrets, we may be unable to protect our interests in proprietary technology, processes and know-how that is not patentable or for which we have elected not to seek patent protection.

In addition to patented technology, we rely upon unpatented proprietary technology, processes and know-how, including, particularly, our biomarker discovery methodologies. In an effort to protect our unpatented proprietary technology, processes and know-how, we require our employees, consultants, collaborators, contract manufacturers and advisors to execute confidentiality agreements. These agreements, however, may not provide us with adequate protection against improper use or disclosure of confidential information, in particular as we are

required to make such information available to a larger pool of people as we seek to validate and commercialize our proposed products. These agreements may be breached, and we may not become aware of, or have adequate remedies in the event of, any such breach. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees and consultants have previous employment or consulting relationships. Also, others may independently develop substantially equivalent technology, processes and know-how or otherwise gain access to our trade secrets. If we are unable to protect the confidentiality of our proprietary technology, processes and know-how, competitors may be able to use this information to develop products that compete with our products, which could adversely impact our business.

Risks Related To the Growth of Our Management Team, Workforce, Manufacturing and Facilities

Following our reduction in force since September 2014, which resulted in the elimination of approximately 77% of our headcount, we may not be able to retain our remaining employees.

Since September 11, 2014, we have implemented a reduction of approximately 77% of our workforce, or 17 people, leaving five employees, which we refer to as the Restructuring. We took this step in order to reduce our operating expenses and extend our cash runway in anticipation of the commercial launch of automated versions of our galectin-3 test. The automated galectin-3 tests are being developed and commercialized by our diagnostic instrument manufacturing partners and will be performed on our partners' automated platforms. The first automated test for galectin-3 was launched in the United States by Abbott in mid-year 2015. The Restructuring primarily eliminated our sales and marketing organization and removed certain positions in other functional areas, while preserving some senior management and other critical roles to support the clinical and commercial adoption of galectin-3 testing by generating, publishing and publicizing data derived from clinical research studies and by expanding the BGM Galectin-3 Test's labeling indications for use through additional clinical studies and clearances by the FDA.

As a result of the Restructuring, we are heavily dependent upon our ability to retain our remaining employees. The loss of the service of any of our remaining employees may significantly delay or prevent our ability to continue our operations. Given the magnitude of our reduction in force since September 2014, the morale of our remaining employees may be lower, employees may be distracted and any one of our remaining employees could terminate his or her employment with us at any time. A departing employee's expertise would be difficult to replace and the failure to do so on a timely basis could have a material adverse effect on our ability to achieve our business goals. There can be no assurance that we will have the financial resources or otherwise to be successful in retaining our remaining personnel and our failure to do so could have a material adverse effect on our business, financial condition and results of operations. In addition, the Restructuring may prove to be more disruptive to our operations than we anticipated. For example, cost savings measures may distract management from our core business, harm our reputation, yield unanticipated consequences, such as attrition beyond the planned Restructuring, or increased difficulties in our day-to-day operations. Any failure to retain our qualified personnel could prevent us from successfully growing our business by expanding the number of health care clinical laboratories, hospitals, and health care providers with which we do business or impair our ability to maintain sales levels of, and/or support sales growth of, our galectin-3 test.

We have only a limited number of employees to manage and operate our business.

As of March 15, 2016, we employed five full-time employees. Due to our limited cash, we have implemented a plan designed to focus our capital resources on our most promising indications and further reduce our cash utilization. Our focus on reducing our cash utilization requires us to manage and operate our business in a highly efficient manner. We cannot assure you that we will be able to retain adequate staffing levels to run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish.

Failures in our information technology and storage systems could significantly disrupt our operations.

Our ability to execute our business plan depends, in part, on the continued and uninterrupted performance of our information technology systems, or IT systems. Despite the implementation of security measures, IT systems are vulnerable to damage from a variety of sources, including computer viruses, unauthorized access, telecommunications or network failures, malicious human acts, terrorism and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our IT systems, sustained or repeated system failures that interrupt our ability to generate and maintain data, could result in a material disruption in our operations. Furthermore, to the extent that any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our business could be significantly harmed.

We rely on a single third party to manufacture and supply our products. Any problems experienced by this vendor could result in a delay or interruption in the supply of our products to us until this vendor cures the problem or until we locate and qualify an alternative source of supply.

The manufacture of our diagnostic products requires specialized equipment and utilizes complicated production processes that would be difficult, time-consuming and costly to duplicate. Corgenix Medical Corporation is currently the sole third-party manufacturer of our BGM Galectin-3 Test. Any prolonged disruption in the operations of our third-party manufacturer could have a significant negative impact on our ability to manufacture products on our own and would cause us to seek additional third-party manufacturing contracts, thereby increasing our commercialization and any development costs, which may not be available on acceptable terms, if at all. We may suffer losses as a result of business interruptions that exceed coverage under our manufacturer's insurance policies. Events beyond our control, such as natural disasters, fire, sabotage or business accidents could have a significant negative impact on our operations by disrupting our product development and commercialization efforts until our third-party manufacturer can repair its facility or put in place third-party contract manufacturers to assume this manufacturing role, which we may not be able to do on reasonable terms, if at all. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer or the re-verification of an existing manufacturer could negatively affect our ability to develop product candidates or produce approved products in a timely manner. Any delay or interruption in our clinical studies for the validation and commercialization of our products or product candidates could negatively affect our business.

If we become subject to product liability claims, we may be required to pay damages that exceed our insurance coverage, and such claims may harm our business in other ways.

Our business exposes us to product liability claims that are inherent in the testing, production, marketing and sale of diagnostic products. Although we currently maintain limited product liability insurance, we may need to secure additional product liability insurance for the development and commercialization of our product candidates. We cannot be certain whether we will be able to secure such insurance on commercially reasonable terms, or at all. A product liability claim in excess of any insurance coverage we may obtain would have to be paid out of our cash reserves and would significantly harm our business. In addition, any injunction or other restriction on our ability to sell against one of our product candidates would also significantly harm our business.

The marketing, sale and use of our current or future diagnostic tests could lead to the filing of product liability claims if someone were to allege that our product failed to perform as it was designed. A product liability claim could result in substantial damages and be costly and time consuming for us to defend. We cannot provide assurance that our product liability insurance would protect us from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our insurance

rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could cause injury to our reputation, result in the recall of our products, or cause current collaborators to terminate existing agreements and potential collaborators to seek other partners, any of which could impact our results of operations.

Risks Related To Our Common Stock

The holders of our Series A Preferred Stock are entitled to rights and preferences that are significantly greater than the rights and preferences of the holders of our common stock, including preferential payments upon a liquidation, as well as dividend and registration rights associated with their shares.

On July 14, 2015, we issued an aggregate of 1,474,443 shares of newly designated Series A Preferred Stock, $0.001 par value per share, or Series A Preferred Stock. Holders of our Series A Preferred Stock are entitled to a number of rights and preferences which holders of our outstanding common stock do not and will not have. Among these rights and preferences is a preference on liquidation of the Company, which means that holders of the Series A Preferred Stock will be entitled to receive the proceeds out of any liquidation of the Company before any such proceeds are paid to holders of our common stock. Upon liquidation, including deemed liquidations pursuant to a merger, consolidation or a sale of all or substantially all of our assets, the holders of Series A Preferred Stock will be entitled to be paid first out of any proceeds in the amount of $1.7003 per share, which was the price at which shares of Series A Preferred Stock were sold on July 14, 2015, plus all accrued but unpaid dividends on the shares of Series A Preferred Stock, and prior to payment of any amounts on our common stock. Thereafter, the holders of Series A Preferred Stock will also share pro rata on an as converted to common stock basis in payments made to the holders of our common stock. Accordingly, the holders of the Series A Preferred Stock will be entitled to receive the proceeds out of any sale or liquidation of the Company before any such proceeds are paid to holders of our common stock and then share in any proceeds paid to holders of our common stock. As a result, only the sale or liquidation proceeds in excess of the liquidation preference plus accrued but unpaid dividends would be available for distribution to holders of our common stock. Therefore, if we wind down our operations for any reason, it is likely that our common stockholders will lose their entire investment in us.

Holders of our Series A Preferred Stock also have significant rights with respect to certain actions that the Company may wish to take from time to time. At any time prior to the conversion of the Series A Preferred Stock, the consent of the holders of at least a majority of the Series A Preferred Stock then outstanding, voting together as a single class, will be required for the Company to take certain actions, including, among other things: liquidating, dissolving or winding up the business and affairs of the Company or effecting any merger, consolidation or other liquidation event; amending, altering or repealing any provision of the Certificate of Incorporation, the Certificate of Designations of the Series A Preferred Stock or the Bylaws of the Company; creating or authorizing any class or series of capital stock ranking senior to or on parity with the Series A Preferred Stock or increasing the number of authorized shares of Series A Preferred Stock; purchasing, redeeming, paying or declaring dividends on any shares of our capital stock, with certain exceptions; increasing or decreasing the size of our board of directors; and certain other actions. As a result, we will not be able to take any of these actions without first seeking and obtaining the approval of the holders of our Series A Preferred Stock. We may not be able to obtain such approval in a timely manner or at all, even if we think that taking the action for which we seek approval is in the best interests of the Company.

On July 14, 2015, we also entered into the Fifth Amended and Restated Investor Rights Agreement, or the Investor Rights Agreement, with the holders of our Series A Preferred Stock, as well as the stockholders who hold shares of our common stock that are registrable securities our then existing Fourth Amended and Restated Investor Rights Agreement dated as of July 10, 2008. Under the terms of the Investor Rights Agreement, we granted certain demand and piggyback registration rights with respect to the shares of common stock issuable upon conversion of the Series A Preferred Stock. Sales of a substantial number of shares of our common stock in the public market could occur in the future. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock.

The holders of the Series A Preferred Stock represent a significant voting interest in the Company.

Each share of Series A Preferred Stock is convertible into one share of our common stock, at any time at the option of each holder and automatically upon the written consent of the holders of a majority of the outstanding shares of Series A Preferred Stock. Assuming the full conversion of all of the shares of Series A Preferred Stock into our common stock, the holders of the Series A Preferred Stock and their affiliates would represent approximately 28.3% of our issued and outstanding capital stock as of March 15, 2016. Prior to such conversion, holders of Series A Preferred Stock will be entitled to vote with the holders of our common stock on an as-converted basis, except that no holder of Series A Preferred Stock will be entitled to cast votes for the number of shares of common stock issuable upon conversion of the Series A Preferred Stock held by such holder that exceeds (subject to a proportionate adjustment in the event of a stock split, stock dividend, combination or other proportionate recapitalization) the quotient of (A) the aggregate purchase price paid by such holder for its Series A Preferred Stock, divided by (B) the greater of (i) $3.20 and (ii) the closing price of our common stock on the trading day immediately prior to the date our Series A Preferred Stock was issued, which was $1.40. Therefore, as of March 15, 2016, the holders of Series A Preferred Stock and their affiliates held approximately 17.3% of the voting power of the Company.

Our common stock is quoted on the OTCQB and we expect to deregister our common stock under the Exchange Act, which could result in a limited market for our common stock. Additionally, our affiliates hold approximately 14.8% of our outstanding shares of common stock, as of March 15, 2016, which substantially reduces the liquidity of our common stock and contributes to the limited trading volume for our common stock.

Our common stock had been listed on The NASDAQ Capital Market until September 15, 2015, when it was suspended for failure to comply with The NASDAQ Capital Market continued listing standards. On September 16, 2015, our common stock began trading on the OTC Markets' OTCQB market tier under the trading symbol "BGMD." In addition, given the significant cost and resource demands of being a public company, we have determined that it is advisable to terminate the registration of our common stock under the Exchange Act and we anticipate filing a Form 15 with the SEC to effect the deregistration in April 2016. Upon the filing of the Form 15, our obligation to file periodic and current reports with the SEC, including Forms 10-K, 10-Q, and 8-K, will be suspended. The delisting of our common stock from The NASDAQ Capital Market and the anticipated deregistration of our common stock under the Exchange Act could substantially further reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, the delisting and the anticipated deregistration could negatively affect us by reducing the number of investors willing to hold or acquire our common stock, which could negatively affect our ability to raise capital, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. We cannot predict whether a more active market for our common stock will develop in the future. An absence of an active trading market could adversely affect our stockholders' ability to sell our common stock at current market prices in short time periods, or possibly at all. Additionally, market visibility for our common stock may be limited and such lack of visibility may have a depressive effect on the market price for our common stock.

Our affiliates hold approximately 14.8% of our outstanding shares of common stock, as of March 15, 2016, which adversely affects the liquidity of the trading market for our common stock; in as much as federal securities laws restrict sales of our shares by these stockholders. If our affiliates continue to hold their shares of common stock, there will be limited trading volume in our common stock, which may make it more difficult for investors to sell their shares or increase the volatility of our stock price.

Our stock price is likely to be volatile and the market price of our common stock may drop.

Prior to our initial public offering in February 2011, there was no public market for our common stock and having been a publicly traded company for only five years, there can be no assurance that an active trading market will develop and continue. There is a limited history, exacerbated by low average daily trading volume, on which to gauge the volatility of our stock price. The stock markets and the markets for medical diagnostics and biotechnology stocks in particular, have experienced volatility that has often been unrelated to the operating

performance of particular companies. For example, our common stock traded as high as $2.77 per share and as low as $0.33 per share during 2015, as adjusted to reflect the 1-for-4 reverse stock split of our common stock effected in July 2015. Some of the many factors that may cause the market price of our common stock to fluctuate include:

- our ability to commercialize the products, if any, that we are able to develop;
- sales of automated tests by our automated partners;
- the progress and results of our product candidate development efforts;
- actions taken by regulatory authorities with respect to our product candidates, or our sales and marketing activities;
- regulatory developments in the United States, the European Union and other jurisdictions;
- the outcome of legal actions to which we may become a party;
- announcements concerning product development results or intellectual property rights of others;
- announcements of technological innovations or new products by us or our competitors;
- changes in financial estimates or recommendations by securities analysts;
- uncertainty as to if and when we will engage in any strategic transaction;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- restatements of our financial results and/or material weaknesses in our internal controls;
- publication of research reports about us or the diagnostic products industry by securities or industry analysts;
- fluctuations in our operating results; and
- deviations in our operating results from the estimates of securities analysts or other analyst comments.

Any broad market fluctuations may adversely affect the trading price of our common stock. Investors may not be able to sell when they desire due to insufficient buyer demand and may realize less than, or lose all of, their investment.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our financial condition, operating results and reputation.

Insiders control a substantial amount of our outstanding common stock and all of our outstanding preferred stock, which could delay or prevent a change in corporate control or result in the entrenchment of management and/or the board of directors.

Our executive officers, directors, principal stockholders and/or their affiliates, including Flagship Ventures, or Flagship, control approximately 14.8% of our outstanding common stock and all of our outstanding Series A Preferred Stock, representing approximately 20.3% of the voting power of the Company as of March 15, 2016. Accordingly, these stockholders, if acting as a group, or Flagship, which alone controls approximately 11.6% of our outstanding common stock and all of our outstanding Series A Preferred Stock, representing approximately 17.3% of the voting power of the Company as of March 15, 2016, will have control or substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors and the approval of significant corporate transactions, and they may in some instances exercise this control or substantial influence in a manner that advances their best interests and not necessarily those of other stockholders. In addition, at any time prior to the conversion of the Series A Preferred Stock, the consent of the holders of at least a majority of the Series A Preferred Stock then outstanding, voting together as a single class, will be required for the Company to take certain actions, including, among other things: liquidating, dissolving or winding up the business and affairs of the Company or effecting any merger, consolidation or other liquidation event; amending, altering or repealing any provision of the Certificate of Incorporation, the Certificate of Designations of the Series A Preferred Stock or the Bylaws of the Company; creating or authorizing any class or series of capital

stock ranking senior to or on parity with the Series A Preferred Stock or increasing the number of authorized shares of Series A Preferred Stock; purchasing, redeeming, paying or declaring dividends on any shares of our capital stock, with certain exceptions; increasing or decreasing the size of our board of directors; and certain other actions. As a result, we will not be able to take any of these actions without first seeking and obtaining the approval of Flagship, as the holder of our Series A Preferred Stock. This concentration of ownership and voting rights may have the effect of delaying, preventing or deterring a change of control, could deprive investors of the opportunity to receive a premium for our common stock as part of a sale and could adversely affect the market price of our common stock.

The requirements of being a public company require greater resources, increase our costs and distract our management, and we may be unable to comply with these requirements in a timely or cost-effective manner.

As a public company with equity securities quoted on the OTC Market's OTCQB market tier, until we voluntarily deregister our common stock under the Exchange Act, we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. We are currently required to comply with certain rules, regulations and requirements with which we were not required to comply prior to becoming a public company.

Until we voluntarily deregister our common stock under the Exchange Act, complying with rules, regulations and requirements requires substantial effort on the part of our board of directors and management and will continue to increase our costs and expenses. As a public company, we are required to:

- institute and maintain a more formalized function of internal control over financial reporting;
- prepare and distribute periodic and current public reports;
- maintain internal policies relating to disclosure controls and procedures and insider trading, among others;
- involve and retain to a greater degree outside counsel and accountants in the above activities; and
- maintain an investor relations function, including the provision of certain information on our website.

Compliance with these rules and regulations will continue to increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these new rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage.

Coverage of our company by securities or industry analysts is very limited and intermittent. If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our common stock adversely, the price and trading volume of our common stock could decline.

The trading market for our common stock is influenced by the research and reports that a very limited number of industry or securities analysts may publish about us or our industry. If one or more analysts make unfavorable comments about our market opportunity or product candidates or downgrade our common stock, the market price of our common stock would likely decline. If one or more analysts fail to publish reports on us, we could lose visibility in the financial markets, which could cause the market price of our common stock or trading volume to decline.

Raising additional capital may cause dilution to existing stockholders, restrict our operations or require us to relinquish rights.

We may seek the additional capital necessary to fund our operations through private equity offerings, debt financings, and collaborative and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing stockholders ownership interests will be diluted and the terms may include liquidation or other preferences that adversely affect their rights as a stockholder. Additional

debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or grant licenses on terms that are not favorable to us.

Because we do not intend to pay dividends for the foreseeable future, our stockholders will benefit from their investment in shares only if our common stock appreciates in value.

We have not paid dividends to our stockholders since our inception. The holders of our Series A Preferred Stock are entitled to receive, out of funds legally available for the payment of dividends under Delaware law, cumulative dividends that accrue daily at an annual rate of 8%, compounded and payable quarterly in cash or in additional shares of Series A Preferred Stock at the election of each holder. The holders of our Series A Preferred Stock will also be entitled to participate in cash dividends and in-kind distributions made on shares of our common stock. At December 31, 2015, the cumulative undeclared dividends on preferred stock total $92,000. In addition, if we declare, make or pay any dividend in respect of our common stock, the holders of our Series A Preferred Stock will be entitled to receive payment of such dividend that would be payable as if the Series A Preferred Stock had been converted into shares of common stock. The payment of cash dividends also requires the consent of the holders of our Series A Preferred Stock. We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. As a result, the success of an investment in our common stock will depend upon any future appreciation in their value.

Provisions of our certificate of incorporation, our bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove the current members of our board and management.

Certain provisions of our restated certificate of incorporation and restated bylaws could discourage, delay or prevent a merger, acquisition or other change of control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove members of our board of directors. These provisions also could limit the price that investors might be willing to pay in the future for our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions:

- allow the authorized number of directors to be changed only by resolution of our board of directors;
- establish a classified board of directors, such that not all members of the board of directors may be elected at one time;
- authorize our board of directors to issue without stockholder approval preferred stock, the rights of which will be determined at the discretion of the board of directors that, if issued, could operate as a “poison pill” to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit stockholder action by written consent;
- establish advance notice requirements for stockholder nominations to our board of directors or for stockholder proposals that can be acted on at stockholder meetings;
- limit who may call stockholder meetings; and
- require the approval of the holders of 80% of the outstanding shares of our capital stock entitled to vote in order to amend certain provisions of our restated certificate of incorporation and restated bylaws.

In addition, pursuant to the Certificate of Designation of our Series A Preferred Stock, holders of our Series A Preferred Stock also have significant rights with respect to certain actions that the Company may wish to take from time to time. At any time prior to the conversion of the Series A Preferred Stock, the consent of the holders

of at least a majority of the Series A Preferred Stock then outstanding, voting together as a single class, will be required for the Company to take certain actions, including, among other things, effecting any merger, consolidation or other liquidation event. As a result, we will not be able to take any of these actions without first seeking and obtaining the approval of the holders of our Series A Preferred Stock. In addition, we may not be able to obtain such approval in a timely manner or at all, even if we think that taking the action for which we seek approval is in the best interests of the Company.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of the voting rights on our common stock, from merging or combining with us for a prescribed period of time.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

We lease approximately 800 square feet of office space at 303 Wyman Street, Waltham, Massachusetts 02451. The term of our current lease expires in June 2016 with an option to renew in six-month increments.

We also lease approximately 11,700 square feet of office space at 880 Winter Street, Waltham, Massachusetts 02451. In June 2015, we subleased the 880 Winter Street office space to a third party from June 1, 2015 through December 31, 2018, covering the balance of the underlying lease term.

Item 3. LEGAL PROCEEDINGS

We are not a party to any litigation in any court, and management is not aware of any pending proceeding by any governmental authority against us.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock began trading on the NASDAQ Global Market on February 4, 2011 under the symbol "BGMD" and was transferred to the NASDAQ Capital Market on January 27, 2014 where it continued to trade under the same symbol until September 15, 2015, when it was suspended for failure to comply with The NASDAQ Capital Market continued listing standards. On September 16, 2015, our common stock began trading on the OTC Markets' OTCQB market tier under the trading symbol "BGMD."

The following table sets forth the high and low sales prices per share of our common stock reported by NASDAQ and the high and low bid quotations per share of our common stock reported by the OTCQB for the applicable periods when the common stock was listed on The NASDAQ Global Market, The NASDAQ Capital Market or the OTCQB, as applicable, for the periods indicated.

On July 8, 2015, we effected a 1-for-4 reverse stock split of our common stock. All of the per share prices in the table below have been adjusted to reflect the effect of this reverse stock split.

2015:	High	Low
First Quarter	$4.88	$1.44
Second Quarter	$3.48	$2.00
Third Quarter	$2.77	$0.34
Fourth Quarter	$0.80	$0.33

2014:	High	Low
First Quarter	$9.68	$4.00
Second Quarter	$8.08	$3.60
Third Quarter	$4.48	$2.00
Fourth Quarter	$2.60	$1.08

Stockholders

As of March 15, 2016, there were approximately 27 stockholders of record of the 11,319,475 outstanding shares of our common stock.

Dividends

We have not paid dividends to our stockholders since our inception. The holders of our Series A Preferred Stock are entitled to receive, out of funds legally available for the payment of dividends under Delaware law, cumulative dividends that accrue daily at an annual rate of 8%, compounded and payable quarterly in cash or in additional shares of Series A Preferred Stock at the election of each holder. The holders of our Series A Preferred Stock will also be entitled to participate in cash dividends and in-kind distributions made on shares of our common stock. At December 31, 2015, the cumulative undeclared dividends on preferred stock total $92,000. In addition, if we declare, make or pay any dividend in respect of our common stock, the holders of our Series A Preferred Stock will be entitled to receive payment of such dividend that would be payable as if the Series A Preferred Stock had been converted into shares of common stock. The payment of cash dividends also requires the consent of the holders of our Series A Preferred Stock. We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future.

Unregistered Sales of Securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. SELECTED FINANCIAL DATA

The following table sets forth our consolidated financial data for each of the five years in the period ended December 31, 2015. The selected financial data for each of the five years in the period ended December 31, 2015 have been derived from our audited consolidated financial statements. The audited consolidated financial statements as of December 31, 2015 and 2014 and for the years ended December 31, 2015, 2014 and 2013, are included elsewhere in this Annual Report on Form 10-K. The information below should be read in conjunction with such audited consolidated financial statements (and notes thereon) and "Management's Discussion and Analysis of Financial Condition and Results of Operations," included in Item 7.

Consolidated statements of operations data:	2015	2014	2013	2012	2011
	(in thousands, except share and per share data)				
Revenues					
Product revenues	$ 1,405	$ 2,698	$ 3,635	$ 2,570	$ 451
Partnership revenues	21	—	—	—	—
Product fee revenues	140	89	48	—	—
Service revenues	—	—	390	245	1,183
Total revenues	1,566	2,787	4,073	2,815	1,634
Costs and operating expenses:					
Product and product fee costs	505	956	1,247	841	172
Service costs	—	—	142	116	447
Research and development	1,774	2,393	3,735	7,582	7,998
Selling and marketing	302	2,293	6,193	9,451	5,293
General and administrative	3,615	4,507	7,130	7,553	5,209
Total costs and operating expenses	6,196	10,149	18,447	25,543	19,119
Loss from operations	(4,630)	(7,362)	(14,374)	(22,728)	(17,485)
Non-cash consideration associated with stock purchase agreement	—	—	(329)	—	—
Interest income	—	2	15	22	31
Interest expense	(159)	(728)	(1,168)	(1,083)	(89)
Other (expense) income	(514)	24	7	20	(39)
Net loss	(5,303)	(8,064)	(15,849)	(23,769)	(17,582)
Preferred stock dividend	(92)	—	—	—	—
Deemed dividend on beneficial conversion feature	(1,507)	—	—	—	—
Accretion of convertible preferred stock to liquidation value	(56)	—	—	—	—
Accretion of redeemable convertible preferred stock	—	—	—	—	(118)
Net loss attributable to common stockholders	(6,958)	$ (8,064)	$ (15,849)	$ (23,769)	$ (17,700)
Net loss attributable to common stockholders per share – basic and diluted	$ (0.72)	$ (0.99)	$ (2.33)	$ (4.70)	$ (4.01)
Weighted-average common shares outstanding used in computing per share amounts – basic and diluted	9,609,408	8,175,805	6,803,209	5,053,989	4,409,535

Consolidated balance sheets data:	As of December 31,				
	2015	2014	2013	2012	2011
			(in thousands)		
Cash, cash equivalents, restricted cash, and marketable securities	$ 1,525	$ 4,123	$ 7,751	$ 13,176	$ 24,439
Total assets	2,133	5,229	9,353	15,241	26,110
Long-term debt, including current portion	—	2,960	7,314	9,857	—
Total liabilities	1,515	4,672	10,422	14,932	5,218
Convertible preferred stock	2,594	—	—	—	—
Accumulated deficit	(166,305)	(161,002)	(152,938)	(137,089)	(113,320)
Total stockholders' (deficit) equity	(1,976)	557	(1,069)	309	20,892

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following in conjunction with the "Selected Financial Data" and our consolidated financial statements and the related notes thereto that appear elsewhere in this Annual Report on Form 10-K. In addition to historical information, the following discussion and analysis includes forward looking information that involves risks, uncertainties and assumptions. Our actual results and the timing of events could differ materially from those anticipated by these forward looking statements as a result of many factors, including those discussed under "Risk Factors" contained in Item 1A of this Annual Report on Form 10-K.

Overview

We are commercializing diagnostic products that may be used to help guide the care and management of patients who suffer from heart failure and related disorders.

Our BGM Galectin-3 ® Test is our first FDA cleared and CE Marked diagnostic product. The BGM Galectin-3 ® Test is an *in vitro* diagnostic device that employs a manual micro-titer platform to quantitatively measure galectin-3 levels in blood plasma or serum for use as an aid in assessing the prognosis of chronic heart failure in conjunction with clinical evaluation. The BGM Galectin-3 ® Test is currently available as a blood test in the United States and the EU.

We have entered into licensing agreements with leading diagnostic instrument manufacturers to develop and commercialize galectin-3 assays that will be performed on automated platforms that have been incorporated into routine practice in laboratories throughout the world. On December 23, 2014, the FDA granted 510(k) clearance for Abbott's ARCHITECT ® Galectin-3 assay, the first FDA cleared automated blood test for galectin-3. The clearance was obtained based on a 510(k) submission made to the FDA in February 2014, on behalf of Abbott, by Fujirebio Diagnostics, Incorporated, or Fujirebio. On May 8, 2015, in anticipation of the U.S. market launch of the ARCHITECT ® Galectin-3 assay, we amended our license and development agreement with Abbott due to market dynamic considerations since the Galectin-3 assay first began development in 2009. On July 6, 2015, we announced that the ARCHITECT ® Galectin-3 assay is available for purchase from Abbott in the United States. This is the first automated test for galectin-3 to be introduced for commercial use in the United States. On November 24, 2015, we further amended our license and distribution agreement with Abbott, in regard to product fees paid to us by Abbott for galectin-3 tests sold by Abbott to reference laboratories, while retaining the previously negotiated product fees for the other customer segments. In consideration for the amendment, Abbott agreed to make an initial payment of $500,000 to us on November 30, 2015 and a second payment of up to $500,000 payable to us by June 30, 2016, subject to achievement of certain commercial milestones. We expect that this modification to the agreement will expedite the transition from manual to automated testing for galectin-3. As a result, the majority of revenues currently generated from sales of manual test kits are expected to be diminished over time and we expect that any future revenues will be primarily derived from product fees that are generated from the sale of automated tests by Abbott (and our other automated partners when and if their automated tests become available).

On June 7, 2015, HDL, the largest customer of our BGM Galectin-3 ® Test (manual micro-titer plate platform) with sales that represented approximately 83% and 75% of our product revenues for the fiscal years ended December 31, 2014 and December 31, 2013, respectively, filed a voluntary petition for bankruptcy protection under Chapter 11 in the United States Bankruptcy Court for the Eastern District of Virginia, Richmond Division. Since HDL's bankruptcy filing, we have received substantially smaller and less frequent orders from HDL than we had received previously. With court approval, HDL continued to operate its business, to purchase tests kits from us in the ordinary course and agreed to accelerated payment terms and a limitation on amounts owed to us on such new orders. Shipments of galectin-3 test kits to HDL resumed on June 15, 2015 at volumes that were initially comparable to those that had been shipped immediately prior to the June 7, 2015 bankruptcy filing, but, subsequently declined beginning in the third quarter of 2015. In accordance with the post-bankruptcy accelerated payment terms, we received timely payment from HDL for kit shipments that we made to them after June 15, 2015. On September 11, 2015, True Health Diagnostics announced the acquisition of HDL, in a court-supervised auction, pursuant to a court approved plan of liquidation or reorganization. True Health Diagnostics declined to assume our supply agreement with HDL, which expired in March of 2016, but has continued to purchase BGM Galectin-3 Test kits from us and to offer galectin-3 testing services to physicians in the United States. Such orders from True Health Diagnostics, however, remain substantially smaller and less frequent than the orders we received previously from HDL. On February 11, 2016, HDL filed its Amended Disclosure Statement, seeking solicitation in favor of its Second Amended Plan of Liquidation, or the Plan. The court approved Disclosure Statement summarized HDL's proposed Plan, which provides that all allowed administrative expense claims will be paid in full and that all allowed general unsecured claims will be paid their pro rata portion of funds in a liquidating trust. A hearing to consider confirmation of the Plan was held on March 29, 2016. To the extent the Plan is confirmed and our administrative expense claim is allowed, we will receive a full distribution on account of such claim from HDL in the amount of $83,356.52, however, it is uncertain when HDL will make such distribution. Further, to the extent the Plan is confirmed, it is, as yet, uncertain what distribution, if any, will be made to us on account of our general unsecured claim to offset our provision for doubtful accounts of $151,000 on account of allowed claims related to the sale of BGM Galectin-3 Test kits to HDL prior to their filing for bankruptcy protection under Chapter 11. HDL, now True Health Diagnostics, accounted for 71% of our product revenues for the fiscal year ended December 31, 2015.

We have evolved from a research and development company to a commercial diagnostics company. Our initial transition to a commercial organization began with the FDA 510(k) clearance of our first diagnostic product, the BGM Galectin-3 Test, in November 2010. The first stage of transition was substantially completed in the first half of 2013 with the elimination of research and development activities no longer core to our commercial strategy. The second stage of transition was initiated in anticipation of the U.S. introduction of automated testing for galectin-3 and the commencement of commercialization activities by our automated partners. In order to reduce operating expenses and extend our cash runway in anticipation of the commercial launch of automated testing for galectin-3, we implemented a reduction in our workforce on September 11, 2014. In so doing, we primarily eliminated our sales and marketing organizations and removed certain positions in other function areas, while preserving some senior management and other critical roles to support the clinical and commercial adoption of galectin-3 testing by providing support to the marketing and selling efforts of our automated partners, by providing support to clinical research studies that have incorporated galectin-3 testing and by expanding the BGM Galectin-3 Test's labeling indications for use through additional clinical studies and clearances by the FDA.

Given the significant cost and resource demands of being a public company, we have determined that it is advisable to terminate the registration of our common stock under the Exchange Act. We anticipate filing a Form 15 with the SEC to effect the deregistration in April 2016. After careful consideration, the Board of Directors decided to deregister based on its belief that the savings we will achieve as a result of deregistration, particularly on costs related to the preparation and filing of SEC reports and compliance with Sarbanes-Oxley obligations, will benefit stockholders, and such benefits will outweigh any advantages of continuing as an SEC reporting company. Upon the filing of the Form 15, our obligation to file periodic and current reports with the SEC, including Forms 10-K, 10-Q, and 8-K, will be suspended.

Critical Accounting Policies and Significant Judgments and Estimates

Our Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of our consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates based on historical experience and make various assumptions, which we believe to be reasonable under the circumstances, which form the basis for judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

A summary of our significant accounting policies is contained in the notes to our audited consolidated financial statements, which are included elsewhere in this Annual Report on Form 10-K. We consider our revenue recognition accounting policies to be critical to the understanding of the results of our operations.

Revenue Recognition

Revenue is recognized when the following criteria have been met: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred and risk of loss has passed; (iii) the seller's price to the buyer is fixed or determinable, and; (iv) collectability is reasonably assured.

Revenues

We recognize four classes of revenues. Product revenues are comprised of payments made to us from the sale of our products to laboratory testing services, hospitals and clinics and diagnostic testing distributors. Partnership and product fee revenues are comprised of payments made to us by our automated partners in consideration for the rights and licenses granted by us to our automated partners. Service revenues have historically been generated through initiatives, collaborations and biomarker discovery and analysis service agreements.

Product Revenues

We sell our products through supply agreements with laboratory testing services and diagnostic testing distributors and directly to hospitals and clinics. We recognize revenue when products are received by customers, at which time both title and risk of loss have passed to the customers. We negotiate credit terms on a customer-by-customer basis and products are shipped at an agreed-upon price.

Revenues are recorded net of taxes collected from customers that are remitted to governmental authorities, with the collected taxes recorded as current liabilities until remitted to the relevant government authority. Freight costs billed to customers are recorded as revenue.

We do not currently provide an allowance for sales returns as returns are only allowed for defects in workmanship. Allowances for doubtful accounts are provided for those outstanding balances considered to be uncollectible based upon historical experience and management's evaluation of the outstanding balances at year end.

Partnership Revenues

Partnership revenues are comprised of payments made to us by our automated partners in consideration for modifications made to our license and distribution agreements or in consideration for achievement of specified commercial milestones. These payments are non-refundable and not to be applied against future product fees owed to us. In the case of contract modifications, we recognize revenue upon receipt of the payments or deferred over an appropriate period based on the nature of the underlying contract changes. We recognize revenue in consideration for achievement of specified commercial milestones as the milestones are met or exceeded.

Product Fee Revenues

Product fee revenues are comprised of contractual payments made to us as consideration for the rights and licenses granted by us to our automated partners. Abbott and bioMérieux pay to us a product fee, as set forth in their respective agreements, for tests sold to third parties.

Service Revenues

Our revenues have historically been generated through initiatives, collaborations and biomarker discovery and analysis services agreements. The services we provide under these agreements typically include the integrated analysis of preclinical and/or clinical samples to identify biomarkers related to disease mechanisms. In some cases, we have retained certain intellectual property rights to the biomarkers identified in the course of these arrangements. The revenue arrangements have a stated term and we have no obligations or ongoing commitments after the specified term of the arrangement. We did not record service revenues in 2014 or 2015 and do not expect to record service revenues in 2016 or beyond.

Revenues generated from collaborations and initiatives include revenue from research services and technology licensing agreements. Under these arrangements, we are contractually obligated to provide research services and project oversight and administration. The rights to the results of the research, including any intellectual property developed, are licensed to all the members of the collaboration at the inception of the arrangement. We have accounted for all deliverables, which include the research services, oversight and administration and the rights to the intellectual property developed, as a single unit of accounting as there is no standalone value to the individual elements. We consider the terms and conditions of each agreement and recognize revenues based upon a proportional performance methodology. This methodology involves recognizing revenue over the term of the agreement, as underlying research costs are incurred, and measured on the basis of input measures such as labor or instrument hours expended. We believe that these input measures approximate the output measures as the costs incurred are directly proportional to the services that are being provided. We make adjustments, if necessary, to the estimates used in its calculations as work progresses and as such changes are known. The principal costs under these agreements are for personnel and instrumentation expenses to conduct research and development but also include costs for materials and other direct and indirect items necessary to complete the research under these agreements. Actual results may vary from our estimates.

Payments received on uncompleted long-term contracts may be greater than incurred costs and estimated earnings and have been recorded as deferred revenues in the accompanying consolidated balance sheets. Payments received prior to commencement of a contract are recorded as customer deposits.

Results of Operations

Comparison of the Years Ended December 31, 2015 and 2014

Revenues

Our revenues consist of product revenues, partnership revenues and product fee revenues.

	Years ended December 31,		% Increase/ (Decrease)
	2015	2014	
	(in thousands)		
Product revenues	$ 1,405	$ 2,698	(48%)
Partnership revenues	21	—	100%
Product fee revenues	140	89	57%
Total revenues	$ 1,566	$ 2,787	(44%)

Our product revenues are derived from sales of our BGM Galectin-3 Test. Our product revenues have been concentrated with a small number of laboratory providers generating a significant percentage of our revenues in

any given reporting period. As a result, the timing of orders from these customers may fluctuate significantly from month to month and quarter to quarter.

Product revenues decreased in 2015 by $1.3 million, to $1.4 million from $2.7 million in 2014. The decrease in product revenues resulted primarily from a 55% decline in orders from our largest customer and is in addition to the decrease experienced from 2013 described below.

Partnership revenue increased in 2015 to $21,000, from $0 in 2014. The increase relates to a $500,000 payment made to us upon execution of the fourth amendment to our agreement with Abbott, which occurred in November 2015. The amendment was principally in regard to the product fees paid to us by Abbott for galectin-3 tests sold by Abbott to reference laboratories, while retaining the previously negotiated product fee for the other customer segments. This payment has been recorded as deferred revenue and is being amortized over 24 months beginning in December 2015.

Product fee revenues are comprised of contractual payments made to us as consideration for the rights and licenses granted by us to our automated partners. Abbott and bioMérieux pay to us a product fee, as set forth in their respective agreements, for tests sold to third parties. Product fee revenues increased in 2015 by $51,000, to $140,000 from $89,000 in 2014. The increase resulted primarily from increased sales by Abbott.

In 2015 and 2014, our top three customers accounted for approximately 86% and 88%, respectively, of our galectin-3 test sales, of which our single largest customer accounted for 73% and 80%, respectively. Because of concentration in the number of our customers, the timing of orders of our galectin-3 test may fluctuate significantly from month to month and quarter to quarter.

Product and product fee costs

Our product and product fee costs consist of expenses related to our BGM Galectin-3 Test and product fees. These expenses include the contract-manufacturing of the tests, the medical device excise tax, freight and royalty expenses payable to the licensor of certain intellectual property relating to galectin-3 based on revenues generated from sales of the test and product fees received from our automated partners. Product costs exclude depreciation and amortization included in operating expenses below.

	Years ended December 31,		% Increase/ (Decrease)
	2015	2014	
	(in thousands)		
Product and product fee costs	$ 505	$ 956	(47%)
Product and product fee gross margin	67%	66%	1%

Product and product fee costs decreased by $451,000, to $505,000 in 2015 as compared to $956,000 in 2014. The decrease in product and product fee costs was commensurate with the decrease in product revenue from decreased sales of the BGM Galectin-3 Test and royalty expenses. The increase in product and product fee gross margin in 2015 relates to the increase in product fee revenues which have a higher gross margin than product revenues.

Operating expenses

	Years ended December 31,		% Decrease
	2015	2014	
	(in thousands)		
Operating expenses			
Research and development	$ 1,774	$ 2,393	(26%)
Selling and marketing	302	2,293	(87%)
General and administrative	3,615	4,507	(20%)
Operating expenses	$ 5,691	$ 9,193	(38%)

Research and development

Historically, we have incurred research and development expenses in connection with our internal biomarker discovery and development efforts. Our research and development expenses consist primarily of direct personnel costs, fees for consultants and outside services, laboratory consumables and overhead expenses. We use consultants and outside services to provide expertise or services which we do not have.

Research and development expenses decreased by 26%, or $619,000, to $1.8 million in 2015 as compared to $2.4 million in 2014. The decrease in research and development expenses for the current period over the prior period was primarily attributable to a decrease in salaries and consultant and professional service fees, partially offset by an increase in stock compensation.

Selling and marketing

Selling and marketing expenses consist primarily of costs related to supporting commercialization activities associated with our BGM Galectin-3 Test.

Selling and marketing expenses decreased by 87%, or $2.0 million, to $302,000 in 2015 as compared to $2.3 million in 2014. The decreased expenditures were primarily due to the elimination of our sales team in the third quarter of 2014.

General and administrative

General and administrative expenses consist primarily of personnel-related expenses, allocated occupancy costs, and expenses related to operating as a public company. These expenses include legal and regulatory costs, directors' and officers' insurance premiums, investor relations services, and accounting and financial reporting expenses.

General and administrative expenses decreased by 20%, or $892,000, to $3.6 million in 2015 compared to $4.5 million in 2014. This decrease is due primarily to decreases in salaries, corporate legal fees, and recruitment/relocation costs, partially offset by increases in consulting fees, bad debt expense and stock compensation.

Other income and expense

The following table summarizes other (expense) income for the years ended December 31, 2015 and 2014:

	Years ended December 31,		% Increase/ (Decrease)
	2015	2014	
	(in thousands)		
Other (expense) income			
Interest income/other income	$ 117	$ 26	350%
Interest expense	(159)	(728)	(78%)
Other expense	(631)	—	(100%)
Total other (expense) income	$ (673)	$ (702)	(4%)

Other (expense) income decreased by 4%, or $29,000, primarily resulting from our repayment of the term loan with General Electric Capital Corporation and Comerica Bank in July 2015, partially offset by a loss on the fair value of the secured convertible notes.

Comparison of the Years Ended December 31, 2014 and 2013

Revenues

Our product revenues are primarily derived from sales of our BGM Galectin-3 Test. Our product revenues have been concentrated with a small number of laboratory providers generating a significant percentage of our revenues in any given reporting period. As a result, the timing of orders from these customers may fluctuate significantly from month to month and quarter to quarter. Product revenues are comprised primarily of sales of our BGM Galectin-3 Test and decreased in 2014 by $937,000, to $2.7 million from $3.6 million in 2013. The decrease in product revenues resulted primarily from a 18% decline in orders from our largest customer.

Product fee revenues are comprised of contractual payments made to us as consideration for the rights and licenses granted by us to our automated partners. Abbott and bioMérieux pay to us a product fee, as set forth in their respective agreements, for tests sold to third parties. Product fee revenues increased in 2014 by $41,000, to $89,000 from $48,000 in 2013. The increase resulted primarily from increased sales by Abbott.

Service revenues

Our service revenues have historically been generated through initiatives, collaborations and biomarker discovery and analysis services agreements. The services we provided under these agreements typically included the integrated analysis of preclinical and/or clinical samples to identify biomarkers related to disease mechanisms. In some cases, we retained certain intellectual property rights to the biomarkers identified in the course of these arrangements. The revenue arrangements had a stated term and we had no obligations or ongoing commitments after the specified term of the arrangement. Service revenues were primarily attributable to the activities from the HRP initiative, for which all revenue has been recorded as of December 31, 2013. We did not record any service revenue in 2014 or 2015 and do not expect to record service revenue in 2016 or beyond.

	Years ended December 31,		% (Decrease) Increase
	2014	2013	
	(in thousands)		
Total revenues			
Product revenues	$ 2,698	$ 3,635	(26%)
Product fee revenues	89	48	85%
Service revenues	—	390	(100%)
Total revenues	$ 2,787	$ 4,073	(32%)

Total revenues decreased by 32%, or $1.3 million, to $2.8 million in 2014 from $4.1 million in 2013.

Product revenues are comprised primarily of sales of our BGM Galectin-3 Test and decreased in 2014 by $937,000, to $2.7 million from $3.6 million in 2013. The decrease in product revenues in 2014 results primarily from decreased sales volume from our largest customer and from third-party clinical research studies.

Product fee revenues are comprised of contractual payments made to us as consideration for the rights and licenses granted by us to our automated partners. Abbott and bioMérieux pay to us a product fee, as set forth in their respective agreements, for tests sold to third parties. Product fee revenues increased $41,000 to $89,000 in 2014 from $48,000 in 2013. The increase resulted from increased sales by both Abbott and bioMérieux.

In 2014 and 2013, our top three customers accounted for approximately 88% and 83%, respectively, of our galectin-3 test sales, of which our single largest customer accounted for 80% and 74%, respectively. Because of concentration in the number of our customers, the timing of orders of our galectin-3 test may fluctuate significantly from month to month and quarter to quarter.

Service revenues decreased by 100%, to $0 in 2014 from $390,000 in 2013. The decrease in service revenues was primarily due to the completion of program activities under our HRP initiative. There was no further revenue to recognize under this project as of December 31, 2013, and accordingly, we did not record service revenues in 2014.

Product and product fee costs

Our product and product fee costs consist of expenses related to our BGM Galectin-3 Test and product fees. These expenses include the contract-manufacturing of the tests, the medical device excise tax, freight and royalty expenses payable to the licensor of certain intellectual property relating to galectin-3 based on revenues generated from sales of the test and product fees received from our automated partners. Product costs exclude depreciation and amortization included in operating expenses below.

	Years ended December 31,		
	2014	2013	% Decrease
	(in thousands)		
Product and product fee costs	$ 956	$ 1,247	(23%)
Product gross margin	66%	66%	(0%)

Product and product fee costs decreased by $291,000, to $956,000 in 2014 as compared to $1.2 million in 2013. The decrease in product and product fee costs was commensurate with the decrease in product revenue from decreased sales of the BGM Galectin-3 Test and royalty expenses. Product gross margin in 2014 was consistent with 2013.

Service costs

Our service costs consisted primarily of expenses incurred to support our initiatives, collaborative research and development agreements and biomarker discovery and analysis services agreements. These expenses included outside services and internal personnel costs, laboratory consumables, license fees and overhead expenses.

	Years ended December 31,		
	2014	2013	% Decrease
	(in thousands)		
Service costs	$ —	$ 142	(100%)

Service costs decreased by 100%, or $142,000, to $0 in 2014 as compared to $142,000 in 2013. The decrease in service costs is attributable to the completion of program activities under the HRP initiative. We did not incur service costs in 2015 and we do not expect to incur service costs in 2016 and beyond.

Operating expenses

	Years ended December 31,		
	2014	2013	% Decrease
	(in thousands)		
Operating expenses			
Research and development	$ 2,393	$ 3,735	(36%)
Selling and marketing	2,293	6,193	(63%)
General and administrative	4,507	7,130	(37%)
Operating expenses	$ 9,193	$ 17,058	(46%)

Research and development

Historically, we have incurred research and development expenses in connection with our internal biomarker discovery and development efforts. Our research and development expenses consist primarily of direct personnel costs, fees for consultants and outside services, laboratory consumables and overhead expenses. We use consultants and outside services to provide expertise or services which we do not have.

Research and development expenses decreased by 36%, or $1.3 million, to $2.4 million in 2014 as compared to $3.7 million in 2013. The decrease was primarily attributable to a decrease in biomarker discovery research costs resulting from a strategic reorganization completed in the first half of 2013, a decrease in costs related to the CardioSCORE medical review and adjudication process, and a decrease in consulting and professional service costs.

Selling and marketing

Selling and marketing expenses consist primarily of costs related to supporting commercialization activities associated with our BGM Galectin-3 Test.

Selling and marketing expenses decreased by 63%, or $3.9 million, to $2.3 million in 2014 as compared to $6.2 million in 2013. The decreased expenditures were primarily due to the refocusing of our marketing activities from market education to commercialization and the elimination of our sales team in the third quarter of 2014.

General and administrative

General and administrative expenses consist primarily of personnel-related expenses, allocated occupancy costs, and expenses related to operating as a public company. These expenses include legal and regulatory costs, directors' and officers' insurance premiums, investor relations services, and accounting and financial reporting expenses.

General and administrative expenses decreased by 37%, or $2.6 million, to $4.5 million in 2014 compared to $7.1 million in 2013. This decrease relates primarily to reductions in compensation related charges and travel, professional fees, facilities costs, and public company expenses.

Other income and expense

The following table summarizes other (expense) income for the years ended December 31, 2014 and 2013:

	Years ended December 31,		
	2014	2013	% Decrease
	(in thousands)		
Other (expense) income			
Non-cash consideration associated with stock purchase agreement	$ —	$ (329)	(100%)
Interest income/other income	26	22	18%
Interest expense	(728)	(1,168)	(38%)
Total other (expense) income	$ (702)	$ (1,475)	(52%)

Other (expense) income decreased by 52%, or $773,000, primarily resulting from lower interest on our term loan, due to continued pay down of principal, and a non-cash commitment fee required by our stock purchase agreement with Aspire Capital Fund, LLC in 2013, whereas no such expense was incurred in 2014.

Liquidity and Capital Resources

Sources of Liquidity

We believe that our existing cash will be sufficient to fund our operations into July 2016. Until we generate significant revenues from product sales and/or product fees generated by sales of automated tests made by our automated partners to reach cash breakeven, we will need to raise additional funds to finance our operations beyond July 2016. To date, our primary sources of liquidity have included our cash balances, sales of our equity securities, our term loan, product revenue from sales of our BGM Galectin-3 Test, and service revenue from the HRP initiative. As of December 31, 2015, we had $1.5 million of cash and working capital of $771,000. As of March 25, 2016, we had cash totaling $1.0 million.

Product, Partnership, Product Fee and Service Revenues

During the fiscal years ended December 31, 2015, 2014 and 2013, we have recognized product revenues of approximately $1.4 million, $2.7 million and $3.6 million, respectively; partnership revenues of approximately $21,000, $0 and $0, respectively; product fee revenues of approximately $140,000, $89,000 and $48,000, respectively; and service revenues related to research and development initiatives and collaborations of approximately $0, $0 and $390,000, respectively. Since all revenue under the HRP initiative has been recorded as of December 31, 2013, we do not expect services revenues to continue into 2016 and beyond.

Initial Public Offering

Prior to our initial public offering in February 2011, our primary sources of liquidity were funds generated from our sale of shares of our preferred stock, debt financings, and cash receipts from our research and development collaborations and service agreements.

In 2011, we closed our initial public offering of 1,437,500 shares of our common stock. The net offering proceeds received by us, after deducting underwriting discounts and commissions and expenses incurred in connection with the offering, were approximately $34.8 million.

Follow-on Underwritten Public Offerings

On January 30, 2013, we closed a follow-on underwritten public offering of 1,725,000 shares of our common stock, which included the sale of 225,000 shares pursuant to the underwriters' over-allotment option. We received net offering proceeds of approximately $12.8 million, after deducting underwriting discounts and commissions and expenses incurred in connection with the offering.

On April 8, 2014, we closed a follow-on underwritten public offering of 1,613,000 shares of our common stock, at an offering price of $6.20 per share, for gross proceeds of $10.0 million. We received net offering proceeds of approximately $9.0 million, after deducting underwriting discounts and commissions and expenses incurred in connection with the offering.

On August 18, 2015, we closed on an underwritten public offering of (i) 2,315,654 Series A units, each consisting of one share of common stock and one half of a warrant to purchase one share of common stock, at a purchase price of $1.00 per Series A unit, and (ii) 184,346 Series B units, in lieu of Series A units, at a purchase price of $1.00 per Series B unit to those purchasers whose purchase of additional Series A units in the offering would result in the purchaser beneficially owning more than 9.99% of the Company's outstanding common stock following the completion of the offering. Each Series B unit consists of one fully pre-funded warrant to purchase one share of common stock and one half of a warrant to purchase one share of common stock. The warrants (other than the fully pre-funded warrants) have an exercise price of $1.00 per share. The net offering proceeds that we received, after deducting discounts and commissions and expenses incurred with the offering were approximately $2.0 million.

Series A Preferred Stock and Secured Convertible Promissory Note Financing

On May 12, 2015, we received additional cash of $0.5 million from the sale of our secured convertible promissory notes to purchasers affiliated with Flagship Ventures in accordance with the terms of a Securities Purchase Agreement, or Series A Purchase Agreement, that we entered into on May 12, 2015. On July 14, 2015, we issued and sold 1,176,262 shares of our newly designated Series A Preferred Stock, $0.001 par value per share, or our Series A Preferred Stock, in a private placement to purchasers affiliated with Flagship Ventures at a purchase price of $1.7003 per share for aggregate gross cash proceeds of approximately $2.0 million. In addition, the $500,000 in aggregate principal amount of our secured convertible promissory notes, plus accrued but unpaid interest, that we previously issued converted into 298,181 shares of Series A Preferred Stock. As of December 31, 2015, we had an aggregate of 1,474,443 shares of Series A Preferred Stock outstanding.

Common Stock Purchase Agreement with Aspire Capital

On January 24, 2013, we entered into a Common Stock Purchase Agreement, or the Aspire Agreement, with Aspire Capital Fund, LLC, or Aspire, to purchase, at our option, up to an aggregate of $12.0 million of shares of our common stock over a two-year term. Under the Aspire Agreement, we initially issued 33,185 shares of our common stock as a commitment fee, but we did not sell any shares under the Aspire Agreement, which expired in June 2015.

Secured Term Loan Facility

In February 2012, we entered into a secured term loan facility with General Electric Capital Corporation and Comerica Bank, and a term loan in the aggregate principal amount of $10.0 million was funded to us upon the closing of the transaction. The term loan accrues interest at a rate of 8% per annum plus the higher of (a) the 3-month LIBOR rate or (b) 1.25%. Interest only payments were made for the first twelve months of the loan term. Following that initial twelve month period, principal and interest payments are required to be paid on a monthly basis through maturity in August 2015. On July 14, 2015, we paid off all of our outstanding obligations under the secured term loan facility and terminated the loan facility. The security interest granted by us to the lenders in our assets in connection with the loan facility was also terminated at the time of the payoff.

At December 31, 2015, we had $0 outstanding under the term loan, having paid off all of our outstanding obligations under the term loan on July 14, 2015.

Warrants

In connection with the loan facility, we initially issued warrants to purchase 9,165 shares of our common stock with an exercise price of $27.28 per share. The warrants expire ten years from the date of issuance. The warrants were valued using the Black-Scholes option pricing model using the following assumptions: fair value of the underlying common stock of $34.04 per share; volatility of 70%; no dividend yield; risk free interest rate of 1.96%; and an expected life of ten years. The relative fair value of the warrants, aggregating $240,000, has been accounted for as a debt discount and is being recognized as interest expense over the term of the loan using the effective interest method. As part of the May 2013 amendment to the loan and security agreement, the number of shares for which the warrants were exercisable increased by 27,600 shares and the warrant price of the warrants was adjusted to $6.80 per share. At the loan modification date, we valued both the amended and the original warrants using the Black-Scholes option pricing model and recorded the incremental value of the amended warrants as additional debt discount in the amount of $163,000, which is being recognized as additional interest expense over the remaining term of the loan using the effective interest method. The warrants under the term loan have been classified as equity instruments and are included within additional paid-in capital. Notwithstanding the payoff of the loan facility in July 2015, the warrants continue to remain outstanding in accordance with their terms and are not affected by the payoff.

Quotation of Our Common Stock on the OTCQB Following NASDAQ De-listing and Anticipated Deregistration of our Common Stock under the Exchange Act

Our common stock had been listed on The NASDAQ Capital Market until September 15, 2015, when it was suspended for failure to comply with The NASDAQ Capital Market continued listing standards. On September 16, 2015, our common stock began trading on the OTC Markets' OTCQB market tier under the trading symbol "BGMD." In addition, given the significant cost and resource demands of being a public company, we have determined that it is advisable to terminate the registration of our common stock under the Exchange Act and we anticipate filing a Form 15 with the SEC to effect the deregistration in April 2016. Upon the filing of the Form 15, our obligation to file periodic and current reports with the SEC, including Forms 10-K, 10-Q, and 8-K, will be suspended. The delisting of our common stock from The NASDAQ Capital Market and the anticipated deregistration of our common stock under the Exchange Act could substantially further reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, the delisting and anticipated deregistration could negatively affect us by reducing the number of investors willing to hold or acquire our common stock, which could negatively affect our ability to raise capital, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities.

Net Cash Flows

Summary Cash Flow Information	Years Ended December 31,			Change	
	2015	2014	2013	2015 vs 2014	2014 vs 2013
			(in thousands)		
Net cash (used in) provided by:					
Operating activities	$(3,667)	$(8,167)	$(15,288)	$ 4,500	$ 7,121
Investing activities	13	—	(32)	13	32
Financing activities	1,056	4,539	10,285	(3,483)	(5,746)
Net decrease in cash and cash equivalents	(2,598)	(3,628)	(5,035)	1,030	1,407
Cash and cash equivalents	$ 1,525	$ 4,123	$ 7,751	$ (2,598)	$ (3,628)

Years Ended December 31, 2015 and 2014

Net cash used in operating activities decreased primarily due to a decrease in our net loss for 2015 compared to 2014, our loss on the fair value of the secured convertible note, and changes in working capital related primarily to decreases in accounts payable and accrued expenses in 2015.

Net cash provided by investing activities increased due to the proceeds received from the sale of office equipment in 2015, whereas no such activity took place in 2014.

In 2015, cash flows from financing activities included net proceeds of $2.0 million received from our follow-on public offering, net proceeds of $1.5 million received from our preferred stock issuance, and $0.5 million received from the issuance of our secured convertible note, partially offset by payments on our term loan of $3.0 million. In 2014, cash flows from financing activities included net proceeds of $9.0 million received from our follow-on public offering, partially offset by payments on our term loan of $4.5 million.

Years Ended December 31, 2014 and 2013

Net cash used in operating activities decreased primarily due to a decrease in our net loss for 2014 compared to 2013 and changes in working capital related primarily to decreases in accounts payable, accrued expenses and other current liabilities in 2014.

Net cash used in investing activities decreased due to the proceeds received from the sale of laboratory equipment in 2013, whereas no such activity took place in 2014.

In 2014, cash flows from financing activities included net proceeds of $9.0 million received from our follow-on public offering, partially offset by payments on our term loan of $4.5 million. In 2013, cash flows from financing

activities included net proceeds of $12.8 million received from our follow-on public offering, partially offset by payments on our term loan of $2.5 million.

Funding Requirements

We believe that our existing cash will be sufficient to fund our operations into July 2016. During 2015, we incurred a net loss of $5.3 million and used $3.7 million of cash in operations, and expect to continue to incur losses and use cash during 2016 and beyond. At December 31, 2015, we had cash totaling $1.5 million, and an outstanding balance of $0 under our secured term loan facility having paid off all of our outstanding obligations under the secured term loan facility on July 14, 2015. As of March 25, 2016, we had cash totaling $1.0 million.

Effective January 1, 2014, the payment rate at which our BGM Galectin-3 Test is reimbursed by CMS was increased to $30.01 from $17.80 per test. In 2015, the national limitation amount for our BGM Galectin-3 Test was reduced to $29.93 and applied across the U.S., except in Ohio and West Virginia where rates of $23.93 and $26.33, respectively, applied. In 2016, the national limitation amount for our BGM Galectin-3 Test was increased to $29.96 and applies across the U.S., except in Ohio and West Virginia where rates of $23.95 and $26.36, respectively, apply. We are in the early stages of commercializing testing for galectin-3. Interest in the galectin-3 testing is increasing as a result of our market development activities, although it has not yet translated into significant revenue. In order to achieve profitability, we will need to generate significant product revenues.

We believe that our existing cash will be sufficient to fund our operations into July 2016. Until we generate significant product revenues to reach cash breakeven, we will need to raise additional funds to finance our operations beyond July 2016. We may not be able to obtain adequate financing to do so when necessary, and the terms of any financing, if any, may not be advantageous to us and any financings may result in dilution to our stockholders.

The above circumstances along with our history and near term forecast of incurring net losses and negative operating cash flows raise substantial doubt regarding our ability to continue as a going concern for a reasonable period of time. The accompanying consolidated financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to our ability to continue as a going concern.

Our forecast of the period of time through which our financial resources will be adequate to support our operations and the cost to develop and commercialize our products are forward-looking statements and involve risks and uncertainties, and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in the “Risk Factors” section of this report. We have based these estimates on assumptions that may prove to be incorrect, and we could utilize our available capital resources sooner than we currently expect.

Our future liquidity and capital funding requirements will depend on numerous factors, including:

- our ability to raise additional funds to finance our operations;
- the revenue generated by sales of our cardiovascular diagnostic tests and revenue from sales of automated tests by our automated partners;
- the rate of progress and cost of our commercialization activities, including with respect to the commercialization activities of our automated partners;
- the rate of adoption by new customers of automated galectin-3 testing and the rate of migration by existing customers of manual galectin-3 testing to automated galectin-3 testing;
- the outcome, costs and timing of seeking regulatory clearance for additional indications for existing products;
- the success of our efforts to demonstrate and differentiate the clinical utility of our existing products;
- the expenses we incur in marketing and selling our products;
- the emergence and effect of competing or complementary products;

- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our ability to retain our current employees and the need and ability to hire additional management and scientific and medical personnel;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- the terms and timing of any collaborative, licensing or other arrangements that we have or may establish;
- the trading price of our common stock; and
- the effect of the quotation of our common stock on the OTCQB, the delisting of our common stock from The NASDAQ Capital Market and the anticipated deregistration of our common stock under the Exchange Act.

Off-Balance Sheet Arrangements

None.

Contractual Obligations and Commitments

The following table sets forth our payment obligations as of December 31, 2015 under contracts that provide for fixed and determinable payments over the periods indicated.

	Total	2016	2017	2018
Operating leases	$1,199	$428	$394	$377
Total	$1,199	$428	$394	$377

We do not have any contractual obligations or commitments which extend beyond 2018.

On June 10, 2013, we entered into a lease agreement with a landlord to lease office space located at 880 Winter Street, Waltham, Massachusetts and we moved our corporate headquarters to that facility in August 2013. We have leased space in that facility for an initial term of five years and four months, with an option to renew for one additional five-year term at the then prevailing market rental rate. The Fixed Rent, as defined, totaled approximately $1.9 million over the initial term. We began monthly rent payments at this facility in December 2013.

On May 5, 2015, we entered into a lease agreement with a landlord to lease office space located at 303 Wyman Street, Waltham, Massachusetts and we moved our corporate headquarters to that facility on June 1, 2015. We are leasing space in the new facility through June 30, 2016, with an option to renew in six-month increments. The rent is approximately $7,000 per month.

In June 2015, we entered into a sublease agreement with a third party for the 880 Winter Street office space. The term of the sublease is from June 1, 2015 through December 31, 2018 covering the balance of the underlying lease term. We have recorded in operating costs total charges of $82,000 with respect to the net present value of the net costs that will continue to be incurred under the lease for its remaining term.

Our contract service obligations relate to product development and other commercial activities. The table does not include any possible milestone payments, royalties or other fees payable under certain of our license agreements. We are obligated to make royalty payments to ACS Biomarker in the future and such royalty payments will be dependent on the amount and nature of the revenues we generate from our galectin-3 test and the other technologies that we have licensed from them. We believe that we are reasonably likely to make additional license payments in the future.

Certain Factors That May Affect Future Results of Operations

The Securities and Exchange Commission encourages companies to disclose forward-looking information so that investors can better understand a company's future prospects and make informed investment decisions. This Annual Report on Form 10-K contains such "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements involve known and unknown risks, uncertainties and other important factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our ability to raise additional funds in the near future to finance our operations;
- our ability to continue as a going concern;
- our estimates of future performance, including the commercialization and sales of our galectin-3 test and the automated tests of our automated partners ;
- our ability to provide sufficient evidence of clinical utility for our galectin-3 test and to differentiate it from competing cardiovascular diagnostics tests;
- our ability to obtain regulatory clearance from the FDA for our CardioSCORE test and certain additional indications for our galectin-3 test;
- our ability to successfully market, commercialize and achieve widespread market penetration for our cardiovascular diagnostic tests;
- our ability to conduct the clinical studies required for regulatory clearance or approval and to demonstrate the clinical benefits and cost-effectiveness to support commercial acceptance of our products;
- the timing, costs and other limitations involved in obtaining regulatory clearance or approval for any of our products;
- the potential benefits of our cardiovascular diagnostic tests over current medical practices or other diagnostics;
- the ability of our automated partners to develop and obtain regulatory clearance of galectin-3 tests that can be performed on their automated platforms and to commercialize any such tests;
- willingness of third-party payers to reimburse for the cost of our tests;
- our ability to enter into collaboration and distribution agreements with respect to our cardiovascular diagnostic tests, the performance of our partners under such agreements and the potential benefits of these arrangements;
- estimates of market sizes and anticipated uses of our cardiovascular diagnostic tests;
- our ability to obtain and maintain intellectual property protections for our products and operate our business without infringing upon the intellectual property rights of others;
- the expected timing, progress or success of our development and commercialization efforts;
- our ability to successfully obtain sufficient and appropriate blood samples for our validation tests in support of our regulatory filings for our cardiovascular tests;
- our ability to enter into a strategic transaction that increases stockholder value;
- the timing and effect of the deregistration of our common stock under the Exchange Act and the effect of the quotation of our common stock on the OTCQB and the delisting of our common stock from the NASDAQ Capital Market;
- the success of competing cardiovascular diagnostic tests that are or become available;
- regulatory developments in the United States and other countries in which we sell or plan to sell our tests;
- the performance of our third-party suppliers and the manufacturer of our galectin-3 tests; and
- our estimates regarding anticipated operating losses, future revenue, expenses, capital requirements and our needs for additional financing.

Words such as "may," "anticipate," "estimate," "expect," "project," "intend," "plan," "believe" and words and terms of similar substance used in connection with any discussion of future operating or financial performance, identify forward-looking statements. All forward-looking statements are management's present expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those described in the forward-looking statements. These risks include, but are not

limited to those set forth under the heading “Risk Factors” contained in Item 1A of this Annual Report on Form 10-K.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this Annual Report on Form 10-K or in any document incorporated by reference might not occur. Stockholders are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise. All subsequent forward-looking statements attributable to BG Medicine, Inc. or to any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to fluctuations in interest rates. At December 31, 2015, our exposure to market risk is limited to our cash. However, we periodically invest in cash equivalents and short-term marketable securities. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We do not enter into investments for trading or speculative purposes. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain a portfolio of cash equivalents that management believes to be of high credit quality. Because of the short-term maturities of our investments, we do not believe that an increase or decrease in interest rates would have a material negative impact on our results of operations or financial position.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this Item 8 is included at the end of this Annual Report on Form 10-K beginning on page F-1.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

a) Evaluation of Disclosure Controls and Procedures. Our management, with the participation and supervision of our Chief Executive Officer and Chief Financial Officer, is responsible for the design, operation and maintenance of our disclosure controls and procedures pursuant to Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified under the Securities and Exchange Commission’s rules and forms. Disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to our principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, under the direction of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2015. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of December 31, 2015, our disclosure controls and procedures were effective.

(b) *Management's Annual Report on Internal Control over Financial Reporting.* Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, the Company's principal executive and principal financial officers, or persons performing similar functions, and effected by the Company's board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and includes those policies and procedures that:

(1) Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of inherent limitations, no matter how well designed and operated, internal control over financial reporting may not prevent or detect misstatements and can only provide reasonable assurance of achieving the desired control objectives. In addition, the design of internal control over financial reporting must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Our Chief Executive Officer and Chief Financial Officer have performed an evaluation of our internal control over financial reporting under the framework in *Internal Control – Integrated Framework (2013)* , issued by the Committee of Sponsoring Organizations of the Treadway Commission. The objective of this assessment was to determine whether our internal control over financial reporting was effective at December 31, 2015. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our internal controls over financial reporting were effective as of the end of the period covered by this report.

(c) *Changes in Internal Control over Financial Reporting.* There have been no changes in our internal control over financial reporting identified in connection with the evaluation of such internal control that occurred during the quarter ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Board of Directors and Corporate Governance,” “Executive Compensation,” “Section 16(a) Beneficial Ownership Reporting Compliance,” and “Code of Conduct and Ethics” in the Company’s Proxy Statement for the 2016 Annual Meeting of Stockholders.

Item 11. EXECUTIVE COMPENSATION

The response to this item is incorporated by reference from the discussion responsive thereto under the caption “Executive Compensation” in the Company’s Proxy Statement for the 2016 Annual Meeting of Stockholders.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in the Company’s Proxy Statement for the 2016 Annual Meeting of Stockholders.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The response to this item is incorporated by reference from the discussion responsive thereto under the caption “Certain Relationships and Related Person Transactions” in the Company’s Proxy Statement for the 2016 Annual Meeting of Stockholders.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The response to this item is incorporated by reference from the discussion responsive thereto under the caption “Independent Registered Public Accounting Firm” in the Company’s Proxy Statement for the 2016 Annual Meeting of Stockholders.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Item 15(a). The following documents are filed as part of this Annual Report on Form 10-K:

Item 15(a)(1) and (2) See "Index to Consolidated Financial Statements and Financial Statement Schedules" at page F-1 in this Annual Report on Form 10-K. Other financial statement schedules have not been included because they are not applicable or the information is included in the financial statements or notes thereto.

Item 15(a)(3) Exhibits

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
3.1.1	Restated Certificate of Incorporation of the Registrant		Form 8-K (Exhibit 3.1)	2/11/11	001-33827
3.1.2	Certificate of Amendment to Restated Certificate of Incorporation of the Registrant, dated July 8, 2015.		Form 8-K (Exhibit 3.1)	7/8/15	001-33827
3.1.3	Amended and Restated Certificate of Designations of Series A Preferred Stock of the Registrant, filed with the Secretary of State of the State of Delaware on August 18, 2015.		Form 8-K (Exhibit 3.1)	8/18/15	001-33827
3.2	Restated Bylaws of the Registrant		Form 8-K (Exhibit 3.2)	2/11/11	001-33827
4.1	Form of Common Stock Certificate		Amendment No. 5 to Form S-1 (Exhibit 4.1)	11/22/10	333-164574
4.2	Fifth Amended and Restated Investor Rights Agreement, dated as of July 14, 2015		Form 8-K (Exhibit 10.2)	7/15/15	001-33827
4.3	Form of Common Stock Warrant issued to General Electric Capital Corporation		Form S-1 (Exhibit 4.4)	1/29/10	333-164574
4.4	Form of Common Stock Bridge Financing Warrant, together with a schedule of warrant holders		Form S-1 (Exhibit 4.5)	1/29/10	333-164574
4.5	Warrant issued to Silicon Valley Bank, dated November 9, 2007		Form S-1 (Exhibit 4.6)	1/29/10	333-164574
4.6	Warrant issued to Silicon Valley Bank, dated March 28, 2008		Form S-1 (Exhibit 4.7)	1/29/10	333-164574
4.7	Form of 2010 Common Stock Bridge Warrant, together with a schedule of warrant holders		Amendment No. 3 to Form S-1 (Exhibit 4.8)	8/31/10	333-164574

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
4.8.1	Warrant issued to GE Capital Equity Investments, Inc., dated as of February 10, 2012		Form 8-K (Exhibit 10.5)	2/16/12	001-33827
4.8.2	Amendment No. 1 to Warrant by and between the Registrant and GE Capital Equity Investments, Inc., dated as of May 8, 2013		Form 8-K (Exhibit 10.2)	5/9/13	001-33827
4.9.1	Warrant issued to Comerica Bank, dated as of February 10, 2012		Form 8-K (Exhibit 10.6)	2/16/12	001-33827
4.9.2	Amendment No. 1 to Warrant by and between the Registrant and Comerica Bank, dated as of May 8, 2013		Form 8-K (Exhibit 10.3)	5/9/13	001-33827
4.10	Form of Senior Indenture		Form S-3 (Exhibit 4.8)	5/19/15	333-204307
4.11	Form of Subordinated Indenture		Form S-3 (Exhibit 4.9)	5/19/15	333-204307
4.12	Registration Rights Agreement, dated as of January 24, 2013, by and between the Registrant and Aspire Capital Fund, LLC		Form 8-K (Exhibit 4.1)	1/24/13	001-33827
4.13	Form of Prefunded Common Stock Purchase Warrant issued to the purchasers in the 2015 public offering		Form 8-K (Exhibit 4.1)	8/18/15	001-33827
4.14	Form of Common Stock Purchase Warrant issued to the purchasers in the 2015 public offering		Form 8-K (Exhibit 4.2)	8/18/15	001-33827
	Lease Agreements				
10.1	Second Amendment to Lease, Sublease, and Assignment, Assumption and Amendment of Sublease by and between the Registrant and 610 Lincoln LLC, dated as of May 19, 2009		Form S-1 (Exhibit 10.1)	1/29/10	333-164574
10.1.1	Lease by and between the Registrant and Waltham Winter Street 880 LP, dated June 10, 2013		Form 10-Q (Exhibit 10.6)	8/9/13	001-33827
10.2	Sublease Agreement by and between the Registrant and GPC Biotech, dated as of April 14, 2005, as amended		Form S-1 (Exhibit 10.2)	1/29/10	333-164574
	Loan Agreements				
10.3.1	Loan and Security Agreement by and among the Registrant, General Electric Capital Corporation as Agent, the Lenders and the Guarantors, dated as of February 10, 2012		Form 8-K (Exhibit 10.1)	2/16/12	001-33827

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.3.2	First Amendment to Loan and Security Agreement by and between the Registrant and General Electric Capital Corporation, dated May 8, 2013		Form 8-K (Exhibit 10.1)	5/9/13	001-33827
10.3.3	Second Amendment to Loan and Security Agreement by and between the Registrant and General Electric Capital Corporation, dated May 12, 2015		Form 8-K/A (Exhibit 10.4)	6/9/15	001-33827
10.4	Promissory Note issued by the Registrant to General Electric Capital Corporation, dated as of February 10, 2012		Form 8-K (Exhibit 10.2)	2/16/12	001-33827
10.5	Promissory Note issued by the Registrant to Comerica Bank, dated as of February 10, 2012		Form 8-K (Exhibit 10.3)	2/16/12	001-33827
10.6	Pledge Agreement by and between the Registrant and General Electric Capital Corporation, dated as of February 10, 2012		Form 8-K (Exhibit 10.4)	2/16/12	001-33827
	Agreements with Respect to Collaborations, Licenses, Research and Development				
10.7.1+	License and Distribution Agreement by and between the Registrant and Abbott Laboratories, dated as of November 11, 2009		Amendment No. 3 to Form S-1 (Exhibit 10.4)	8/31/10	333-164574
10.7.2+	First Amendment to License and Distribution Agreement by and between the Registrant and Abbott Laboratories, dated as of February 3, 2010		Amendment No. 2 to Form S-1 (Exhibit 10.4.1)	3/12/10	333-164574
10.7.3+	Third Amendment to License and Distribution Agreement by and between the Registrant and Abbott Laboratories, dated as of May 8, 2015		Form 10-Q/A (Exhibit 10.6)	8/17/15	001-33827
10.7.4#	Fourth Amendment to License and Distribution Agreement by and between the Registrant and Abbott Laboratories, dated as of November 24, 2015	X			
10.8.1+	Product License and Collaboration Agreement, Licensing Addendum No. 1 and Licensing Addendum No. 2 by and between the Registrant and ACS Biomarker B.V., dated as of May 4, 2007		Amendment No. 1 to Form S-1 (Exhibit 10.5)	2/12/10	333-164574
10.8.2+	Sublicense Agreement between the Registrant and ACS Biomarker B.V. dated July 11, 2012		Form 10-Q (Exhibit 10.2)	11/13/12	001-33827

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.9+	Strategic Agreement by and between the Registrant and Humana Inc., dated as of May 25, 2007, as amended May 12, 2008 and August 12, 2009		Amendment No. 1 to Form S-1 (Exhibit 10.6)	2/12/10	333-164574
10.10+	Participation Agreement by and between the Registrant and Philips Medical Systems Nederland B.V., dated as of December 22, 2006		Amendment No. 2 to Form S-1 (Exhibit 10.8)	3/12/10	333-164574
10.11.1+	Participation Agreement by and between the Registrant and AstraZeneca AB, dated as of November 24, 2006, as amended August 20, 2007		Amendment No. 2 to Form S-1 (Exhibit 10.9)	3/12/10	333-164574
10.11.2+	Amendment to the Participation Agreement by and between the Registrant and AstraZeneca AB, dated November 23, 2010		Form 10-K (Exhibit 10.11.2)	3/30/12	001-33827
10.12.1+	Participation Agreement by and between the Registrant and Merck & Co., Inc., dated as of July 28, 2006, as amended October 10, 2006 and June 14, 2007		Amendment No. 2 to Form S-1 (Exhibit 10.10)	3/12/10	333-164574
10.12.2+	Amendment to the Participation Agreement by and between the Registrant and Merck Sharp & Dohme Corp. (formerly Merck & Co., Inc.), dated as of May 28, 2010		Form 10-K (Exhibit 10.12.2)	3/30/12	001-33827
10.13+	Participation Agreement by and between the Registrant and Abbott Laboratories, dated as of March 28, 2008		Amendment No. 2 to Form S-1 (Exhibit 10.11)	3/12/10	333-164574
10.14.1	Participation Agreement by and between the Registrant and Takeda Pharmaceutical Company Limited, dated as of March 31, 2008		Amendment No. 2 to Form S-1 (Exhibit 10.12)	3/12/10	333-164574
10.14.2+	Amendment to the Participation Agreement by and between the Registrant and Takeda Pharmaceutical Company Limited, dated as of January 5, 2011		Form 10-K (Exhibit 10.14.2)	3/30/12	001-33827
10.15+	Supply Agreement by and between the Registrant and Corgenix Medical Corporation, dated as of March 20, 2009		Amendment No. 2 to Form S-1 (Exhibit 10.13)	3/12/10	333-164574
10.16+	License and Supply Agreement by and between the Registrant and Laboratory Corporation of America Holdings, dated as of May 13, 2010		Amendment No. 3 to Form S-1 (Exhibit 10.14)	8/31/10	333-164574

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.17+	License and Distribution Agreement by and between the Registrant and Inverness Medical Innovations, Inc. (predecessor to Alere Inc.), dated as of March 19, 2010		Amendment No. 4 to Form S-1 (Exhibit 10.15)	11/8/10	333-164574
10.18+	License and Distribution Agreement by and between the Registrant and bioMérieux SA, dated as of May 29, 2010		Amendment No. 4 to Form S-1 (Exhibit 10.16)	11/8/10	333-164574
10.19+	License and Distribution Agreement by and between the Registrant and Siemens Healthcare Diagnostics Inc., dated as of December 14, 2010		Amendment No. 9 to Form S-1 (Exhibit 10.17)	2/3/11	333-164574
10.20+	Supply Agreement by and between the Registrant and Health Diagnostic Laboratory, Inc., dated as of March 15, 2011		Amendment No. 1 to Form 10-Q (Exhibit 10.1)	10/4/11	001-33827
	Agreements with Executive Officers				
10.21*	Amended and Restated Change of Control Cash Severance Agreement by and between the Registrant and Pieter Muntendam, dated as of August 1, 2007		Form S-1 (Exhibit 10.11)	1/29/10	333-164574
10.22*	Amended and Restated Change of Control Cash Severance Agreement by and between the Registrant and Neal Gordon, dated as of December 22, 2008		Form S-1 (Exhibit 10.12)	1/29/10	333-164574
10.23*	Amended and Restated Cash Severance Agreement by and between the Registrant and Aram Adourian, dated as of August 1, 2007		Amendment No. 4 to Form S-1 (Exhibit 10.23)	11/8/10	333-164574
10.24*	Amended and Restated Cash Severance Agreement by and between the Registrant and Anastasia Rader, dated as of August 1, 2007		Amendment No. 4 to Form S-1 (Exhibit 10.24)	11/8/10	333-164574
10.25*	Form of Indemnification Agreement between the Registrant and its Directors and Executive Officers		Amendment No. 3 to Form S-1 (Exhibit 10.21)	8/31/10	333-164574
10.26*	Severance Agreement and Release by and between the Registrant and William Densel, dated as of March 26, 2013		Form 10-Q (Exhibit 10.1)	5/10/13	001-33827
10.27*	Severance Agreement and Release by and between the Registrant and Neal Gordon, effective as of January 10, 2013		Form 10-K (Exhibit10.33)	3/18/13	001-33827
10.28*	Consulting Agreement by and between the Registrant and Neal Gordon, effective as of January 1, 2013		Form 10-K (Exhibit10.34)	3/18/13	001-33827

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.29*	Side Letter Agreement by and between the Registrant and Aram Adourian, effective as of October 4, 2012		Form 10-K (Exhibit10.35)	3/18/13	001-33827
10.30*	Separation and Release Agreement by and between the Registrant and Charles H. Abdalian, Jr., effective as of November 13, 2013		Form 10-K (Exhibit 10.30)	3/27/14	001-33827
10.31*	Salary Modification Agreement by and between the Registrant and Anastasia Rader, effective as of January 7, 2013		Form 10-K (Exhibit10.37)	3/18/13	001-33827
10.32*	Employment Agreement by and between the Registrant and Paul Sohmer, M.D., dated May 8, 2013		Form 10-Q (Exhibit 10.4)	8/9/13	001-33827
10.32.1*	First Amendment to Employment Agreement by and between the Registrant and Paul Sohmer, M.D., dated May 14, 2014		Form 10-K (Exhibit 10.32.1)	3/31/15	001-33827
10.32.2*	Second Amendment to Employment Agreement by and between the Registrant and Paul Sohmer, M.D., dated January 1, 2015		Form 10-K (Exhibit 10.32.2)	3/31/15	001-33827
10.33*	Employment Agreement by and between the Registrant and Stephen P. Hall, dated November 13, 2013		Form 10-K (Exhibit 10.33)	3/27/14	001-33827
10.33.1*	First Amendment to Employment Agreement by and between the Registrant and Stephen P. Hall, dated January 1, 2015		Form 10-K (Exhibit 10.33.1)	3/31/15	001-33827
	Equity Compensation Plans				
10.34*	2001 Stock Option and Incentive Plan, as amended		Form S-1 (Exhibit 10.15)	1/29/10	333-164574
10.35*	Form of Incentive Stock Option Agreement under the 2001 Stock Option and Incentive Plan		Form S-1 (Exhibit 10.16)	1/29/10	333-164574
10.36*	Form of Non-Qualified Stock Option Agreement under the 2001 Stock Option and Incentive Plan		Form S-1 (Exhibit 10.17)	1/29/10	333-164574
10.37*	Non-Qualified Stock Option Agreement by and between the Registrant and Paul Sohmer, M.D., dated May 8, 2013		Form 10-Q (Exhibit 10.5)	8/9/13	001-33827
10.38*	2010 Employee, Director and Consultant Stock Plan		Amendment No. 3 to Form S-1 (Exhibit 10.25)	8/31/10	333-164574

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.39*	Form of Stock Option Agreement under the 2010 Employee, Director and Consultant Stock Plan		Amendment No. 3 to Form S-1 (Exhibit 10.26)	8/31/10	333-164574
10.40*	Form of Restricted Stock Agreement under the 2010 Employee, Director and Consultant Stock Plan		Amendment No. 3 to Form S-1 (Exhibit 10.27)	8/31/10	333-164574
10.41*	2010 Employee Stock Purchase Plan		Amendment No. 3 to Form S-1 (Exhibit 10.28)	8/31/10	333-164574
10.42*	Amended and Restated Non-Employee Director Compensation Policy		Form 8-K (Exhibit 10.1)	11/20/15	001-33827
	Agreements with Investors				
10.43	Common Stock Purchase Agreement, dated as of January 24, 2013, by and between the Registrant and Aspire Capital Fund, LLC		Form 8-K (Exhibit 10.1)	1/24/13	001-33827
10.44	Securities Purchase Agreement by and between the Registrant and the purchasers named therein, dated May 12, 2015		Form 8-K/A (Exhibit 10.1)	6/9/15	001-33827
10.44.1	First Amendment to Securities Purchase Agreement by and between the Registrant and the purchasers named therein, dated July 14, 2015		Form 8-K (Exhibit 10.1)	7/15/15	001-33827
10.45	Security Agreement by and between the Registrant and the purchasers named therein, dated May 12, 2015.		Form 8-K/A (Exhibit 10.2)	6/9/15	001-33827
10.46	Subordination and Intercreditor Agreement by and between the Registrant, the purchasers named therein and General Electric Capital Corporation, dated May 12, 2015.		Form 8-K/A (Exhibit 10.3)	6/9/15	001-33827
	Other Exhibits				
21.1	Subsidiaries of the Registrant		Form 10-K (Exhibit 21.1)	3/27/14	001-33827
31.1	Certification of the Chief Executive Officer	X			
31.2	Certification of the Chief Financial Officer	X			
32.1	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
101	The following materials from the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2015, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 31, 2015 and 2014, (ii) Consolidated Statements of Operations for the Years Ended December 31, 2015, 2014 and 2013, (iii) Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2015, 2014, and 2013; (iv) Consolidated Statements Stockholders' (Deficit) Equity for the Years Ended December 31, 2015, 2014 and 2013, (v) Consolidated Statements of Cash Flows for the Years Ended December 31, 2015, 2014, and 2013, and (vi) Notes to Consolidated Financial Statements.	X			

(*) Management contract or compensatory plan or arrangement.

(+) Confidential treatment has been granted by the Securities and Exchange Commission as to certain portions of this Exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission as part of an application for confidential treatment pursuant to the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended, as applicable.

(#) Confidential treatment has been requested for portions of this exhibit which have been filed separately with the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BG MEDICINE, INC.

Date: April 4, 2016

By: /s/ Paul R. Sohmer
Paul R. Sohmer, M.D.
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated below and on the dates indicated.

Signatures	Title	Date
By: /s/ Paul R. Sohmer Paul R. Sohmer, M.D.	President, Chief Executive Officer and Director (principal executive officer)	April 4, 2016
By: /s/ Stephen P. Hall Stephen P. Hall	Executive Vice President, Chief Financial Officer and Treasurer (principal financial officer and principal accounting officer)	April 4, 2016
By: /s/ Jeffrey R. Luber Jeffrey R. Luber	Director	April 4, 2016
By: /s/ James F. O'Connor James F. O'Connor	Director	April 4, 2016
By: /s/ Stelios Papadopoulos, Ph.D. Stelios Papadopoulos, Ph.D.	Director, Vice Chairman of the Board	April 4, 2016
By: /s/ Harry W. Wilcox Harry W. Wilcox	Director, Chairman of the Board	April 4, 2016

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRMS

To the Board of Directors and Stockholders of
BG Medicine, Inc.
Waltham, Massachusetts

We have audited the accompanying consolidated balance sheets of BG Medicine, Inc. and subsidiary (the "Company") as of December 31, 2014, and the related consolidated statements of operations, stockholders' (deficit) equity, and cash flows for each of the two years in the period ended December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of BG Medicine, Inc. and subsidiary as of December 31, 2014, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2014, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company's recurring losses from operations, recurring cash used in operating activities and accumulated deficit raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also discussed in Note 1 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/S/ DELOITTE & TOUCHE LLP

Boston, Massachusetts
March 31, 2015

To the Audit Committee of the
Board of Directors and Stockholders
of BG Medicine, Inc.

We have audited the accompanying consolidated balance sheet of BG Medicine, Inc. and subsidiary (the "Company") as of December 31, 2015 and the related consolidated statement of operations, stockholders' deficit and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audit provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of BG Medicine, Inc. and subsidiary, as of December 31, 2015, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company's recurring losses from operations, recurring cash used in operating activities and accumulated deficit raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also discussed in Note 1 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that result from the outcome of this uncertainty.

/s/ Marcum LLP
New York, NY
April 4, 2016

BG Medicine, Inc. and Subsidiary

CONSOLIDATED BALANCE SHEETS

	As of December 31,	
	2015	**2014**
	(in thousands, except share and per share data)	
Assets		
Current assets		
Cash and cash equivalents	$ 1,525	$ 4,123
Accounts receivable (net of allowance for doubtful accounts of $151 and $0 as of December 31, 2015 and December 31, 2014, respectively)	181	174
Inventory	145	400
Prepaid expenses and other current assets	100	154
Total current assets	1,951	4,851
Property and equipment, net	11	117
Intangible assets, net	77	135
Deposits and other assets	94	126
Total assets	$ 2,133	$ 5,229
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities		
Term loan	-	2,960
Accounts payable	558	695
Accrued expenses	345	906
Current portion of deferred revenue	250	-
Other current liabilities	27	18
Total current liabilities	1,180	4,579
Deferred revenue, net of current portion	229	-
Other liabilities	106	93
Total liabilities	1,515	4,672
Commitments and contingencies (Note 13)		
Convertible preferred stock; $.001 par value; 5,000,000 shares authorized at December 31, 2015 and December 31, 2014; 1,474,443 and 0 shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively; liquidation preference of $2,599 at December 31, 2015	2,594	-
Stockholders' (deficit) equity		
Common stock; $.001 par value; 100,000,000 shares authorized at December 31, 2015 and December 31, 2014; 11,319,475 and 8,632,810 shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively	11	9
Additional paid-in capital	164,318	161,550
Accumulated deficit	(166,305)	(161,002)
Total stockholders' (deficit) equity	(1,976)	557
Total liabilities and stockholders' (deficit) equity	$ 2,133	$ 5,229

The accompanying notes are an integral part of these consolidated financial statements.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years ended December 31,		
	2015	2014	2013
	(in thousands, except share and per share data)		
Revenues:			
Product revenues	$ 1,405	$ 2,698	$ 3,635
Partnership revenues	21	-	-
Product fee revenues	140	89	48
Service revenues	-	-	390
Total revenues	1,566	2,787	4,073
Costs and operating expenses:			
Product and product fee costs	505	956	1,247
Service costs	-	-	142
Research and development	1,774	2,393	3,735
Selling and marketing	302	2,293	6,193
General and administrative	3,615	4,507	7,130
Total costs and operating expenses	6,196	10,149	18,447
Loss from operations	(4,630)	(7,362)	(14,374)
Non-cash consideration associated with stock purchase agreement	-	-	(329)
Interest income	-	2	15
Interest expense	(159)	(728)	(1,168)
Other (expense) income	(514)	24	7
Net loss	(5,303)	(8,064)	(15,849)
Preferred stock dividend	(92)	-	-
Deemed dividend on beneficial conversion feature	(1,507)	-	-
Accretion of convertible preferred stock to liquidation value	(56)	-	-
Net loss attributable to common stockholders	(6,958)	(8,064)	(15,849)
Net loss per share attributable to common stockholders – basic and diluted	$ (0.72)	$ (0.99)	$ (2.33)
Weighted-average common shares outstanding used in computing per share amounts – basic and diluted	9,609,408	8,175,805	6,803,209

The accompanying notes are an integral part of these consolidated financial statements.

BG Medicine, Inc. and Subsidiary

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' (DEFICIT) EQUITY FOR THE YEARS ENDED DECEMBER 31, 2015, 2014 AND 2013

	Series A convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' (deficit) equity
	Shares	Amount	Shares	Amount			
	(in thousands, except share data)						
At January 1, 2013	-	$ -	5,128,850	$ 5	$ 137,393	$ (137,089)	$ 309
Net loss	-	-	-	-	-	(15,849)	(15,849)
Issuance of shares upon public offering, net of offering costs of approximately $1.0 million	-	-	1,725,000	2	12,767	-	12,769
Issuance of shares under stock purchase agreement	-	-	33,186	-	329	-	329
Issuance of common stock upon exercise of warrants, net	-	-	81,715	-	-	-	-
Issuance of common stock upon exercise of stock options	-	-	7,534	-	27	-	27
Issuance of common stock under employee stock purchase plan	-	-	7,772	-	22	-	22
Issuance of warrants	-	-	-	-	163	-	163
Stock-based compensation	-	-	-	-	1,161	-	1,161
At December 31, 2013	-	-	6,984,056	7	151,862	(152,938)	(1,069)
Net loss	-	-	-	-	-	(8,064)	(8,064)
Issuance of shares upon public offering, net of offering costs of approximately $0.2 million	-	-	1,613,000	2	8,993	-	8,995
Issuance of common stock upon exercise of warrants, net	-	-	28,497	-	-	-	-
Issuance of common stock upon exercise of stock options	-	-	6,007	-	22	-	22
Issuance of common stock under employee stock purchase plan	-	-	1,250	-	2	-	2
Stock-based compensation	-	-	-	-	671	-	671
At December 31, 2014	-	-	8,632,810	9	161,550	(161,002)	557
Net loss	-	-	-	-	-	(5,303)	(5,303)
Issuance of preferred shares, net of offering costs of approximately $0.5 million	1,474,443	2,594	-	-	(56)	-	(56)
Issuance of shares upon public offering, net of offering costs of approximately $0.5 million	-	-	2,315,654	2	1,993	-	1,995
Issuance of common stock upon exercise of warrants, net	-	-	262,931	-	-	-	-
Issuance of common stock upon vesting of restricted stock units, net	-	-	107,315	-	-	-	-
Fractional shares from reverse stock split	-	-	765	-	-	-	-
Stock-based compensation	-	-	-	-	831	-	831
At December 31, 2015	1,474,443	$ 2,594	11,319,475	$ 11	$ 164,318	$ (166,305)	$ (1,976)

The accompanying notes are an integral part of these consolidated financial statements.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years ended December 31,		
	2015	2014	2013
	(in thousands)		
Cash flows from operating activities			
Net loss	$(5,303)	$(8,064)	$(15,849)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	87	131	165
Impairment of intangible asset	-	-	105
Stock-based compensation	831	671	1,161
Non-cash interest expense	40	222	221
Provision for doubtful accounts	151		
Non-cash consideration associated with stock purchase agreement	-	-	329
Loss (gain) on sale of property and equipment	64	-	(53)
Loss on fair value of secured convertible note	487	-	-
Changes in operating assets and liabilities			
Restricted cash	-	-	390
Accounts receivable	(158)	145	76
Inventory	255	59	(12)
Prepaid expenses and other assets	46	109	214
Accounts payable, accrued expenses and other liabilities	(635)	(1,401)	(1,650)
Deferred rent, deferred revenue and deposits	468	(39)	(385)
Net cash flows used in operating activities	(3,667)	(8,167)	(15,288)
Cash flows from investing activities			
Purchases of property and equipment	-	-	(132)
Proceeds from the sale of property and equipment	13	-	100
Net cash flows provided by/(used) in investing activities	13	-	(32)
Cash flows from financing activities			
Proceeds from public offering	2,500	9,238	13,058
Proceeds from secured convertible note	500	-	-
Proceeds from issuance of preferred stock	2,000	-	-
Payments on term loan	(2,984)	(4,480)	(2,533)
Costs related to public offering	(504)	(243)	(289)
Costs related to issuance of preferred stock	(456)	-	-
Proceeds from ESPP purchase	-	2	22
Proceeds from the exercise of stock options	-	22	27
Net cash flows provided by financing activities	1,056	4,539	10,285
Net decrease in cash and cash equivalents	(2,598)	(3,628)	(5,035)
Cash and cash equivalents, beginning of year	4,123	7,751	12,786
Cash and cash equivalents, end of year	$ 1,525	$ 4,123	$ 7,751
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 119	$ 506	$ 863
Supplemental disclosure of non-cash activities			
Issuance of common stock warrants	-	-	163
Conversion of convertible notes payable to preferred stock	987	-	-
Conversion of interest to preferred stock	7	-	-
Deemed dividend on beneficial conversion feature	1,507	-	-
Accretion of convertible preferred stock to liquidation value	56	-	-

The accompanying notes are an integral part of these consolidated financial statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2015, 2014 AND 2013

1. Description of Business, Basis of Presentation and Going Concern

Description of Business

BG Medicine, Inc. ("BG Medicine" or the "Company") is a commercial stage company that is focused on the delivery of diagnostic solutions to aid in the clinical management of heart failure and related disorders.

The Company's BGM Galectin-3 ® Test is an *in vitro* diagnostic device that employs a manual micro-titer platform to quantitatively measure galectin-3 levels in blood plasma or serum for use as an aid in assessing the prognosis of chronic heart failure in conjunction with clinical evaluation. The BGM Galectin-3 ® Test is cleared by the U.S. Food and Drug Administration (the "FDA"), is CE-marked and is currently available as a blood test in the United States and the European Union ("EU").

The Company has entered into licensing agreements with leading diagnostic instrument manufacturers to develop and commercialize galectin-3 assays to be performed on automated platforms that have been incorporated into routine practice in laboratories throughout the world. On December 23, 2014, the FDA granted 510(k) clearance for the ARCHITECT ® Galectin-3 assay, the first FDA cleared automated blood test for Galectin-3, as an aid in assessing the prognosis of patients diagnosed with chronic heart failure in conjunction with clinical evaluation. On July 6, 2015, the Company announced that the ARCHITECT ® Galectin-3 assay is now available in the United States. This is the first automated test for galectin-3 to be introduced for commercial use in the United States. The ARCHITECT ® Galectin-3 assay is performed using the Abbott Laboratories ("Abbott") ARCHITECT ® automated immunoassay analyzer and is being commercialized through an agreement between the Company and Abbott.

The Company has evolved from a research and development company to a commercial diagnostics company. Its initial transition to a commercial organization began with the FDA 510(k) clearance of our first diagnostic product, the BGM Galectin-3 Test, in November 2010. The first stage of transition was substantially completed in the first half of 2013 with the elimination of research and development activities no longer core to the Company's commercial strategy. The second 11stage of transition was initiated in anticipation of the U.S. introduction of automated testing for galectin-3 and the commencement of commercialization activities by the Company's automated partners. In order to reduce operating expenses and extend cash runway in anticipation of the commercial launch of automated testing for galectin-3, the Company implemented a reduction in its workforce on September 11, 2014. In so doing, the Company primarily eliminated its sales and marketing organizations and removed certain positions in other function areas, while preserving some senior management and other critical roles to support the clinical and commercial adoption of galectin-3 testing by providing support to the marketing and selling efforts of the Company's automated partners, clinical research studies that have incorporated galectin-3 testing and by expanding the BGM Galectin-3 Test's labeling indications for use through additional clinical studies and clearances by the FDA.

Basis of Presentation

The accompanying consolidated financial statements have been prepared on a basis which assumes that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business, and includes the accounts of the Company and its wholly-owned subsidiary, BG Medicine N.V., a company organized under the laws of the Netherlands. All intercompany accounts and transactions have been eliminated in consolidation.

On July 8, 2015, the Company effected a 1-for-4 reverse stock split of its common stock. All previously reported common stock share amounts in the accompanying financial statements and related notes have been retroactively adjusted to reflect the reverse stock split. As a result of the reverse stock split, the stated

capital on the Company's balance sheet attributable to its common stock, which consists of the par value per share of its common stock multiplied by the aggregate number of shares of its common stock issued and outstanding, has been reduced in proportion to the size of the reverse stock split. Correspondingly, the Company's additional paid-in capital account, which consists of the difference between its stated capital and the aggregate amount paid to the Company upon issuance of all currently outstanding shares of its common stock, has been credited with the amount by which the stated capital is reduced.

At December 31, 2015 and 2014, the Company had cash totaling $1.5 million and $4.1 million, debt of $0 and $3.0 million, and stockholders' deficit of $2.0 million and 0.6 million, respectively. During the year ended December 31, 2015 and 2014, the Company incurred a net loss totaling $5.3 million and $8.1 million, and used cash in operating activities totaling $3.7 million and $8.2 million, respectively. The Company expects to continue to incur losses and use cash in operating activities in 2016 and beyond.

The Company is in the early stages of commercializing its BGM Galectin-3 Test. Interest in the BGM Galectin-3 Test is increasing as a result of the Company's market development activities, although it has not yet translated into significant revenue. In order to achieve profitability, the Company will need to generate significant product revenues.

In August 2015, the Company closed on a follow-on underwritten public offering of (i) 2,315,654 Series A units, each consisting of one share of common stock and one half of a warrant to purchase one share of common stock, at a purchase price of $1.00 per Series A unit, and (ii) 184,346 Series B units, in lieu of Series A units, at a purchase price of $1.00 per Series B unit to those purchasers whose purchase of additional Series A units in the offering would result in the purchaser beneficially owning more than 9.99% of the Company's outstanding common stock following the completion of the offering. Each Series B unit consists of one fully pre-funded warrant to purchase one share of common stock and one half of a warrant to purchase one share of common stock. The warrants (other than the fully pre-funded warrants) have an exercise price of $1.00 per share. The net offering proceeds received by the Company, after deducting discounts and commissions and expenses incurred with the offering were approximately $2.0 million.

In May 2015, the Company entered into a Securities Purchase Agreement (the "Series A Purchase Agreement") with the Company's principal stockholders, pursuant to the terms and subject to the conditions contained in the Series A Purchase Agreement, the Company issued and sold to the purchasers (the "Purchasers") secured convertible promissory notes in an aggregate principal amount of $500,000. In addition and pursuant to the terms of the Series A Purchase Agreement, and as approved by the Company's stockholders at the Company's 2015 annual meeting of stockholders (the "2015 Annual Meeting") and the satisfaction or waiver of other closing conditions, the Company issued and sold to the purchasers $2,000,000 of shares of newly created Series A Preferred Stock, $0.001 par value per share of the Company at the second closing that was held on July 14, 2015 following the Company's 2015 Annual Meeting.

On April 8, 2014, the Company closed a follow-on underwritten public offering of 1,613,000 shares of its common stock, at an offering price of $6.20 per share, for gross proceeds of $10.0 million. The net offering proceeds received by the Company, after deducting underwriting discounts and commissions and expenses incurred in connection with the offering, were approximately $9.0 million.

In June 2015, the Company entered into a sublease agreement with a third party for the office space the Company leases located at 880 Winter Street, Waltham, Massachusetts . The term of the sublease is from June 1, 2015 through December 31, 2018 covering the balance of the underlying lease term. The Company has recorded in operating costs total charges of $82,000 with respect to the net present value of the net costs that will continue to be incurred under the lease for its remaining term. The Company has obtained

office space on a short term rental basis and expects to generate annualized savings of approximately $240,000.

Effective January 1, 2014, the payment rate at which the Company's BGM Galectin-3 Test is reimbursed by the Centers for Medicare and Medicaid Services ("CMS"), was increased to $30.01 from $17.80 per test. The Company is in the early stages of commercializing its BGM Galectin-3 Test. In 2015, the national limitation amount for the Company's BGM Galectin-3 Test was reduced to $29.93 and applied across the U.S., except in Ohio and West Virginia where rates of $23.93 and $26.33, respectively, applied. In 2016, the national limitation amount for the Company's BGM Galectin-3 Test was increased to $29.96 and applies across the U.S., except in Ohio and West Virginia where rates of $23.95 and $26.36, respectively, apply. The Company has entered into licensing and commercialization agreements with four leading diagnostic instrument manufacturers to develop and commercialize automated instrument versions of its galectin-3 test. Abbott, one of such manufacturers, began commercializing the ARCHITECT ® Galectin-3 assay in the United States in July 2015.

Since September 11, 2014, the Company implemented a reduction of approximately 77% of its workforce, or 17 people (the "Restructuring"), leaving 5 employees. The Company took this step in order to reduce its operating expenses and extend its cash runway in anticipation of the commercial launch of automated versions of the Company's galectin-3 test. The automated galectin-3 tests are being developed and commercialized by the Company's diagnostic instrument manufacturing partners and will be performed on the partners' automated platforms.

The Restructuring primarily eliminated the Company's sales and marketing organization and removed certain positions in other functional areas, while preserving some senior management and other critical roles to support the clinical and commercial adoption of galectin-3 testing by providing support to clinical research studies that have incorporated our BGM Galectin-3 Test and by expanding the BGM Galectin-3 Test's labeling indications for use through additional clinical studies and clearances by the FDA.

Employees affected by the Restructuring were notified beginning on September 11, 2014 and were provided with severance arrangements including outplacement assistance. As a result of the Restructuring, the Company has recorded total charges with respect to severance payments and benefits continuation of approximately $157,000 and $404,000 during 2015 and 2014, respectively. Of the total $404,000 in charges recorded in 2014, $128,000 was recorded in research and development, $114,000 was recorded in sales and marketing, and $162,000 was recorded in general and administrative expense. Of the $157,000 in charges recorded in 2015, $99,000 was recorded in research and development and $58,000 was recorded in sales and marketing expense. The Company paid approximately $277,000 of such expenses during the third and fourth quarters of 2014, $244,000 of such expenses during 2015, and has paid the remaining $40,000, included in accrued expenses, during the first quarter of 2016. As a result of the Restructuring, the Company estimates it will generate annualized expense savings of approximately $2.6 million primarily from savings in employee salaries and benefits.

As further described in Note 8, the Company had a term loan facility that was secured by substantially all of the Company's assets. Prior to being fully paid off, the loan and security agreement contained customary events of default that entitled the lenders to cause any or all of the Company's indebtedness under the loan and security agreement to become immediately due and payable and could cause the lenders to foreclose on the collateral securing the indebtedness, including the Company's cash. The events of default included, among others, the occurrence of a material adverse effect which could cause the lender to accelerate the payments by the Company under the term loan. As of March 27, 2015, the Company had approximately $1.7 million in cash and $1.9 million outstanding under the term loan. On July 14, 2015, the Company paid off all of its outstanding obligations under the term loan.

Going Concern

The Company believes that its existing cash will be sufficient to fund its operations into July 2016. For the foreseeable future and until the Company generates significant product revenues to reach cash breakeven, the Company will need to raise additional funds to finance its operations beyond July 2016. The Company may not be able to obtain adequate financing to do so when necessary, and the terms of any financings may not be advantageous to the Company and any financings may result in dilution to the Company's stockholders.

The above circumstances along with the Company's history, the near term forecast of incurring net losses and negative operating cash flows, the Company's dependence on near-term revenues generated from product fees due from a single automated partner, the Company's limited experience with the amount and timing of sales made by its automated partners and its inability to predict the timing of the market introduction of automated tests and product fees generated by the sale of automated tests by its other automated partners raise substantial doubt regarding the Company's ability to continue as a going concern for a reasonable period of time. The Company for the year ended December 31, 2015 incurred a loss of $5.3 million and used $3.7 million of cash from operations. The accompanying consolidated financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to its ability to continue as a going concern.

Deregistration

On March 25, 2016, the Company's Board of Directors voted to the voluntarily deregister the Company's common stock under the Exchange Act and become a non-reporting company. In connection therewith, the Board of Directors approved the filing with the SEC of a Form 15 to voluntarily deregister its securities under Section 12(g) of the Exchange Act and suspend its reporting obligations under Section 15(d) of the Exchange Act. The Company expects to file the Form 15 in April 2016. The Company expects that its obligations to file periodic reports, such as Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, will be suspended immediately upon the filing of the Form 15 with the SEC, and its proxy statement, Section 16 and other Section 12(g) reporting responsibilities will terminate effective 90 days after the filing of the Form 15. The Company is eligible to deregister under the Exchange Act because its common stock is held by fewer than 300 stockholders of record. Following deregistration, the Company does not expect to publish periodic financial information or furnish such information to its stockholders except as may be required by applicable laws. As a result of the foregoing factors, deregistration will result in less disclosure about the Company and may negatively affect its ability to raise additional funds, the ability of its stockholders to sell its securities and the liquidity and trading prices of its common stock.

2. Significant Accounting Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reported periods. Actual results could differ from those estimates.

Restricted Cash

Restricted cash was used solely to fund the research and development efforts under the High Risk Plaque Initiative Program (HRP) (Note 15). The Company has reported the changes in restricted cash as an operating activity in the statements of cash flows as a result of the Company receiving cash in prepayment of planned expenditures that was restricted for funding HRP expenses. At December 31, 2013, the HRP initiative had met its goals and all funding from the participating companies had been applied to initiative expenses, with no restricted cash remaining.

Accounts Receivable

Accounts receivable are stated at the amount management expects to collect from outstanding balances. Allowances for doubtful accounts are provided for those outstanding balances considered to be uncollectible based upon historical experience and management's evaluation of the outstanding balances at year end. Bad debts, if any, are written off against the allowance when identified and offset by recoveries when received.

Concentration of Credit Risk and Significant Customers

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and accounts receivable. The Company maintains its cash and cash equivalents at one financial institution that management believes to be of high quality, which balance exceeds federally insured limits throughout the year. To reduce credit risk associated with accounts receivable, the Company routinely assesses the financial strength of its customers and, as a consequence, believes that accounts receivable credit risk exposure is limited. The Company does not require collateral from its customers.

The Company has one customer which generated 73%, 80% and 74% of its product revenues in 2015, 2014 and 2013, respectively. That same customer represented 87% and 78% of its accounts receivable at December 31, 2015 and 2014, respectively.

Concentration of Supplier Risk

The Company obtains materials included in its BGM Galectin-3 Test from a small group of suppliers. The Company carries significant strategic inventories of these materials to reduce the risk associated with this small group of suppliers. Strategic inventories are managed based on demand. To date, the Company has been able to obtain adequate supplies of the materials used in the production of its products in a timely manner from existing sources.

Inventory

Inventory is stated at the lower of cost or market. Costs are determined under the first-in, first-out (FIFO) method. Inventories consisted of the following at December 31:

(in thousands)	2015	2014
Raw materials	$ 46	$ 64
Finished goods	99	336
Total inventories	$ 145	$ 400

Revenue Recognition

Revenue is recognized when the following criteria have been met: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred and risk of loss has passed; (iii) the seller's price to the buyer is fixed or determinable; and (iv) collectability is reasonably assured.

Revenues

We recognize four classes of revenues. Product revenues are comprised of payments made to us from the sale of our products to laboratory testing services, hospitals and clinics and diagnostic testing distributors. Partnership and product fee revenues are comprised of payments made to us by our automated partners in consideration for the rights and licenses granted by us to our automated partners. Service revenues have historically been generated through initiatives, collaborations and biomarker discovery and analysis service agreements.

Product Revenues

The Company sells its products through supply agreements with laboratory testing services and diagnostic testing distributors and directly to hospitals and clinics. The Company recognizes revenue when products are received by customers, at which time both title and risk of loss have passed to the customers. The Company negotiates credit terms on a customer-by-customer basis and products are shipped at an agreed-upon price.

Revenue is recorded net of taxes collected from customers that are remitted to governmental authorities, with the collected taxes recorded as current liabilities until remitted to the relevant government authority. Freight costs billed to customers are recorded as revenue.

The Company does not currently provide a reserve for sales returns as returns are only allowed for defects in workmanship. Allowances for doubtful accounts are provided for those outstanding balances considered to be uncollectible based upon historical experience and management's evaluation of the outstanding balances at year end.

Partnership Revenues

Partnership revenues are comprised of payments made to us by our automated partners in consideration for modifications made to our license and distribution agreements or in consideration for achievement of specified commercial milestones. These payments are non-refundable and not to be applied against future product fees owed to us. In the case of contract modifications, we recognize revenue upon receipt of the payments or deferred over an appropriate period based on the nature of the underlying contract changes. We recognize revenue in consideration for achievement of specified commercial milestones as the milestones are met or exceeded.

Partnership revenue increased in 2015 to $21,000, from $0 in 2014. The increase relates to a $500,000 payment made to us upon execution of the fourth amendment to our agreement with Abbott, which occurred in November 2015. The amendment was principally in regard to the product fees paid to us by Abbott for galectin-3 tests sold by Abbott to reference laboratories, while retaining the previously negotiated product fee for the other customer segments. This payment has been recorded as deferred revenue and is being amortized over 24 months beginning in December 2015.

Product Fee Revenues

The Company recognizes product fee revenue when it receives quarterly test sales reporting and payments thereunder from its partners. The Company has entered into worldwide license, development and commercialization agreements with Abbott, bioMérieux SA, ("bioMérieux"), Siemens Healthcare Diagnostics Inc., ("Siemens"), and Alere Inc., ("Alere"). As consideration for the rights and licenses granted by the Company to its partners, the licensees pay to the Company a product fee, as set forth in the respective agreements, for tests sold to third parties. To date, only Abbott and bioMérieux have paid product fees to the Company.

Service Revenues

Service revenues are primarily attributable to the activities from the HRP initiative, for which all revenue has been recorded as of December 31, 2013. The Company did not record service revenues in 2014 or 2015 and does not expect to record service revenues in 2016 or beyond.

The Company's revenue has historically been generated through initiatives, collaborations and biomarker discovery and analysis services agreements. The services the Company provides under these agreements typically include the integrated analysis of preclinical and/or clinical samples to identify biomarkers related to disease mechanisms. In some cases, the Company has retained certain intellectual property rights to the biomarkers identified in the course of these arrangements. The revenue arrangements have a stated term and the Company has no obligations or ongoing commitments after the specified term of the arrangement.

Revenue generated from collaborations and initiatives, such as the HRP initiative described in Note 15, includes revenue from research services and technology licensing agreements. Under these arrangements, the Company is contractually obligated to provide research services and project oversight and administration. The rights to the results of the research, including any intellectual property developed, are licensed to all the members of the collaboration at the inception of the arrangement. The Company has accounted for all deliverables, which include the research services, oversight and administration and the rights to the intellectual property developed, as a single unit of accounting as there is no stand-alone value to the individual elements. The Company considers the terms and conditions of each agreement and recognizes revenues based upon a proportional performance methodology. This methodology involves recognizing revenue over the term of the agreement, as underlying research costs are incurred, and measured on the basis of input measures such as labor or instrument hours expended. The Company believes that these input measures approximate the output measures as the costs incurred are directly proportional to the services that are being provided. The Company makes adjustments, if necessary, to the estimates used in its calculations as work progresses and as such changes are known. The principal costs under these agreements are for personnel and instrumentation expenses to conduct research and development but also include costs for materials and other direct and indirect items necessary to complete the research under these agreements. Actual results may vary from the Company's estimates.

Payments received on uncompleted long-term contracts may be greater than incurred costs and estimated earnings and have been recorded as deferred revenues and classified as other current liabilities in the accompanying consolidated balance sheets.

Product Fee Reclassification

Beginning in the third quarter of 2015, the Company began disclosing product fee revenue separately from product revenue. To maintain comparability, all previously reported product revenue figures in the accompanying consolidated financial statements have been retroactively adjusted to break out the product fee revenue recognized during those periods. Management evaluated the amount and nature of the change and concluded that it was not material to either the previously reported annual or quarterly financial statement results of operations. Nonetheless, the Company has reclassified the historical statements of operations amounts included in this filing as follows (in thousands):

	As reported Year ended December 31, 2014	As reclassified Year ended December 31, 2014	As reported Year ended December 31, 2013	As reclassified Year ended December 31, 2013
Product Revenues	$ 2,787	$ 2,698	$ 3,683	$ 3,635
Product Fee Revenues	-	89	-	48
Total Revenues	$ 2,787	$ 2,787	$ 3,683	$ 3,683

Product and Product Fee Costs

Product and product fee costs consist of contract-manufacturing for the BGM Galectin-3 Test, freight, and revenue-based royalty expenses for certain galectin-3 in-licensed intellectual property. In 2013, the Company became subject to excise taxes due to the classification of the galectin-3 test as a taxable medical device. The excise tax is included in product costs.

Service Costs

Service costs consist primarily of expenses incurred in connection with the collaborative research and development agreements and biomarker discovery and analysis services agreements. Expenses include outside services and internal personnel costs, laboratory consumables, license fees and overhead expenses related to providing these services. The majority of the cost of service revenue in the periods presented was incurred in connection with the HRP initiative discussed in Note 15.

Research and Development Costs

Research and development costs are expensed as incurred. Nonrefundable advance payments, if any, for goods and services used in research and development are recognized as expenses as the related goods are delivered or services are performed. Research and development costs include labor, materials and supplies and overhead.

Intangible Assets and Long Lived Assets

The only intangible asset recognized at December 31, 2015 and 2014 relates to the cost of completed technology acquired for use in connection with the Company's development of the galectin-3 test and certain other technologies. The assigned life is 10 years, which contemplates a three to five year phase of development of the diagnostic test followed by the expected commercial life of the test. Amortization of this asset has been recorded within research and development expense for all periods presented.

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets, including intangible assets, may not be recoverable. When such events occur, the Company compares the carrying amounts of the assets to their undiscounted expected future cash flows. If this comparison indicates that there is impairment, the amount of the impairment is calculated as the difference between the carrying value and fair value.

Stock-Based Compensation

Stock-based compensation expense is recognized based on the grant-date fair value using the Black-Scholes valuation model. The Company recognizes compensation expense only for those stock-based awards expected to vest after considering expected forfeitures. Stock-based compensation is recognized on a straight-line basis over the service period of each award. Stock compensation costs have not been capitalized by the Company.

The Company accounts for stock-based awards issued to non-employees by recognizing compensation expense based on the fair value of such awards when the services are completed over the vesting period of the award.

Income Taxes

Deferred tax assets and liabilities are recorded to reflect the impact of temporary differences between amounts of assets and liabilities for financial reporting purposes and such amounts as measured under enacted tax laws. A valuation allowance is provided to offset any net deferred tax assets if, based upon the available evidence, it is more likely than not that some or all of the deferred tax asset will not be realized.

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions. The Company recognizes tax benefits when a position is more likely than not to be sustained upon examination by the applicable taxing authority. The tax benefits recognized in the financial statements from such positions are then measured based on the largest benefit that has a greater than 50% likelihood of being realized upon settlement. The Company recognizes interest and penalties related to uncertain tax positions within the provision for income taxes. Potential interest and penalties associated with such uncertain tax positions are recorded as a component of income tax expense.

Net Loss Per Share Attributable to Common Stockholders

Basic and diluted net loss per share attributable to common stockholders is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period. The Company applied the two-class method to calculate its basic and diluted net loss per share of common stock, as its convertible preferred stock, common stock, and warrants to purchase common stock are participating securities. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. However, the two-class method does not impact the net loss per share of common stock as the Company was in a loss position for each of the periods presented, and neither preferred stockholders nor warrant holders participate in losses.

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders for the years ended December 31:

	2015	2014	2013
	(in thousands, except share and per share data)		
Net loss	$ (5,303)	$ (8,064)	$ (15,849)
Preferred stock dividend	(92)	-	-
Deemed dividend on beneficial conversion feature	(1,507)	-	-
Accretion of convertible preferred stock	(56)	-	-
Net loss attributable to common stockholders	$ (6,958)	$ (8,064)	$ (15,849)
Weighted average number of common shares outstanding - basic and diluted	9,609,408	8,175,805	6,803,209
Net loss per share attributable to common stockholders - basic and diluted	$ (0.72)	$ (0.99)	$ (2.33)

The following potential common shares were excluded from the computation of diluted net loss per share because they had an antidilutive impact due to the losses reported:

	2015	2014	2013
Options to purchase common stock	603,643	580,207	649,280
Unvested restricted stock units	88,238	250,475	-
Warrants to purchase common stock	1,353,927	186,450	216,156
Convertible preferred stock	2,598,616	-	-
Total	4,644,424	1,017,132	865,436

Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker ("CODM") in making decisions regarding resource allocation and assessing performance. The Company's chief executive officer is the CODM, and he uses consolidated financial information in determining how to allocate resources and assess performance. The Company has determined that it operates in one segment. All of the Company's assets are located in the United States and substantially all of the Company's revenues are from customers in the United States.

New Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-02, "Leases," which changes financial reporting around leasing transactions and more closely aligns accounting for leases with the recently issued International Financial Reporting Standard. Among other things, the update requires a lessee to recognize assets and liabilities on the balance sheet for operating leases and changes many key definitions, including the definition of a lease. The standard is effective for fiscal years beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted. The Company is currently evaluating the impact that ASU 2016-02 will have on its consolidated financial statements and related disclosures.

In January 2016, the FASB issued ASU 2016-01, "Financial Instruments – Recognition and Measurement of Financial Assets and Financial Liabilities", which provides new guidance for the recognition, measurement, presentation, and disclosure of financial assets and liabilities. The standard is effective for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019, and early adoption is permitted. The Company is currently evaluating the effect, if any, that the standard will have on its consolidated financial statements and related disclosures.

In July 2015, the FASB issued ASU 2015-11, "Simplifying the Measurement of Inventory". The update replaces the concept of "lower of cost or market" with that of "lower of cost and net realizable value", which requires companies to measure certain inventory at the lower of cost and net realizable value. This accounting guidance is effective for fiscal years beginning after December 15, 2016, and interim periods within those years on a prospective basis. Early application is permitted. The Company is currently evaluating the impact of this accounting standard update on its consolidated financial position, results of operations and cash flows and does not expect the impact to be material.

In April 2015, the FASB issued ASU 2015-03, "Simplifying the Presentation of Debt Issuance Costs". This ASU, which is effective for fiscal years and interim periods beginning after December 15, 2015, requires debt issuance costs to be presented in the balance sheet as a direct deduction from the related debt liability rather than as an asset. Early adoption is permitted and retrospective application is required. The adoption of ASU 2015-03 is not expected to have a material impact on the Company's results of operations or financial condition.

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers", which supersedes existing accounting standards for revenue recognition and creates a single framework. This standard provides principles for recognizing revenue for the transfer of promised goods or services to customers with the consideration to which the entity expects to be entitled in exchange for those goods or services and specifies the accounting for certain costs to obtain or fulfill a contract with a customer. On July 9, 2015, the FASB decided to delay the effective date of this new accounting guidance by one year, which will result in it being effective for annual periods beginning after December 15, 2017. The Company is currently evaluating the potential impact on its consolidated financial statements and the related disclosures, as well as the available transition methods.

Reclassifications

Certain prior year amounts have been reclassified to the current year presentation. The reclassifications did not have any effect of reported net income/(loss) for any period presented.

3. Fair Value of Financial Instruments

At December 31, 2015, the Company's financial instruments consisted of cash, accounts receivable, and accounts payable. The carrying amounts of accounts receivable and accounts payable are considered reasonable estimates of their fair value, due to the short maturity of these instruments.

In accordance with U.S. generally accepted accounting standards, fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last is considered unobservable, that may be used to measure fair value which are the following:

Level 1 – Quoted prices in active markets for identical assets or liabilities.

Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The assets or liabilities fair value measurement level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Valuation techniques used need to maximize the use of observable inputs and minimize the use of unobservable inputs.

The table below sets forth a summary of changes in the fair value of the Company's level 3 liability (preferred stock liability) for the year ended December 31, 2015:

	2015 (in thousands)
Beginning balance	$ -
Loss on recognition of preferred stock liability	79
Gain on revaluation of preferred stock liability	(79)
Ending balance	$ -

The resulting initial recognition and subsequent revaluation were recorded as other income (expense) in the consolidated statements of operations.

The table below sets forth a summary of changes in the fair value of the Company's secured convertible notes for the year ended December 31, 2015:

	2015 (in thousands)
Beginning balance	$ -
Proceeds from secured convertible note	500
Loss on fair value adjustment	487
Conversion of secured convertible notes	(987)
Ending balance	$ -

The resulting fair value adjustment was recorded as other income (expense) in the consolidated statements of operations.

The preferred stock liability was valued using the Black-Scholes option pricing model as of May 12, 2015, the issuance date of the secured convertible notes, resulting in a fair value of $79,000. This valuation considered an underlying security price of $2.12, strike price of $2.68, risk-free interest rate of 0.02%, expected dividend yield of 0%, volatility factor of 73.8%, and expected term of 0.22 years. As of July 14, 2015, the mandatory conversion of the secured convertible notes into preferred stock occurred, resulting in a remaining term of zero and thereby a fair value of zero.

The secured convertible promissory notes valuation analysis was based on the probability-weighted expected return method ("PWERM") utilizing various scenarios for the expected payout of the instrument covering the full range of the potential outcomes. The PWERM determines the value of an instrument, based upon an analysis of future values for the subject instruments, which takes into consideration the full range of the potential cash flows available to the subject instrument. The instrument value is based upon the present value of the probability of each future outcome becoming available to the instrument, and the economic rights and preferences of the instrument.

Due to the lack of relevant and market reflective Level 1 and Level 2 inputs, the Company valued the instruments using Level 3 inputs, which require significant judgment and estimates on behalf of management in developing model assumptions. At the conversion date of July 14, 2015, the following inputs were utilized in valuing the convertible debt instrument: (1) conversion price of $3.33 per share, (2) current common stock price of $1.54 per share, (3) discount rate of 18.0%, and (4) expected stock price volatility of 56.2%.

4. Property and Equipment

Property and equipment consist of the following as of December 31:

	Estimated Useful Life	2015	2014
		(in thousands)	
Computer equipment and software	3 years	$ 279	$ 411
Laboratory equipment	3-5 years	164	164
Office furniture	5 years	39	147
Leasehold improvements	4 years	-	29
		482	751
Less: Accumulated depreciation		(471)	(634)
Property and equipment, net		$ 11	$ 117

Depreciation expense for the years ended December 31, 2015, 2014 and 2013 was $30,000, $74,000 and $92,000, respectively.

5. Intangible Assets

Intangible assets with an original cost of $750,000 are comprised of a completed technology that was obtained under a perpetual license (Note 14). In 2013, the Company abandoned one of the licensed patents included in this completed technology, with an original cost of $250,000 resulting in an impairment charge

of $105,000. In 2014 and 2015, impairment tests found no indicators of impairment, and as such, no impairment charges were taken. The remaining assets are being amortized over their economic lives, a weighted-average amortization period of 8.7 years, and the weighted-average remaining life was 1.3 years as of December 31, 2015. Accumulated amortization totaled $423,000 and $365,000 at December 31, 2015 and 2014, respectively. Amortization expense for the years ended December 31, 2015, 2014 and 2013 was $57,000, $57,000 and $75,000, respectively. The amortization expense for the next year is expected to approximate $58,000 and amortization expense in the final year is expected to approximate $20,000.

6. Accrued Expenses

Accrued expenses at December 31 consist of:

	2015		2014
		(in thousands)	
Consulting and professional service fees	$ 228		$ 431
Accrued interest expense	-		222
Employee compensation and related costs	58		149
Contract research and development	23		42
Other	36		62
Total accrued expenses	$ 345		$ 906

7. Income Taxes

The tax benefit arising from the Company's net losses has been offset by increases in the valuation allowance. Accordingly, the Company had no net income tax provision or benefit during the years ended December 31, 2015, 2014 and 2013. Components of the net deferred tax asset at December 31, 2015 and 2014 are as follows:

	2015		2014
		(in thousands)	
Net operating loss carryforwards	$ 50,217		$ 48,113
Tax credit carryforwards	3,162		3,128
Allowance for doubtful accounts	62		-
Capitalized research and development costs	1,421		1,749
Non-qualified employee stock options	566		931
Other temporary differences	285		270
	55,713		54,191
Valuation allowance	(55,713)		(54,191)
Net deferred tax asset	$ -		$ -

At December 31, 2015, the Company had available federal and state net operating loss carryforwards of $136,733,000 and 99,687,000, respectively, which expire at various dates through 2035. The gross deferred

tax asset reflected for federal net operating losses excludes excess benefits related to the exercise of stock options of $1,526,000 and $1,341,000, respectively, when utilized, will be recorded through additional paid in capital. In assessing the realizability of net deferred tax assets, management considers whether it is more likely than not that the net deferred tax assets will be realized. The ultimate realization of net deferred tax assets is dependent upon the generation of future taxable income during the periods in which temporary differences representing future deductible amounts become deductible. Management has established a full valuation allowance against the net deferred tax assets at December 31, 2015 and 2014 since it is more likely than not that these future tax benefits will not be realized. During 2015, 2014 and 2013, the valuation allowance increased by approximately $1,522,000, $1,576,000, and $3,262,000 respectively.

At December 31, 2015, the Company had federal and state research and development credit carryforwards of $2,143,000 and $1,511,000, respectively. The net credit carryforwards may be used to offset future income taxes and expire at various dates through 2035. Changes in the Company's ownership, as defined in the U.S. Internal Revenue Code, may limit the Company's ability to utilize the tax credit and net operating loss carryforwards.

The Company files tax returns in the United States, Massachusetts and other states. The tax years 2011 through 2015 remain open to examination by major taxing jurisdictions to which the Company is subject, which are primarily the United States and Massachusetts, as carryforward attributes generated in years past may still be adjusted upon examination by the Internal Revenue Service or state tax authorities if they have or will be used in a future period. The Company is currently not under examination by the Internal Revenue Service or any other jurisdictions for any tax years. The Company recognizes both accrued interest and penalties related to unrecognized benefits within the provision for income taxes. The Company has not recorded any interest or penalties on any unrecognized tax benefits since its inception. The Company anticipates the amount of unrecognized tax benefits recorded will not materially change in the next twelve months.

Under the provisions of the Internal Revenue Code, the net operating losses and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Services ("IRS") and state tax authorities. Net operating losses and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Section 382 and 383 of the Internal Revenue Code, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in the future years. The Company has not performed a full comprehensive Section 382 study to determine any potential loss limitation with regards to the net operating loss carryforwards and tax credits in the U.S.

A reconciliation of income tax (expense) benefit at the statutory federal income tax rate and income taxes as reflected in the financial statements at December 31, 2015, 2014 and 2013 is as follows:

	2015	2014	2013
Federal income tax at statutory rate	34.00%	34.00%	34.00%
State income tax, net of federal benefit	12.39%	3.22%	4.47%
Book compensation related to stock options	(11.24)%	(1.65)%	(5.45)%
Change in state tax rates	7.95%	(3.45)%	(5.46)%
Permanent differences	(3.13)%	(4.54)%	(6.74)%
Other	0.82%	7.06%	0.98%
Expired attributes	(12.07)%	(15.10)%	(1.05)%
Increase in valuation allowance	(28.72)%	(19.54)%	(20.75)%
Effective tax rate	0%	0%	0%

8. Term Loan

On February 10, 2012, the Company entered into a secured term loan facility, and a term loan in the aggregate principal amount of $10.0 million was funded upon the closing of the transaction.

In May 2013, the Company amended its secured term loan facility to allow for a three month deferral of principal payments beginning May 1, 2013 and to allow for up to an additional three months of deferral based on the Company meeting certain minimum liquidity requirements, as defined in the amendment. The Company made principal payments in March and April 2013 prior to the signing of the amendment. The Company did not meet the additional liquidity requirements, as defined in the amendment, and, accordingly, principal payments resumed on August 1, 2013. The amendment also increased certain loan fees by $50,000, and amended the terms of the warrants, as discussed below.

On July 14, 2015, the Company paid off all of its outstanding obligations under the secured term loan facility and terminated the loan facility. The security interest granted by the Company to the lenders in its assets in connection with the loan facility was also terminated at the time of the payoff.

Warrants related to the Term Loan

In connection with the loan facility, the Company initially issued to the lenders warrants to purchase 9,165 shares of its common stock with an exercise price of $27.28 per share. The warrants expire ten years from the date of issuance. The warrants were valued using the Black-Scholes option pricing model using the following assumptions: fair value of the underlying common stock of $34.04 per share; volatility of 70%; no dividend yield; risk free interest rate of 1.96%; and an expected life of ten years. The relative fair value of the warrants, aggregating $240,000, has been accounted for as a debt discount and is being recognized as interest expense over the term of the loan using the effective interest method. These warrants have been classified as equity instruments and are included within additional paid-in capital. As part of the May 2013 amendment to the loan and security agreement, the number of shares for which the warrants were exercisable increased by 27,600 shares and the exercise price of the warrants was adjusted to $6.80 per share. At the loan modification date, the Company valued both the amended and the original warrants using the Black-Scholes option pricing model and recorded the incremental value of the amended warrants as additional debt discount in the amount of $163,000, which was recognized as additional interest expense over the remaining term of the loan until its payoff on July 14, 2015 using the effective interest method. Notwithstanding the payoff of the loan facility in July 2015, the warrants continue to remain outstanding in accordance with their terms and are not affected by the payoff.

At December 31, 2015, the Company had $0 outstanding under the term loan and no unamortized debt discount, having extinguished the debt in July 2015.

9. Common Stock Purchase Agreement

On January 24, 2013, the Company entered into a Common Stock Purchase Agreement, or the Aspire Purchase Agreement, with Aspire Capital Fund, LLC, or Aspire, to purchase, at the Company's option, up to an aggregate of $12.0 million of shares of its common stock over a two-year term, which expired on June 7, 2015. Under the Aspire Purchase Agreement, the Company initially issued 33,186 shares of its common stock as a commitment fee. The Company did not sell any shares of its common stock under the Aspire Purchase Agreement, which expired in June 2015.

The Company also entered into a Registration Rights Agreement with Aspire, which required, among other things, that the Company maintain the effectiveness of the Company's registration statement that registered the shares issued to Aspire under the Aspire Purchase Agreement.

10. Follow-on Public Offerings

On January 30, 2013, the Company closed a follow-on underwritten public offering of 1,725,000 shares of its common stock, at an offering price of $8.00 per share, for gross proceeds of $13.8 million. The net offering proceeds received by the Company, after deducting underwriting discounts and commissions and expenses incurred in connection with the offering, were approximately $12.8 million.

On April 8, 2014, the Company closed a follow-on underwritten public offering of 1,613,000 shares of its common stock, at an offering price of $6.20 per share, for gross proceeds of $10.0 million. The net offering proceeds received by the Company, after deducting underwriting discounts and commissions and expenses incurred in connection with the offering, were approximately $9.0 million.

On August 18, 2015, the Company closed on an underwritten public offering of (i) 2,315,654 Series A units, each consisting of one share of common stock and one half of a warrant to purchase one share of common stock, at a purchase price of $1.00 per Series A unit, and (ii) 184,346 Series B units, in lieu of Series A units, at a purchase price of $1.00 per Series B unit to those purchasers whose purchase of additional Series A units in the offering would result in the purchaser beneficially owning more than 9.99% of the Company's outstanding common stock following the completion of the offering. Each Series B unit consists of one fully pre-funded warrant to purchase one share of common stock and one half of a warrant to purchase one share of common stock. The warrants (other than the fully pre-funded warrants) have an exercise price of $1.00 per share. The net offering proceeds received by the Company, after deducting discounts and commissions and expenses incurred with the offering, were approximately $2.0 million.

11. Convertible Promissory Notes and Series A Preferred Stock

On May 12, 2015, the Company entered into the Series A Purchase Agreement with the Company's principal stockholders. On May 12, 2015 (the "Initial Closing"), pursuant to the terms and subject to the conditions contained in the Series A Purchase Agreement, the Company issued and sold to the Purchasers secured convertible promissory notes in the aggregate principal amount of $0.5 million (the "Notes"). In addition, the Company agreed to issue to the Purchasers, and the Purchasers agreed to purchase from the Company, an aggregate of $2.0 million of shares of Series A Preferred Stock, $0.001 par value per share (the "Series A Preferred Stock"), at the second closing. The Company determined that the liability to issue the Series A Preferred Stock (the "Preferred Stock Liability") at a future date was a freestanding instrument

and should be accounted for as a liability. The Company remeasures the Preferred Stock Liability at fair value at each reporting period, with changes being recorded within other (loss) income. At December 31, 2015, no Preferred Stock Liability was recorded due to the conversion of the Notes in July 2015.

The Notes contained a compound embedded derivative that requires separate accounting from the host debt instrument. The Company elected the fair value option for the Notes as management believes recording the Notes at fair value better reflects the underlying economics of the transaction. The Company remeasures the Notes at fair value at each reporting period, with changes being recorded within other (loss) income in the consolidated statements of operations.

Upon consummation of the Series A Purchase Agreement, the Company allocated the total principal proceeds of $0.5 million between the Preferred Stock Liability and the fair-valued Notes and recorded a loss of $0.5 million in other (loss) income in the consolidated statements of operations.

Pursuant to the terms of the Series A Purchase Agreement, and as approved by the Company's stockholders at the Company's 2015 Annual Meeting, the Company issued and sold to the Purchasers $2.0 million in shares of Series A Preferred Stock at the second closing that was held on July 14, 2015 (the "Second Closing").

Secured Convertible Promissory Notes and Related Agreements

At the Second Closing, the Notes were automatically converted pursuant to their terms into that number of shares of Series A Preferred Stock equal to the principal amount of the Notes plus all accrued but unpaid interest thereon divided by the purchase price of the Series A Preferred Stock of $1.7003 per share (the "Purchase Price").

Contemporaneously with the execution and delivery of the Series A Purchase Agreement and the issuance of the Notes by the Company to the Purchasers, the Company and the Purchasers entered into a Security Agreement (the "Security Agreement"), dated May 12, 2015, pursuant to which the Company granted to the Purchasers a security interest in substantially all of the Company's assets, other than the Company's intellectual property, to secure the Company's obligations under the Notes. Pursuant to the terms of the Security Agreement, the Company's intellectual property would have become subject to the security interest granted by the Company to the Purchasers upon repayment of all amounts owed under that certain Loan and Security Agreement by and among the Company, General Electric Capital Corporation ("GECC") as Agent, the Lenders and the Guarantors dated as of February 10, 2012, as amended ("the "GECC Agreement") referred as the "Term Loan" (See Note 8). Pursuant to a Subordination and Intercreditor Agreement by and among the Company, the Purchasers and GECC, dated May 12, 2015, entered into contemporaneously with the execution and delivery of the Series A Purchase Agreement, the Company's payment obligations under the Notes were subordinated to the Company's payment obligations under the GECC Agreement and the security interest granted by the Company to the Purchasers to secure the Company's obligations under the Notes was subordinated to the security interest granted by the Company to GECC to secure the Company's obligations under the GECC Agreement. In connection with the entry into the Series A Purchase Agreement, the Company and GECC amended the GECC Agreement, dated May 12, 2015, to, among other things, permit the Company to enter into the Series A Purchase Agreement and related agreements. Upon the conversion of the Notes into shares of Series A Preferred Stock at the Second Closing, the security interest granted under the Security Agreement was terminated.

The Second Closing was subject to the approval of the Company's stockholders at the 2015 Annual Meeting in July 2015 and the satisfaction or waiver of other closing conditions. The Company's stockholders approved the issuance of shares of Series A Preferred Stock, shares of Series A Preferred

Stock issuable upon conversion of the Notes and common stock issuable upon conversion of Series A Preferred Stock, at the 2015 Annual Meeting held on July 7, 2015.

On July 14, 2015, the Company and the Purchasers entered into the First Amendment to the Series A Purchase Agreement (the "First Amendment") pursuant to which the Company and the Purchasers agreed to extend the period of time following the Company's 2015 Annual Meeting for the Second Closing to occur until July 14, 2015. At the Second Closing, pursuant to the terms of the Series A Purchase Agreement, the Company issued and sold to the Purchasers 1,176,262 shares of newly designated Series A Preferred Stock of the Company at the Purchase Price of $1.7003 per share for aggregate gross cash proceeds of approximately $2.0 million. In addition, at the Second Closing, the $0.5 million in aggregate principal amount of Notes, plus accrued but unpaid interest, that the Company had issued to the Purchasers in the Initial Closing, converted into 298,181 shares of Series A Preferred Stock at the Purchase Price. Following the Second Closing in July 2015, the Company had issued an aggregate of 1,474,443 shares of Series A Preferred Stock, which remain outstanding and held by the Purchasers.

The shares of Series A Preferred Stock have the rights, preferences and privileges set forth in the Restated Certificate of Designations to the Company's Restated Certificate of Incorporation (the "Certificate of Designations") that was filed by the Company on August 18, 2015 with the Secretary of State of the State of Delaware. The rights, preferences and privileges of the Series A Preferred Stock are as follows:

Dividends

Holders of Series A Preferred Stock will be entitled to receive, out of funds legally available for the payment of dividends under Delaware law, cumulative dividends that accrue daily at an annual rate of 8%, compounded and payable quarterly in cash or in additional shares of Series A Preferred Stock at the election of each holder. The holders of Series A Preferred Stock will also be entitled to participate in cash dividends and in-kind distributions made on shares of common stock.

The Board of Directors has not declared any dividends on common or preferred stock. At December 31, 2015, the cumulative undeclared dividends on preferred stock totals $92,000, and are included as a deduction in determining net loss per share attributable to common stockholders. The carrying value of the Series A Preferred Stock was not adjusted for the cumulative undeclared dividends as the Series A Preferred Stock is not probable of becoming redeemable.

Voting Rights

Holders of Series A Preferred Stock will be entitled to vote with the holders of the common stock on an as-converted basis, except that no holder of Series A Preferred Stock will be entitled to cast votes for the number of shares of common stock issuable upon conversion of the Series A Preferred Stock held by such holder that exceeds (subject to a proportionate adjustment in the event of a stock split, stock dividend, combination or other proportionate recapitalization) the quotient of (A) the aggregate purchase price paid by such holder for its Series A Preferred Stock, divided by (B) the greater of (i) $3.20 and (ii) the closing price of the common stock on the trading day immediately prior to the date its Series A Preferred Stock is issued, which was $1.40. In addition, prior to the conversion of the Series A Preferred Stock, the consent of the holders of at least a majority of the Series A Preferred Stock then outstanding, voting together as a single class, will be required for the Company to take certain actions, including, among other things: liquidating, dissolving or winding up the business and affairs of the Company or effecting any merger, consolidation or other liquidation event; amending, altering or repealing any provision of the Certificate of Incorporation, the Certificate of Designations or the Bylaws of the Company; creating or authorizing any class or series of capital stock ranking senior to or on parity with the Series A Preferred Stock or increasing

the number of authorized shares of Series A Preferred Stock; purchasing, redeeming, paying or declaring dividends on any shares of capital stock of the Company, with certain exceptions; increasing or decreasing the size of the Board of Directors of the Company (the "Board"); and certain other actions.

Conversion Rights

Each share of Series A Preferred Stock is convertible into one share of common stock at any time at the option of each holder and automatically upon the written consent of the holders of a majority of the outstanding shares of Series A Preferred Stock. The conversion price will be subject to adjustment in connection with stock splits, combinations, dividends and other corporate transactions affecting the common stock. All other anti-dilution protections that had been provided to the Series A Preferred Stock upon issuance terminated following the Second Closing.

A contingent beneficial conversion feature was recognized during 2015 as a result of the conversion price being adjusted from $1.7003 to $1.00 at the time of the Second Closing. The Company recorded $1.5 million relating to the contingent beneficial conversion as a deemed dividend. The $1.5 million was included within additional paid-in capital in the consolidated financial statements, and reduced the carrying value of the Series A Preferred Stock. Since the Series A Preferred Stock has no stated redemption date and is immediately convertible, the $1.5 million deemed dividend was immediately accreted, resulting in an increase in the carrying value of the Series A Preferred Stock. The deemed dividend was included as a deduction in determining net loss per share attributable to common stockholders. The conversion price adjustment feature expired following the Second Closing.

Redemption Rights

All redemption rights that had been provided to the Series A Preferred Stock upon issuance terminated following the Second Closing.

Ranking

The Series A Preferred Stock will rank senior in preference and priority to the Company's common stock and each other class or series of capital stock of the Company, except for any class or series of capital stock issued in compliance with the terms of the Restated Certificate of Designations.

Liquidation Preference

Upon liquidation, including deemed liquidations pursuant to a merger, consolidation or a sale of all or substantially all of the Company's assets, the holders of Series A Preferred Stock will be entitled to be paid first out of any proceeds in an amount per share equal to the price at which shares of Series A Preferred Stock were sold in the Series A Preferred Stock financing, plus all accrued but unpaid dividends on each share of Series A Preferred Stock, and prior to payment of any amounts on the Company's common stock. Thereafter, the holders of Series A Preferred Stock will also share pro rata on an as converted to common stock basis in payments made to the holders the Company's common stock. Accordingly, the holders of the Series A Preferred Stock will be entitled to receive the proceeds out of any sale or liquidation of the Company before any such proceeds are paid to holders of the Company's common stock and then share in any proceeds paid to holders of the Company's common stock. As a result, only the sale or liquidation proceeds in excess of the liquidation preference plus accrued but unpaid dividends would be available for distribution to holders of the Company's common stock.

The commissions and issuance costs associated with the Series A Preferred Stock financing were deducted from the carrying value of the Series A Preferred Stock, resulting in the carrying value of the Series A

Preferred Stock being reduced below its liquidation value. The Company accretes the carrying value of the Series A Preferred Stock over the period from the date of issuance to the earliest redemption date using the effective interest method. During 2015, the Company recorded one month of accretion, totaling $56,000, at which point the Company ceased accretion as the Series A Preferred stock was not probable of becoming redeemable.

Board of Directors

Holders of Series A Preferred Stock will be entitled to nominate one director to the Board (the "Series A Director"). Subject to applicable law and stock exchange requirements, the Series A Director will be entitled to serve as a member of each committee of the Board. The rights to nominate a Series A Director will terminate if less than 20% of the shares of Series A Preferred Stock issued under the Securities Purchase Agreement dated May 12, 2015, as amended, by and between the Company and the holders of Series A Preferred Stock are no longer outstanding.

Registration Rights

In connection with the Second Closing, the Company also entered into the Fifth Amended and Restated Investor Rights Agreement (the "Investor Rights Agreement") with the Purchasers as well as the stockholders who hold shares of the Company's common stock that are registrable securities (the "Prior Registrable Securities") under the Company's existing Fourth Amended and Restated Investor Rights Agreement dated as of July 10, 2008 (the "Existing IRA"). Under the terms of the Investor Rights Agreement, the Existing IRA was amended and restated to grant certain demand and piggyback registration rights with respect to the shares of common stock issuable upon conversion of the Series A Preferred Stock. These registration rights are subject to certain conditions and limitations, including the right of the underwriters of an offering to limit the number of shares of the Company's common stock included in any such registration under certain circumstances. The Company is generally required to pay all expenses incurred in connection with registrations effected in connection with the registration rights, excluding underwriting discounts and commissions.

As the holders of the Series A Preferred Stock are entitled to receive liquidation preferences to which other equity holders are not entitled, the Company determined that the preferred stock should be classified as temporary equity in the consolidated financial statements.

The Company reviews the rights and preferences of its equity securities for any changes in terms, rights or preferences to determine if such change is a modification or an extinguishment. The Company evaluates amendments to equity securities using a qualitative method which considers the business purpose for the amendment and whether it adds, deletes or significantly changes a substantive contractual term or the nature of the equity securities. An amendment that changes a substantive contractual term or fundamentally changes the nature of the share of preferred stock is considered an extinguishment. If considered an extinguishment, the Company accounts for the removal of the carrying value of the old securities and recognizes the new securities at their current fair value. An amendment that does not meet these criteria is a modification. If considered a modification, the Company estimates the fair value of the equity security pre- and post- modification and recognizes the incremental fair value, if any, resulting from the modified terms. During 2015, the Company determined that all changes to the terms of the Series A Preferred Stock resulting from amendments made to the Certificates of Designations were not substantive and should be accounted for as a modification. The amendments did not result in a material change to the fair value of the Series A Preferred Stock.

12. Stock-Based Compensation

Stock Options

The Company's 2010 Employee, Director and Consultant Stock Plan (the "2010 Stock Plan") became effective in February 2011, upon the closing of the initial public offering and will expire in August 2020. Under the 2010 Stock Plan, the Company may grant incentive stock options, non-qualified stock options, restricted and unrestricted stock awards and other stock-based awards. The Company's 2001 Stock Option and Incentive Plan (the "2001 Stock Plan") was terminated in February 2011 effective upon the completion of the Company's initial public offering. At December 31, 2015, there were options to purchase 47,783 shares of common stock outstanding under the 2001 Stock Plan and no further options will be granted under the 2001 Stock Plan. In addition to options outstanding under the 2010 Stock Plan and the 2001 Stock Plan, the Company has issued options to purchase 175,000 shares of common stock outside of the Company's stockholder-approved equity plans as an inducement for the Company's President & Chief Executive Officer's employment with the Company, all of which were outstanding at December 31, 2015.

As of December 31, 2015, there were 749,982 shares of the Company's common stock reserved under the 2010 Stock Plan. In addition, the 2010 Stock Plan contains an "evergreen" provision, which allows for an annual increase in the number of shares of the Company's common stock available for issuance under the plan on the first day of each fiscal year during the period beginning in fiscal year 2012. At December 31, 2015, there were options to purchase 172,876 shares of common stock available for issuance and options to purchase 380,860 shares of common stock outstanding under the 2010 Stock Plan. In addition, during 2012, 694 shares of common stock were issued in lieu of bonus under the 2010 Stock Plan. Options granted under the 2010 Plan have a term of ten years. Vesting of options under the 2010 Stock Plan is determined by the compensation committee or the board of directors, but is generally a four-year term.

The fair value of options at date of grant was estimated using the Black-Scholes option-pricing model with the following assumptions:

	2015	2014	2013
Risk-free interest rate	1.77% – 1.79%	1.62% – 2.09%	0.68% – 1.90%
Expected dividend yield	0%	0%	0%
Expected life	5.50 – 6.11 years	5.50 – 7.00 years	5.10 – 6.69 years
Expected volatility	115% – 118%	64% – 69%	66% – 72%
Weighted-average grant date fair value	$2.36	$2.84	$3.76

The Company does not have a significant history of market prices of its common stock as it was not a public company prior to February 4, 2011, and, as such, volatility was estimated using historical volatilities of similar public companies. The expected life of the awards is estimated based on the simplified method, which calculates the expected life based upon the midpoint of the term of the award and the vesting period. The Company uses the simplified method because it does not have sufficient option exercise data to provide a reasonable basis upon which to estimate the expected term. The Company has no history of paying dividends nor does management expect to pay dividends over the contractual terms of these options. The risk-free interest rates are based on the United States Treasury yield curve in effect at the time of grant, with maturities approximating the expected life of the stock options.

The following table summarizes information about stock options activity during 2015 and 2014:

	Number of shares	Weighted-average exercise price	Weighted - average remaining contractual term	Aggregate intrinsic value
Outstanding, January 1, 2014	649,280	$ 13.93		
Granted	177,829	4.57		
Exercised	(6,007)	3.60		
Forfeited	(226,453)	11.14		
Expired	(14,442)	3.71		
Outstanding, December 31, 2014	580,207	$ 12.52		
Granted	147,500	2.77		
Exercised	-	-		
Forfeited	(108,156)	23.77		
Expired	(15,908)	10.58		
Outstanding, December 31, 2015	603,643	$ 8.17	7.51	$ -
Exercisable, December 31, 2015	295,765	$ 12.12		
Vested and expected to vest, December 31, 2015	603,643	$ 8.177	7.51	$ -

During 2015, 2014 and 2013, the Company received $0, $22,000 and $27,000 upon exercise of stock options. The intrinsic value of the options exercised in 2015, 2014 and 2013 was $0, $9,000 and $42,000, respectively. Unrecognized compensation expense related to unvested awards as of December 31, 2015 was approximately $753,000 and will be recognized over the remaining vesting periods of the underlying awards. The weighted-average period over which such compensation is expected to be recognized is 2.0 years.

Restricted Stock Units

In October 2014, the Company granted retention restricted stock units to its remaining employees at no cost to them, which cannot be sold, assigned, transferred or pledged during the vesting period. The restricted stock units vest through the passage of time and are accelerated in the event of termination without cause or a change in control. The restricted stock units are forfeited upon an employee's voluntary termination of employment. The fair value of the award at the time of the grant is expensed on a straight line basis over the vesting period, which was initially approximately 1.5 years. These awards were granted under the Company's 2010 Plan.

The following table summarizes restricted stock unit activity for the year ended December 31, 2015:

	Number of shares	Weighted - average grant date fair value
Nonvested, January 1, 2014	-	
Granted	255,125	$ 1.67
Forfeited	(4,650)	$ 1.88
Nonvested, December 31, 2014	250,475	$ 1.66
Vested and issued	(107,315)	$ 1.71
Forfeited	(54,922)	$ 1.72
Nonvested, December 31, 2015	88,238	$ 1.57

The total compensation expense recognized during 2015 and 2014 was $308,000 and $55,000, respectively. As of December 31, 2015, there was $55,000 of total unrecognized compensation cost, net of forfeitures, related to unvested restricted stock units. That cost is expected to be recognized over a weighted-average remaining period of 0.2 years.

Employee Stock Purchase Plan

In August 2010, the Board of Directors approved the 2010 Employee Stock Purchase Plan (the "ESPP") and the Company's stockholders approved the plan in November 2010. The ESPP became effective in February 2011 upon the closing of the Company's initial public offering. The ESPP provides employees with an opportunity to purchase the Company's common stock at a 15% discount. As of December 31, 2015, there are 74,998 shares of common stock authorized for issuance under the ESPP. In addition, the ESPP contains an "evergreen" provision, which allows for an annual increase in the number of shares of the Company's common stock available for issuance under the plan on the first day of each fiscal year during the period beginning in fiscal year 2012.

The ESPP allows eligible employees to purchase the Company's stock at the lower of 85% of the fair market value of the shares on the offering date or the exercise date. The Company uses the Black-Scholes option valuation model to value shares issued under the ESPP. For the years ended December 31, 2015, 2014 and 2013, 0, 1,250 and 7,771 shares, respectively, were issued under the ESPP. At December 31, 2015, there were 59,298 shares available for issuance under the ESPP.

Total stock compensation expense for stock options, restricted stock units, and the ESPP has been recognized in the statements of operations as follows for the years ended December 31:

	2015	2014	2013
		(in thousands)	
Research and development expense	$ 340	$ 260	$ 186
Selling and marketing expense	39	57	5
General and administrative expense	452	354	970
Total stock compensation expense	$ 831	$ 671	$ 1,161

At December 31, 2015, 924,055 shares of common stock were available for future issuance under the Company's stock plans.

Warrants

At December 31, 2015, the Company had warrants to purchase 1,353,927 shares of common stock outstanding. Warrants issued prior to 2015 have a contractual term of ten years from the date of issuance and may be net share-settled at the option of the warrant holder. Warrants issued during 2015 have a contractual term of five years from the date of issuance and may be net share-settled at the option of the warrant holder.

The following is a summary of activity for common stock warrants for the year ended December 31, 2015:

	Common stock warrants	Weighted-average exercise price
Outstanding, January 1, 2014	216,156	$ 4.15
Exercised	(29,706)	0.08
Outstanding, December 31, 2014	186,450	4.80
Granted	1,434,346	1.00
Exercised	(268,213)	0.72
Dilution adjustments	1,344	11.05
Outstanding, December 31, 2015	1,353,927	$ 1.58

All exercises of common stock warrants for the year ended December 31, 2015 were cashless and resulted in the issuance of an aggregate of 262,931 shares of common stock.

The following is a summary of all outstanding common stock warrants as of December 31, 2015:

Warrants outstanding	Weighted-average exercise price	Expiration date
15,668	$ 2.56	2016
958	21.40	2017
15,051	0.08	2018
1,271,639	0.98	2020
13,846	43.32	2021
36,765	6.80	2022
1,353,927		

13. Commitments and Contingencies

Operating Leases

In 2013, the Company entered into a non-cancelable operating lease for office facilities located in Waltham, Massachusetts through December 2018, with a renewal option of five years. In June 2015, the Company entered into a sublease agreement with a third party for these office facilities. The term of the sublease is from June 1, 2015 through December 31, 2018 covering the balance of the underlying lease term. The Company has obtained office space on a short term rental basis. Rent expense under these operating leases totaled $265,000, $368,000 and $594,000 for the years ended December 31, 2015, 2014 and 2013, respectively.

Future minimum payments under the Company's operating leases at December 31, 2015, are as follows:

Year	Operating lease obligations
	(in thousands)
2016	$ 428
2017	394
2018	377
Total minimum lease payments	$ 1,199

Under the sublease agreement, the Company may receive a total of $1,107,000 from the third party over the remaining future sublease term. During the year ended December 31, 2015, the Company received $204,000 under the sublease agreement, which directly offset rent expense.

Employment Agreements

The Company has entered into agreements with certain members of its senior management. The terms of these agreements include non-compete and nondisclosure provisions as well as provide for defined severance payments and acceleration of vesting of share based awards.

Other Commitments

The Company may be subject to product liability claims that are inherent in the testing, production, marketing and sale of diagnostic tests, for which the Company currently maintains limited product liability insurance. At December 31, 2015, the Company was not aware of any product liability claims with respect to the Company's diagnostic tests.

Contingencies

From time to time, the Company may be subject to various legal proceedings and claims arising in the ordinary course of business. The Company assesses contingencies to determine the degree of probability and range of possible loss for potential accrual in its financial statements. An estimated loss contingency is accrued in the financial statements if it is possible that a liability has been incurred and the amount of the loss can be reasonably estimated.

No amounts related to contingencies are accrued at December 31, 2015

14. Licensing Agreements

In May 2007, the Company entered into an initial biomarker product license and collaboration agreement with ACS Biomarker B.V. ("ACS Biomarker") and in July 2012, the Company entered into a sublicense agreement with ACS Biomarker, which superseded the initial agreement in its entirety. Pursuant to the agreement, ACS Biomarker granted the Company an exclusive, worldwide sublicense to develop and commercialize two proprietary cardiovascular biomarkers for congestive heart failure, galectin-3 and thrombospondin-2. The agreement permits the Company to sublicense the rights to third parties.

As consideration for the sublicense, the Company was required to pay ACS Biomarker an upfront payment and milestone payments as well as royalty prepayments to the extent that the Company achieves specified

development and regulatory milestones. Additionally, the Company is obligated to pay ACS Biomarker royalties on any net sales, together with a percentage of any sublicense revenue, from its galectin-3 tests and any other products that the Company develops using the licensed intellectual property. Through December 31, 2015, the Company has paid ACS Biomarker a total of $1.0 million in up-front, milestone and royalty prepayments. Payments of $750,000 were capitalized as an intangible asset. The intangible asset is being amortized over the economic life of the intellectual property (Note 5). Royalty prepayments of $250,000 were capitalized as a prepaid expense and are being amortized as sales of the BGM Galectin-3 Test are recorded. At December 31, 2015, there was $9,000 of royalty prepayments remaining to be amortized.

15. HRP Initiative

In 2006, the Company initiated and led the HRP initiative for atherothrombotic cardiovascular disease. The HRP initiative consisted of a series of pre-competitive, multi-party research and development projects, which were administered and coordinated by the Company pursuant to participation agreements with Abbott Pharmaceuticals, AstraZeneca, Merck & Co., Inc., Royal Philips Electronics, and Takeda Pharmaceuticals. Since the inception of the HRP initiative, these participating companies supported the research and development projects by providing approximately $26.6 million in funding. The overall goals of the HRP initiative were to advance the understanding, recognition and management of atherothrombotic cardiovascular disease; to provide a roadmap for the development and registration of screening, diagnostic and therapeutic interventions for high-risk plaque; and to promote the use of these interventions by patients, pharmaceutical companies and third-party payers.

The HRP initiative was governed by a joint steering committee (“JSC”), which was comprised of designees from the participating companies, and was led by a scientific program board consisting of academic experts in the cardiovascular field, who advised the JSC and assisted in the design of research protocols. The JSC was responsible for overseeing the conduct and progress of the HRP initiative, including finalizing and approving program activities, program and activity budgets, external communications, patent filings, third-party licensing and commercialization of data and rights under the HRP initiative. The Company functioned as the coordinator and administrator for the HRP initiative, and the Company owns any inventions and data that were conceived in the conduct of the HRP initiative. The Company granted each participating company a non-exclusive, perpetual, royalty-free license to all such inventions and data for any and all uses. Each participation agreement expired upon the earlier of the completion of the HRP initiative or the fifth anniversary of such agreement, unless otherwise terminated.

The HRP initiative has met its goals and no additional research projects will be initiated nor is additional funding expected from the participating companies.

HRP initiative revenues recognized during the years ended December 31, 2015, 2014 and 2013 totaled $0, $0 and $390,000, respectively. At December 31, 2013, all funding from the participating companies had been applied to the expenses related to the HRP initiative and no restricted cash or deferred revenue remained to be spent or recognized.

16. 401(k) Savings Plan

In October 2001, the Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code covering all of its employees. Employees may make contributions by withholding a percentage of their salary. In April 2012, the Company amended the plan to include an employer match of 50% up to 3% of eligible compensation. During the years ended December 31, 2015 and 2014, the Company has expensed $6,000 and $21,000 for the employer match contribution, respectively.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2015, 2014 AND 2013

17. Selected Quarterly Financial Data (Unaudited)

The following table contains quarterly financial information for 2015 and 2014. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

	Quarterly Results for the Year Ended December 31, 2015			
	March 31	**June 30**	**Sept 30**	**Dec 31**
	(in thousands, except per share data)			
Revenues	$ 437	$ 505	$ 334	$ 290
Total costs and operating expenses	1,693	1,950	1,360	1,193
Net loss attributable to common stockholders	(1,348)	(2,029)	(1,023)	(903)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.15)	$ (0.22)	$ (0.27)	$ (0.08)

	Quarterly Results for the Year Ended December 31, 2014			
	March 31	**June 30**	**Sept 30**	**Dec 31**
	(in thousands, except per share data)			
Revenues	$ 739	$ 799	$ 695	$ 554
Total costs and operating expenses	2,686	2,770	2,928	1,765
Net loss attributable to common stockholders	(2,179)	(2,169)	(2,397)	(1,319)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.31)	$ (0.25)	$ (0.28)	$ (0.15)

Exhibit 10.7.4

FOURTH AMENDMENT TO
GALECTIN-3 LICENSE AND DISTRIBUTION AGREEMENT

THIS **FOURTH** AMENDMENT TO GALECTIN-3 LICENSE AND DISTRIBUTION AGREEMENT (this "Fourth Amendment") is entered into as of November 24, 2015 and effective as of November 1, 2015 (the "Fourth Amendment Effective Date") by and between Abbott Laboratories, a corporation of the state of Illinois, having its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064-3500 ("Abbott") and BG Medicine, Inc., a corporation of the state of Delaware, having its principal place of business at 303 Wyman, Suite 300, Waltham, Massachusetts 02451 ("BGM").

RECITALS

A. Abbott and BGM are parties to that certain Galectin-3 License and Distribution Agreement, dated as of November 11, 2009, as amended, (the "Agreement"), pursuant to which BGM granted Abbott a license under BGM's Patent Rights to commercialize Products in the Territory.

B. The Parties now desire to amend the Agreement to amend the Product Fee paid by Abbott, among other things.

NOW, THEREFORE, in consideration of the mutual covenants and agreement contained herein, and upon the terms and subject to the conditions set forth below, Abbott and BGM hereby agree as follows:

AMENDMENT

1. Except as modified by this Amendment, capitalized terms used and not otherwise defined herein shall have the meanings given to them in the Agreement.
2. Section 1.2, "AUP", is hereby deleted in its entirety and replaced with the following:

   1.2 "AUP" shall mean those references made in this Agreement comprised of both AUP-H and AUP-R collectively, or individually, as appropriate and all such references within a Section, Subsection, Table or Exhibit to this Agreement unless otherwise indicated.

   1.2(h) "AUP-H" is the total sales of Tests to unaffiliated Hospital Customers (as hereinafter defined), calculated in Dollars on a Calendar Quarter basis, in an arm's length transaction, divided by the number of Tests sold to unaffiliated Hospital Customers in an arm's length transaction by Abbott or its Affiliates in such Calendar Quarter.

   1.2(r) "AUP-R" is the total sales of Tests to unaffiliated Reference Lab Customers (as hereinafter defined), calculated in Dollars on a Calendar Quarter basis, in an arm's length

transaction, divided by the number of Tests sold to unaffiliated Reference Lab Customers in an arm's length transaction by Abbott or its Affiliates in such Calendar Quarter.

3. Section 1.9 is hereby deleted in its entirety and replaced with the following:

1.9 " Hospital Customer " means any Third Party to whom Tests are sold and billed by Abbott for such Tests, where such billed Third Party is a hospital, university, public health facility, clinic or physician office.

4. A new Section 1.13A shall be added to the Agreement as follows:

1.13A " Reference Lab Customer " means any Third Party to whom Tests are sold other than a Hospital Customer. For the avoidance of doubt, a laboratory housed in a hospital, university, public health facility or physician office that is owned, managed or operated by a Third Party that has been retained by such hospital, university, public health facility or physician office to provide clinical laboratory services through, as an example, test outsourcing, management outsourcing, or other professional and/or consulting services, is considered a Reference Lab Customer.

5. Section 3.1 is hereby deleted in its entirety and replaced with the following:

3.1 Product Fee .

(a) [***], as consideration for the rights and licenses granted by BGM to Abbott and its Affiliates and BGM's agreement to the other terms and conditions set forth in this Agreement, Abbott shall pay to BGM a fee as set forth in this Section 3.1, and as shown below in Table 3.1 (the " Product Fee ") for Tests sold to Third Parties in the Territory.

(b) Unless otherwise agreed to by the Parties in writing, or as provided in Section 3.1(f) below, the Product Fee applicable for each Test sold to a Hospital Customer [***] the following tiers shall apply to the Product Fee owed in such Calendar Quarter for sales of Tests to Hospital Customers:

(i) Cumulative Test sales by Abbott or its Affiliates to unaffiliated Third Parties from [***];

(ii) Cumulative Test sales by Abbott or its Affiliates to unaffiliated Third Parties from [***]; and

(iii) Cumulative Test sales by Abbott or its Affiliates to unaffiliated Third Parties from [***].

(c) [***] Abbott shall pay the Product Fee stipulated in Section 3.1(b), subject to the provisions of Section 3.13 on completion of the renegotiation.

(d) [***] Provided, however, that in no event shall [***] that was being paid by Abbott for [***] immediately prior to the [***].

Table 3.1
PRODUCT FEE APPLICABLE TO SALES OF TESTS [***]

AUP-H	TIER 1 [***] (baseline Product Fee)		TIER 2 [***] [***]		TIER 3 [***] [***]	
	Product Fee	[***]	Product Fee	[***]	Product Fee	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]

Cumulative Test sales volume from [***]

(e) [***] unless otherwise agreed to by the Parties in writing, or as provided in Section 3.1(f) below, the Product Fee applicable for each Test sold to a Reference Lab Customer [***] shall be [***].

(f) Subject to the other terms and conditions of this Agreement, [***] the Parties shall [***].

6. A new Section 3.2(c) shall be added to the Agreement as follows:

3.2(c) In consideration for the reduction of the Product Fee applicable for each Test sold to a Reference Lab Customer as part of this Fourth Amendment, and as a buy-down of future Product Fees owed for such sales, Abbott shall pay BGM the following payments:

(i) Five Hundred Thousand Dollars ($500,000) within thirty (30) days of the Fourth Amendment's Effective Date. This payment set forth in this Section 3.2(c)(i) shall be non-refundable and shall not be applied against future Product Fees owed by Abbott to BGM under this Agreement; and

(ii) An amount not to exceed Five Hundred Thousand Dollars ($500,000.00) payable by June 30, 2016, if the following [***] have been met: [***]. The total amount payable by Abbott, if any, shall be calculated as follows:

TABLE 3.2(c)(ii)
PAYMENT CALCULATION

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Once paid, this payment set forth in this Section 3.2(c)(ii) shall be non-refundable and shall not be applied against future Product Fees owed by Abbott to BGM under this Agreement.

7. Except as expressly amended by this Fourth Amendment, all of the terms and conditions of the Agreement remain in full force and effect.

8. This Fourth Amendment may be executed in two (2) original counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties have executed this Fourth Amendment as of the date first above written.

ABBOTT LABORATORIES

By: /s/ Brian J. Blaser
Name: Brian J. Blaser
Title: Executive Vice President
President, Diagnostics

BG MEDICINE, INC.

By: /s/ Paul R. Sohmer
Name: Paul R. Sohmer
Title: President & CEO

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

I, Paul R. Sohmer, certify that:

1. I have reviewed this annual report on Form 10-K of BG Medicine, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 4, 2016

/s/ Paul R. Sohmer

Paul R. Sohmer, M.D.
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Stephen P. Hall, certify that:

1. I have reviewed this annual report on Form 10-K of BG Medicine, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 4, 2016

/s/ Stephen P. Hall

Stephen P. Hall
Executive Vice President, Chief Financial Officer and Treasurer
(principal financial officer)

Exhibit 32.1

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of BG Medicine, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2015 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 4, 2016

/s/ Paul R. Sohmer

Paul R. Sohmer, M.D.
President and Chief Executive Officer
(principal executive officer)

Date: April 4, 2016

/s/ Stephen P. Hall

Stephen P. Hall
Executive Vice President, Chief Financial Officer and Treasurer
(principal financial officer)