Zacks Small-Cap Research

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Brian Marckx, CFA
bmarckx@zacks.com
Ph (312) 265-9474

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

# Great Basin Scientific (GBSN-NASDAQ)

**GBSN: Novel, Low-Cost MDx Infectious Disease Platform Targets Underserved Market. Initiating at Buy**

| | |
|---|---|
| **Current Recommendation** | **Buy** |
| Prior Recommendation | N/A |
| Date of Last Change | 07/16/2015 |
| Current Price (07/16/15) | $2.73 |
| **Target Price** | **$6.50** |

## OUTLOOK

GBSN develops, manufactures and markets molecular diagnostic instrumentation and test kits for infectious diseases, with a particular focus in hospital-acquired infections. Their system uses a unique amplification technology and chip-based detection which afford rapid test turnaround and high sensitivity at a relatively low-price point. These benefits provide what GBSN believes is an attractive value proposition, particularly for their targeted customer base of small-to-medium sized hospitals. C. diff test launched in 2012 and their second test in July. Five more tests could launch by 2016. Customer adoption has been brisk at the expense of competitors and we think this results in accelerating revenue growth, particularly going into 2016. We are initiating coverage with a Buy recommendation and $6.50/share price target.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$9.08** |
| **52-Week Low** | **$1.48** |
| **One-Year Return (%)** | **N/A** |
| **Beta** | **N/A** |
| **Average Daily Volume (sh)** | **995,148** |
| **Shares Outstanding (mil)** | **6** |
| **Market Capitalization ($mil)** | **$18** |
| **Short Interest Ratio (days)** | **0.50** |
| **Institutional Ownership (%)** | **1** |
| **Insider Ownership (%)** | **34** |
| **Annual Cash Dividend** | **$0.00** |
| **Dividend Yield (%)** | **0.00** |
| **5-Yr. Historical Growth Rates** | |
| **Sales (%)** | **N/A** |
| **Earnings Per Share (%)** | **N/A** |
| **Dividend (%)** | **N/A** |
| **P/E using TTM EPS** | **N/A** |
| **P/E using 2015 Estimate** | **N/A** |
| **P/E using 2016 Estimate** | **N/A** |
| **Zacks Rank** | **N/A** |

| | |
|---|---|
| **Risk Level** | **High,** |
| **Type of Stock** | **N/A** |
| **Industry** | **Med Instruments** |

## ZACKS ESTIMATES

**Revenue**
(in millions of $)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2014 | | | | | 1.60 A |
| 2015 | 0.5 A | 0.5 E | 0.7 E | 0.8 E | 2.5 E |
| 2016 | | | | | 8.2 E |
| 2017 | | | | | 16.6 E |

**Earnings per Share**

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2014 | | | | | -$17.3 A |
| 2015 | -$13.99 A | -$0.67 E | -$0.57 E | -$0.39 E | -$11.2 E |
| 2016 | | | | | -$0.39 E |
| 2017 | | | | | -$0.27 E |

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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## SNAPSHOT

Great Basin Scientific, Inc. (GBSN), headquartered in Salt Lake City, Utah, develops, manufactures and markets molecular diagnostic instrumentation and test kits for infectious diseases, with a particular focus in hospital-acquired infections. The company's automated molecular diagnostics system uses a unique amplification technology and chip-based detection which afford rapid test turnaround and high sensitivity at a relatively low-price point. These benefits provide what GBSN believes is an attractive value proposition, particularly for their targeted customer base of small-to-medium sized hospitals.

The company currently offers diagnostic tests for Clostridium difficile (C.diff) and Group B streptococcus. The C. diff test, following requisite regulatory approvals, was launched in Europe and the U.S. in early and late 2012, respectively, while the Group B test launched in July. The R&D pipeline includes two other tests which could launch in the near term – those being tests for Staphylococcus (510k filing expected in 2015) and Shiga toxin producing E. coli (clinical trial commenced Q1 2015). In addition, GBSN also has under development a Staphyloccocus aureus pre-surgical nasal screen, a food-borne pathogen panel and a panel to test for candida blood infections, all of which the company hopes to have in clinical trials during the current year.

Great Basin is looking to capitalize on the ongoing shift from legacy diagnostic methods to molecular testing, the latter which affords greater speed and accuracy and which industry research predicts will increase at a CAGR of more than 20% over the next several years. GBSN estimates the aggregate annual market for their molecular tests (commercialized and under development) is approximately $1.5 billion. The company's domestic commercialization strategy focuses on the ~85% (~4.9k) of U.S. hospitals with less than 400 beds. Management views this as the low-hanging fruit given the affordability and high performance of their system and the fact that more than half of these small-to-medium sized hospitals have yet to adopt molecular testing due to the high price tag of most other molecular diagnostic platforms. Growth in this small-to-medium hospital segment is expected to be particularly robust in hospital acquired infection testing.

Costs for treatment and diagnosis of many hospital-acquired infections, a specific focus for GBSN, are not reimbursed by most private and public payers. As such, hospitals have a financial interest in efficiently, effectively and rapidly identifying and treating these illnesses. Accelerating demand from smaller hospitals for molecular testing of the problematic MRSA infection has been one of the catalysts in driving adoption of molecular platforms. GBSN is positioning itself to capitalize on this demand with the expected near-term roll-out of their pipeline, which includes a test for MRSA.

GBSN employs a razor / razor-blade (or what management refers to as a "vending machine") business model whereby the analyzers are placed at little-to-no cost (which helps to facilitate and speed adoption) to the customer and test cartridges are then sold to the installed base. Great Basin sells direct in the U.S. with a small sales force and through third-party distributors in parts of Europe and New Zealand. The U.S. market represents the source of the vast majority of the company's historical and expected future revenue and where the bulk of management's focus for growth lies.

Competitive benefits of the Great Basin technology include low cost, both low-plex and multiplexing abilities, ease-of-use and quick turnaround time which are a combination of features that are not shared by competing technologies offered by other molecular diagnostic companies.

The company is using a portion of the almost $20.5 million (net) raised from a March 2015 public offering (convertible preferred with warrants) to fund a growth strategy that includes hiring additional U.S. sales reps, expanding the test menu (which has the dual benefit of incremental revenue and increasing competitiveness of the entire platform) and automating manufacturing. Management expects this growth strategy to result in accelerating customer wins and push the U.S. user base up from 112+ today to 170 or more by the current year-end. And with the restocked cash balance being pumped into speeding product development of the late-stage pipeline, management is aiming to have seven FDA-cleared tests on the U.S. market by the first half of 2016 (up from just two today).

Along with an emphasis on growing revenue, the company is intently focused on improving profitability. Their strategy to do so includes widening gross margins through increasing sales volumes of their already commercialized C.diff. test, bringing their pipeline to market (these tests are expected to carry higher margins then C. diff.) and reducing manufacturing costs through greater automation.

## BACKGROUND

Molecular diagnostics (MDx) involves analysis of an individual's specific genetic make-up (i.e. – at a molecular level) to determine whether a person is afflicted with or susceptible to a particular illness or condition. While molecular diagnostics has been in existence since the 1970's, it wasn't until the completion of the Human Genome Project in 2003 that interest in this testing platform really began to burgeon.

Molecular diagnostics now makes up approximately 11% of the total worldwide in-vitro diagnostics market and, per Frost and Sullivan, is expected to grow at about 10% through the year 2018, about 40% faster than the 7% growth predicted for the entire diagnostics industry. And specific to molecular diagnostics for infectious diseases, which is GBSN's area of focus, Frost & Sullivan notes that this market is growing at better than 15%.

**GBSN's Molecular Diagnostics Platform**
The GBSN molecular diagnostics platform consists of a bench top analyzer, which incorporates a proprietary amplification method, and single-use, self-contained test cartridges. The platform is billed as not only relatively inexpensive but also user-friendly requiring minimal touch-points with rapid turnaround time. The detection on-a-chip technology also offers the ability to run both low-plex (i.e. analysis of 1-3 markers) as well as multiplex (analysis of up to 64 markers) tests.

The diagnosis process provides rapid sample-to-results processing and, unlike many competing technologies, typically requires only about three to five sample preparation steps which take about five minutes to complete. Following receipt of a biological sample, the process involves putting the sample in the disposable cartridge and inserting the cartridge into the analyzer. Results are usually available within 90 minutes (or less), a significantly shorter time than what is possible with most other molecular diagnostic systems. The system process is automated with little manual activity involved and no user interpretation of the results required.

**Highlights of the GBSN platform**

- **Sample-to-result**: no culturing of the sample is required. Culturing, has error issues and is relatively time consuming. GBSN's technology is low-touch, rapid and does not require user interpretation, eliminating issues of legacy diagnostic methods
- **High sensitivity**: unique bpHDA target amplification affords high sensitivity at an attractive price point. Proprietary amPED detection provides sensitivity
- **Low- and Multi-plexing capabilities**: 64 probes allows for detection of 64 individual targets in a single test. Low-plexing capabilities means even greater affordability for those (typically smaller) hospitals that may not currently have sufficient volume to purchase an expensive stand-alone multiplexing system offered by competitors
- **Low cost:** commercial attractiveness of the high sensitivity and robustness of the platform was not compromised by cost. Analyzer and consumable manufacturing costs have been optimized by use of readily available components, affording a viable razor/razor-blade business model

***Amplification and Detection Methods Provide Sensitivity, Speed and Cost Advantages…***
Molecular diagnostics requires extensive copying, or target amplification, of DNA to improve sensitivity. To do so, DNA (which is double-stranded) is unwound and the single strands are then annealed (i.e. bound) with DNA primers (i.e. short strands of RNA or DNA that are complementary to the target DNA). DNA targets are "labeled" with certain specific molecules (such as biotin) in order for the primers to correctly identify their corresponding target DNA. The primers then form the basis for a new, identical strand of the DNA target. This process is replicated until billions of copies of the DNA are created.

The most common target DNA amplification method is polymerase chain reaction (PCR) which uses thermal cycling (i.e. alternate cycles of high heat and cooling). High heat is used to unwind the DNA, the temperature is then lowered for primer annealing and then the temperature is again cycled higher to allow for synthesis and extension of a new DNA strand. There are certain drawbacks of PCR including that it requires the use of a large and expensive thermal cycler.

Unlike PCR, helicase-dependent amplification (HDA), does not use high heat but instead utilizes helicase, an enzyme, to unwind double-stranded DNA. As HDA is accomplished at a constant temperature (i.e. isothermally), it does not require the use of a thermal cycler and therefore can be accomplished at lower expense than PCR.

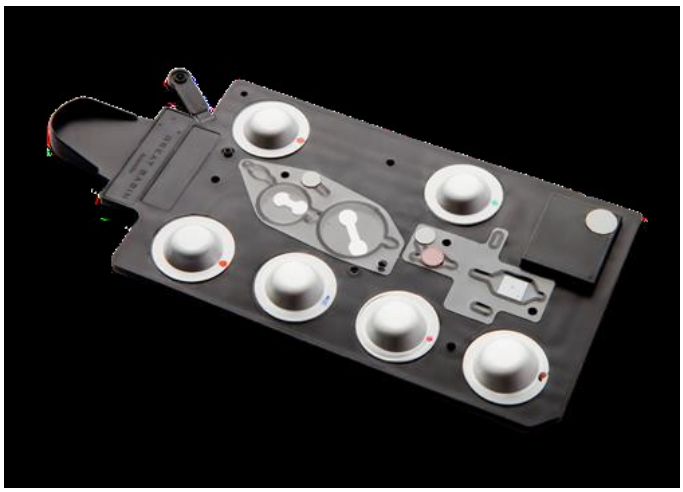
However, the drawback with HDA is that it is prone to error if the temperature is too low during primer annealing, which can cause the primer to bind to non-target DNA and result in copies non-interest DNA and cause loss of diagnostic sensitivity and speed.

In order to avoid this issue GBSN's technology incorporates bpHDA. The blocked primers block annealing at lower temperatures, thereby avoiding the problem inherent with HDA. As the temperature is increased, the blocked primers become ineffective, allowing for correct hybridization of the DNA primer and affording more stable amplification. Amplification via bpHDA is referred to "hot start".

GBSN owns three method and method/composition patents related to detection and amplification; *Methods of isothermal amplification using blocked primers* (8,936,921 issued Jan 2015), *Systems and methods for point-of-care amplification and detection of polynucleotides* (8,637,250 issued Jan 2014) and *Methods and compositions for amplifying a detectable signal* (8,574,833 issued Nov 2013). The company also has a non-exclusive license with BioHelix for use of that company's patented isothermal amplification method using HDA as well as a license agreement with Integrated DNA Technologies (IDT) for the use of blocked primers in combination with HAD.

In addition to target DNA amplification, GBSN's diagnostics platform also incorporates signal amplification through a method called acetate modified polymer enhanced detection, or amPED. amPED connects a bridging molecule between the DNA target label (i.e. biotin) to a molecular structure which contains 80 biotins. This amplifies the signal by up to 80 times, further enhancing sensitivity and speed as compared to target amplification alone.

**Single-Use Cartridges…**
Great Basin's disposable diagnostic cartridges are self-contained with all the reagents included. Lance and stirring devices on the cartridge puncture reagent blister packs and mix the fluids. All of the processes occur within the cartridge including specimen cleaning, amplification and detection. A silicon chip on the cartridge has on it up to 64 DNA probes, with each probe producing results for a given DNA target, affording significant multiplexing ability. GBSN notes that the chip can be manufactured for approximately $0.09 each.



**Analyzer…**
Great Basin designed their analyzer to be manufactured largely with off-the-shelf components to keep costs down and for ease of sourcing and production without a sacrifice to performance. While much of the system is fairly basic with few moving parts and utilizing mostly generic components, the heart of the technology (amplification and detection) is novel.

The processing portion of the analyzer includes reagent flow, thermal control and optical imaging. Actuators control the flow of fluid and engage the lance which punctures the blister packs. Motors move the fluids through channels and into reaction chambers with optical sensors guiding the fluid movements. Heaters inside the analyzer modify temperature for the respective processing functions. A digital camera records the results, which are interpreted by computer algorithm and displayed electronically and/or printed.



**Assays:** *C. Diff and Group B Currently Commercialized, 5 Others Expected to Launch By 1H 2016…*
An assay for C. diff. was the company's first commercialized test. The test is CE Marked and FDA (510K) cleared and was launched in Europe and the U.S. in early and late 2012, respectively. In addition, a test for Group B streptococcus (GBS) received FDA 510(k) clearance in April of this year and launched in the U.S. in July. The GBS test is also CE Marked for sale in Europe. Under development are two other tests which could launch in the near term – those being tests for Staphylococcus (510k filing expected in 2015) and Shiga toxin producing E. coli (clinical trial commenced Q1 2015). In addition, GBSN is also working on a Staphyloccocus aureus pre-surgical nasal screen, a food-borne pathogen panel and a panel to test for candida blood infections, all of which the company hopes to have in clinical trials during the current year.

- C. diff: Clostridium difficile is a spore-forming bacteria often found in soil and also present in about 3% of the human population. Human transmission of C. diff is via the fecal-to-oral route. The bacteria is particularly robust, surviving for extended periods in and outside of the body, able to withstand many hand cleansers, stomach acid and antibiotics. While gut flora (i.e. "good bacteria") in the stomach and digestive system controls or kills C. diff, use of broad spectrum antibiotics (for unrelated conditions) can compromise gut flora and result in C. diff related illness. Typical symptoms include diarrhea, fever, weakness and nausea, among others. In severe cases and instances of relapse, C. diff can be fatal, particularly when there is severe inflammation of the colon.

  Incidence of C. diff is on the rise and currently causes about 3M cases of diarrhea and colitis each year in the U.S., causing between 14k and 30k deaths annually. The majority of cases occur in hospitals, with (depending on the source) as much as 30% of hospitalized patients becoming afflicted with the illness.

  There are several non-molecular methods to test for C. diff. including stool culture, rapid antigen tests and toxin testing using tissue culture and enzyme immunoassay. However, all of these suffer from drawbacks as compared to molecular C. diff. toxin detection.

  - Stool culture: tests for the C. diff organism. Has been considered the gold-standard but suffers from high rates of false-positives as it can incorrectly flag non-toxic strains as positives. The test also is time-consuming (2 – 4 days for results) due to the need to culture the sample and requires highly trained technicians to perform.
  - Rapid antigen: test for C. diff antigen. While results are available almost immediately, the tests suffer from relatively low accuracy.
  - Toxin tissue culture: tests for C. diff toxin A (TcdB). Time consuming with results not available for 1 – 2 days, requires highly trained staff and has relatively lower accuracy than other methods. Toxin culturing is inherently problematic as the viability of the C. diff. toxin vitiates fairly rapidly when kept at room temperature.

- Enzyme immunoassay: tests for both toxin A and toxin B. Results are typically available within one day which is advantageous to most other methods but sensitivity may be lower than tissue culture.

***C. Diff screening moving towards molecular platforms, including GBSN's Portrait …***

Molecular tests have quickly begun replacing stool culture organism testing and tissue culture toxin testing, which have been considered the historical gold standards in C. diff diagnosis. Molecular tests have shown to have superior sensitivity and specificity to these legacy methods and can return a result relatively rapidly. In addition, as culturing is not required, degradation of toxins is a non-issue like it is with legacy methods. The main impediment to greater adoption of molecular testing has been cost. However, GBSN, with a business model that provides the analyzer free of charge, addresses much of the cost issue.

And with the advent of the Affordable Care Act, which will penalize hospitals with higher readmission rates, accurate C. diff diagnosis and appropriate treatment should be a high priority for hospital administrators. A recent study by researchers at the Detroit Medical Center found that 30% of patients with C. diff were readmitted to the hospital after 30 days, compared to just 14% of patients discharged for any cause. Authors of the study, which looked at over 51k patient discharges, concluded that, "Reductions in hospital-onset CDI (C. diff infections) and readmission of patients with an index CDI can provide tremendous cost savings to hospitals. This call for better infection control and antibiotic stewardship measures toward CDI management in the hospital and as patients transition to the next level of care."[1]

This follows an unrelated study that showed significantly more efficient treatment, fewer tests ordered and better patient outcomes when a small hospital (GBSN's specific target market) switched from culture-based (enzyme immunoassay) to molecular testing for C. diff.[2]

Supporting GBSN's FDA submission seeking regulatory clearance for their Portrait Toxigenic C. Diff assay was a multi-site, 540 stool-sample study which compared their assay to culture/cell cytotoxin neutralization assay (considered the gold-standard). The samples were also tested by competing molecular diagnostic platforms from Cepheid, Meridian Bioscience and Becton Dickinson. Compared to the gold standard, Portrait had a sensitivity and specificity of 98% and 93%.

**Table 1. Clinical Trial Data. Portrait Toxigenic *C. difficile* Assay compared to toxigenic culture (gold standard)**

| Site | Total Tested | True Positive | False Positive | True Negative | False Negative | Sensitivity (95% C.I.) | Specificity (95% C.I.) |
|---|---|---|---|---|---|---|---|
| A | 169 | 37 | 4 | 127 | 1 | 97.4% (86-99) | 96.9% (92-99) |
| B | 219 | 44 | 16 | 159 | 0 | 100% (91-100) | 90.9% (85-94) |
| C | 96 | 15 | 9 | 72 | 0 | 100% (78-100) | 88.9% (79-94) |
| D | 56 | 13 | 2 | 40 | 1 | 92.9% (66-99) | 95.2% (83-99) |
| **Total** | **540** | **109** | **31** | **398** | **2** | **98.2% (93-99)** | **92.8% (89-95)** |

*SOURCE: Footnote [3]*

This compared to sensitivities and specificities of 100% / 92% (Ceiphed's Xpert), 93% / 95% (Meridian's Illumigene) and 97% / 99% (Becton's GeneOhm). Given the on-par performance yet lower cost of Portrait compared to competing molecular diagnostic platforms and inherent advantages of molecular C. diff testing compared to culture-based methods, we think GBSN's technology can be very competitive, particularly with (more budget conscious) smaller hospitals.

[1] Chopra, T et al. *Burden of Clostridium difficile infection on hospital readmissions and its potential impact under the Hospital Readmissions Reduction Program.* Amer Journ of Inf Control April 2015: 43(4): 314-317

[2] Catanzaro, M., Cirone, J. *Real-time polymerase chain reaction testing for Clostridium difficile reduces isolation time and improves patient management in a small community hospital.* Amer Journ of Inf Control Sep 2012: 40(7): 663-666

[3] Buchanan BW, et al. *Multicenter Clinical Evaluation of the Portrait Toxigenic C. difficile Assay for Detection of Toxigenic Clostridium difficile Strains in Clinical Stool Specimens.* Journ of Clinic Microbiology. Dec 2012 50(12): 3932-3936

Table 2. Comparison of the Portrait Toxigenic *C. difficile* Assay to other molecular methods

| Method | Total Tested | Portrait (+) Comparator (+) | Portrait (+) Comparator (-) | Portrait (-) Comparator (+) | Portrait (-) Comparator (-) | Agreement |
|---|---|---|---|---|---|---|
| Gene Xpert | 275 | 72 | 3[a] | 4[b] | 196 | 97.5% |
| GeneOHM | 169 | 37 | 4[c] | 2[d] | 126 | 96.4% |
| Illumigene | 96 | 18 | 6[e] | 0 | 72 | 93.8% |
| **Total** | **540** | **127** | **13** | **6** | **394** | **96.5%** |

[a]All 3 were culture negative
[b]3 were culture negative, 1 was culture positive
[c]3 were culture negative, 1 was culture positive
[d]1 was culture negative, 1 was culture positive
[e]5 were culture negative, 1 was culture positive

*SOURCE: Footnote[3]*

- Group B streptococcus (GBS): GBS is a bacteria which colonizes in the vagina, GI tract and respiratory tract. It is present in about 30% of all women and is usually associated with other illnesses which have compromised the immune system. Pregnant women infected with GBS can transmit it to their child while giving birth and there is no effective method to prevent this from happening. It is the most common cause of neonatal sepsis and as a result, routine screening of pregnant women for GBS is done in the U.S. and many countries in Europe.

  Testing for GBS involves swabbing the vagina and rectum. The samples are then cultured and analyzed. However, with the advent of molecular testing, this has become an alternative option for GBS screening. The domestic market for GBS screening is represented by the ~4 million annual births in this country.

  GBSN received FDA 510(k) clearance in April 2015 and the test is also CE Marked. The 510(k) application, submitted in November 2014, was supported by results of a 518-sample clinical study collected from multiple hospital laboratories. The test launched in the U.S. in July. GBSN indicated in the press release announcing the launch that the test has already been well received with two labs already converted to using the test and another 40 sites actively evaluating it. The company also noted that customers are forecasting usage of the GBS test at volumes 50% higher than that of the C. diff test.

- Staphylococcus aureus: Staphylococcus aureus (S. aureus) is carried on the skin and in the respiratory tract (commonly the nasal passages). Approximately 20% of the population is estimated to carry the bacteria which can cause a wide range of ailments from rather benign, such as pimples, to potentially deadly, such as meningitis and sepsis. Methicillin-resistant Staphylococcus aureus, or MRSA, is a particularly difficult strain to combat as it has become resistant to antibiotics used to treat staph infections. MRSA is typically acquired in hospitals, although it can also spread in a community setting such as locker rooms where conditions, such as close contact and open wounds, are favorable. Approximately 500k people in the U.S. become infected with S. aureus each year.

  Blood culture has been the preferred method of diagnosing S. aureus infections although molecular diagnosis is making headway here as well given the relatively long processing time of culturing and other issues, such as risk of contamination. High false positive rates of culturing due to contamination is a widely recognized problem with S. aureus testing and often results in improper or less effective therapy, higher treatment costs and longer hospital stays.

  GBSN's Staphylococcus Identification and Resistance Blood Infection Panel (Staph ID/R) is designed as a multiplex assay capable of identifying and differentiate between seven species of staph infections including detection of the mecA gene, a marker for antibiotic-resistant strains. Differentiation is important as it allows more targeted and effective treatment planning which, in turn, can reduce therapy cost and improve overall patient care. GBSN's panel is expected to provide a result within one hour and in clinical trials has demonstrated 99% positive predictive value and 99% accuracy in identifying different staph strains.

  The company initiated a second clinical study in December 2014 which is being performed at three hospital labs and is expected to include a total of approximately 750 – 800 samples. Results will be compared to two culture based methods. Upon completion, and assuming positive results, GBSN will file for 510(k) FDA clearance – which management thinks could happen in Q3 of this year. If all goes well the test could be on the U.S. market sometime in early 2016.

We think this blood infection panel as well as the pre-surgical screen (discussed below), assuming requisite FDA clearances, can be big winners for GBSN given the explosion in MRSA testing and the competitive attributes of the company's platform. Per research firm IVDMarketReach MRSA testing has experienced very rapid growth due to public and private payers refusing to reimburse for the hospital acquired infection and hospitals' resultant efforts to minimize risk of the disease. The research firm further notes that, "the market (for MRSA testing) remains under-penetrated with ample room for additional market growth, both in the U.S. and globally."[4]

- Shiga toxin-producing E. coli (STEC) test: Shiga toxins, named after the founder of the bacterial origin, are represented by two major families; Stx1 and Stx2. STEC is one of the most common sources of Shiga toxin and while most forms are harmless and exist in the gut, some are pathogenic and can be responsible for food poisoning and cause vomiting and diarrhea.

  GBSN's STEC test is being developed to identify shiga toxin produced by E. coli including serotype O157, the most pathogenic variety which often results in food poisoning. A clinical study which is expected to support an eventual FDA submission commenced in February. The study, being conducted at the same three sites as the S. aureus trial, is expected to include a total of approximately 1,000 samples and will compare GBSN's assay to three commonly used methods; an enzyme immunoassay, DNA sequencing and latex agglutination.

  On the Q4 2014 earnings call in mid-March management noted that both the S. aureus and STEC trials are showing promising results and are "exceeding our expectation for sensitivity and specificity." Assuming no unforeseen delays, we think results from the STEC study could be available before current year-end.

- Staphyloccocus aureus pre-surgical nasal screen: S. aureus, while also found on the skin, is most prevalent in the nasal passages. S. aureus infection from nasal colonization is a serious concern, particularly with patients undergoing cardiac and joint replacement procedures. A recent study found that S. aureus nasal screening and decolonization prior to surgery in cases with positive results significantly reduced the risk of infection. GBSN's assay, whereby a nasal swab will be used as the sample, is being designed to detect S. aureus in the nasal passages in patients prior to surgery. Timelines or proposed protocol for a clinical study have not yet been provided.

- Food-borne pathogens panel: Also under development is a food-borne pathogen panel. GBSN has yet to announce the specific markers that will be included on the panel but notes it will be developed to detect the main causes of food poisoning.

  We note that there are a long-list of potential pathogens that could be included on the assay. Bacteria, such as Campylobacter jejuni, Salmonella and E. Coli are common food-borne pathogens as is S. aureus, which is an enterotoxin. The company has not yet provided a development or clinical trial timeline for their food pathogen assay.

- Candida blood infections panel: the final assay under development is a multiplex panel which is expected to be able to identify five species of Candida from blood samples. Candida has various species, many of which are harmless but some which can cause fungal infections. Candidiasis albicans is the most common species to cause infection, which is usually localized to the outer edges of the mouth or vagina and causes soreness. In immune compromised individuals or in cases where the fungus is introduced intravenously, it can cause bloodstream infections and result in more serious symptoms including nausea and vomiting.

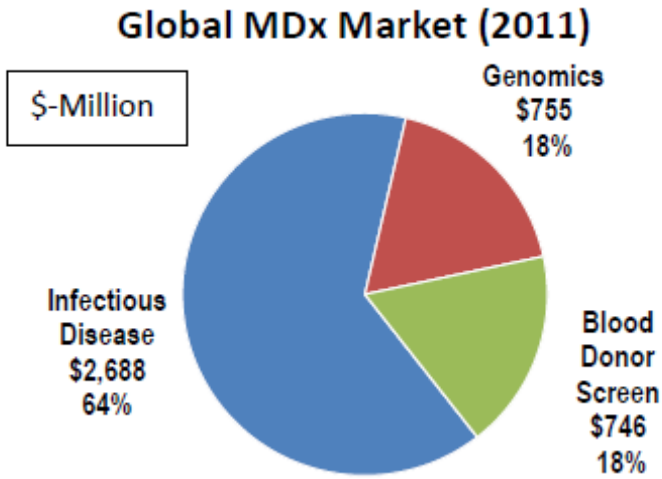
  GBSN has not revealed the five species that will be included on the panel. In September 2014 FDA approved T2Biosystems's five species Candida panel – the first such direct blood molecular multiplex test to be approved in the U.S. The species on the panel, which may be what will also be included on GBSN's test, are C. albicans. C. tropicalis, C. parapsilosis, C. glabrata and C. krusei. GBSN's current timeline for their Candida panel is to complete development and begin a clinical study in the second half of 2015.

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[4] Hughes M. *Molecular Diagnostics Market Trends and Outlook.* IVDMarketReach, Enterprise Analysis. 2013

## MARKETS

While estimates differ (source dependent), the markets for the company's current and in-development tests look to be sufficiently sized, on both an individual and aggregate basis. Individually, GBSN estimates that they range from $80 million to $900 million and in aggregate represent a total annual market worth approximately $1.5 billion. We include our own estimates, which are similar or in some cases somewhat more conservative but, again, calculate to attractive sizes. Another source, research firm IVDMarketReach,estimates just the hospital-acquired infections market is approximately $400 million and the total global infectious disease MDx market is worth $2.7B (and accounts for 64% of the global MDx market).




*SOURCE: IVDMarketReach, Enterprise Analysis. 2013*

An accurate estimate of the market revenue opportunity for each of GBSN's assays requires an accurate estimate of average pricing / reimbursement as well as the size of the potential patient population of each of the tests. An estimate of the potential patient population of each condition that the company's assays diagnose is available from public sources such as the Centers for Disease Control and Prevention (CDC). Estimates of average pricing / reimbursement of each test is much more ambiguous given that many of the tests are generally not covered by private or public payers and if reimbursement is available, amounts may be highly variable. In addition, the Affordable Care Act and related legislation is having a dramatic effect on Medicare reimbursement policy including tying payment decisions and rates to quality of patient care and outcomes.

So given the ambiguity of potential pricing, we use a general approach to calculate the market revenue opportunity of each of the company's tests, which is generally in-line with company's estimates, albeit somewhat more conservative. But we think this provides a fair estimate of the potential market sizes for each of the assays. Our methodology assumes all of the company's tests are priced at the average (of years 2013 and 2014) of their C. diff test and multiply this by the respective patient populations of each of the conditions. Average pricing of the C. diff test in years 2013 and 2014 was approximately $21 per test. We note, however, that our $21/test average may be erring on the side of conservatism (particularly for the multiplex panels) given the robust demand for affordable molecular diagnostic platforms and the potential that GBSN can leverage this for pricing power.

- **C. diff:** causes as many as 3 million cases of diarrhea and colitis in the U.S. each year. At $21/test, this aggregates to a total potential U.S. market of approximately $63M. This is similar to IVDMarketReach estimate of $60M (as of 2011). GBSN estimates the C. diff testing market at $110M - $120M.
- **Group B Strep:** the domestic market for GBS screening is represented by the ~4 million annual births in this country. At $21/test this represents a total potential U.S. market of approximately $84M. GBSN estimates the GBS testing market at $80M - $120M.
- **Staphylococcus aureus panel:** GBSN uses the 4.2M positive blood cultures as a proxy for the market opportunity for its S.aureus panel and estimates the market at $100M - $150M. Our methodology approximates it at $88M.
- **Shiga Toxin:** there are about 73k cases of STEC diagnosed each year but the market for STEC testing is much larger given that this is typically done as part of a battery of tests when a person presents with gastrointestinal problems. GBSN uses the ~5M hospital visits for gastrointestinal distress each year as a

proxy for the market opportunity for its STEC test and estimates the market at $100M - $150M. Our methodology approximates it at $105M.

- **S. aureus pre-surgical screen:** using the 51M surgeries performed each year as a proxy for the S. aureus nasal screen calculates (using our methodology) to a market size of ~$1.1B, similar to GBSN's estimate of $800M - $900M. A subset proxy could be the ~8.5M annual joint replacement and cardiac-related surgeries which represents (using our methodology) a market size of $179M.
- **Food-borne pathogens panel:** this panel and the STEC test would presumably be used as a battery of tests for gastrointestinal distress, which we have calculated (above) to be approximately $105M.

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## COMPETITION

The molecular diagnostics market is highly concentrated among just a handful of relatively large companies including Roche Holding which holds the most dominant share. According to Kalorama Information 60% of the MDx market is held by just five companies which, along with Roche ($230B market cap), includes Becton, Dickinson & Co. ($27B mc), Abbott Labs ($70B mc), Hologic ($9B mc) and Qiagen ($6B mc).

But, Kalorama also indicates that innovation will be key to capitalize on the growth of the MDx market and mentions that (the much smaller) Meridian Biosciences ($800M mc) and GenMark Diagnostics ($500M mc) have made headway in that regard with user-friendly infectious disease tests. IVD MarketReach seems to echo the sentiment that while the molecular diagnostics market is highly concentrated among just a few large companies that smaller players are breaking into the big-boys club. Per IVDMarketReach, "Eight companies controlled 86% of the $4.2B MDx market in 2011. Nonetheless, numerous small companies continue to emerge and grow in this dynamic market."

IVDMarketReach further notes that new "sample-to-answer" (or what GBSN terms "sample-to-result") platforms and expansion of test menus will facilitate a shift of molecular diagnostic testing from central labs to small-to-medium hospitals. Which, again, is GBSN's target market.

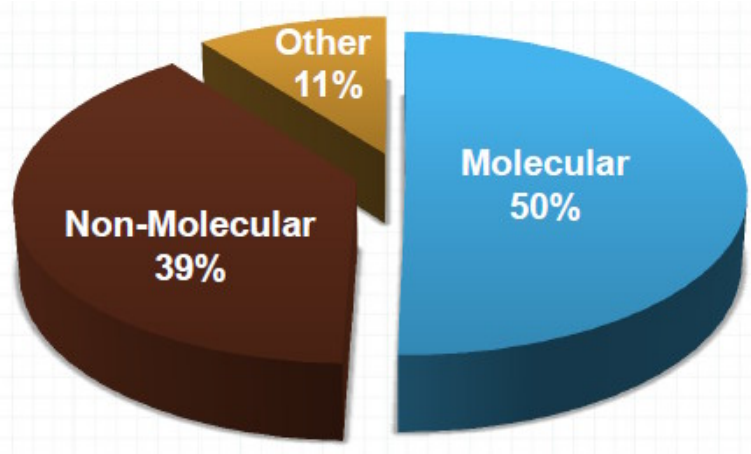
The MDx "majors" are largely focused on the large-hospital segment with systems that capable of covering the three categories of MDx testing; infectious disease, genomics and blood donor screening. As such, we view the likes of Roche, BD, Abbott Hologic and Qiagen as more indirect competitors of GBSN, which is solely focused on infectious diseases and the small-to-medium hospital market.

However, we do view other MDx companies, including Meridian, GenMark, Nanosphere, Cepheid and smaller privately held companies as direct competitors given their similar focus as Great Basin. We think GBSN can be competitive in this segment given the benefits of their technology including low cost, both low-plex and multiplexing abilities, ease-of-use and quick turnaround time which are a combination of features that are not shared by its direct competitors. These features, as we explain further under "Commercialization", are all potentially important to smaller hospitals when considering which diagnostics platform to adopt.

So, for example, while Meridian employs a similar low-cost revenue model as GBSN, placing the analyzer for free, their technology requires a significantly greater number of steps to perform. Many of the other direct competitors' technologies, including that from Cepheid which is the leader in hospital-acquired infections MDx, are capable of sample-to-result testing but have higher cost (and greater commitment) revenue models (i.e. charge for the analyzer) and / or do not have the ability to run both low and multiplex tests.

And while the ongoing shift from legacy to molecular diagnostics, particularly in the small-to-medium hospital segment, is a catalyst which GSBN is looking to capitalize on, their recent share gains have mostly come against competing MDx platforms. Per GBSN, approximately one-half of recent analyzer placements have come from customers replacing competitors' systems with their Portrait system.

**50% of Recent Customer Wins Came at Expense of Competing MDx Systems**




*SOURCE: Great Basin Scientific*

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## COMMERCIALIZATION

GBSN employs a razor / razor-blade (or what management refers to as a "vending machine") business model whereby the analyzers are placed at little-to-no cost (which helps to facilitate and speed adoption) to the customer and test cartridges are then sold to the installed base. Great Basin sells direct in the U.S. with a small sales force and through third-party distributors in parts of Europe and New Zealand. The U.S. market represents the source of the vast majority of the company's historical and expected future revenue and where the bulk of management's focus for growth lies.

The target market is focused primarily on the ~85% (~4.9k) of U.S. hospitals with less than 400 beds. Management views this as the low-hanging fruit given the affordability, ease-of-use and high performance of their system and the fact that more than half of these small-to-medium sized hospitals have yet to adopt molecular testing due to the high price tag of most competing platforms. The ongoing shift from legacy diagnostic methods to molecular testing represents an attractive opportunity given that the market for molecular diagnostics for hospital-acquired infections is expected to grow at an annual rate of more than 20% over the next several years.

A key component of the commercialization strategy, as we alluded to earlier, is expansion of the testing menu. A bigger menu of tests has the dual benefit of incremental revenue and increasing competitiveness of the entire platform. GBSN has had early success with adoption of their system with just the C. diff assay but we think their customer base and instrument utilization begins to show a greater rate of growth as the pipeline is monetized. The indicated warm reception that the GBS test has apparently enjoyed since just launching in early July may be a harbinger of accelerated adoption going forward as additional tests come to market. Management is aiming to have seven FDA cleared assays on the market by 1H 2016 (up from just two today).

Proceeds from the recent $20.5M (net) capital raise are being strategically used to improve production efficiency and grow the customer base. GBSN is well into the first phase of broadening the customer base, that being increasing the number of potential customers evaluating their system. The second phase, converting more evaluations to customer wins is now on the front-end and showing promise for potential significant growth by current year-end.

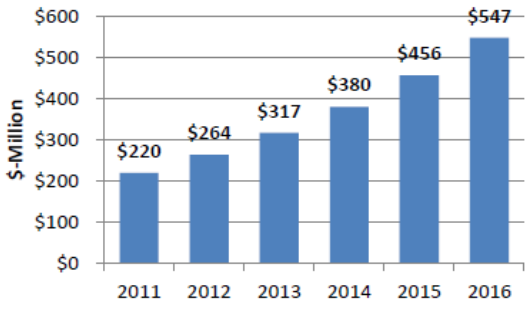
***Small-to-Medium Sized Hospitals:*** *Low volume, tight budgets and still using legacy diagnostic technologies…* Approximately 80% of the ~5.7k hospitals in the U.S. have less than 400 beds. Given certain attractive characteristics of these small-to-medium sized facilities, GBSN views these hospitals as their ideal target customers.

Smaller hospitals typically have smaller budgets which can limit their capital equipment purchasing decisions to instruments which meet pre-defined expense limits. GBSN's strategy of placing their analyzer for free or at minimal cost means they should not be automatically disqualified based on budget constraints (while competitors may be).

Smaller hospitals with lower patient flow also typically run fewer tests than their larger brethren. Fewer tests mean less margin to cover fixed and semi-fixed (training, overhead, etc) costs related to instrumentation, providing another impetus for these facilities to use lower-cost diagnostic systems.

In addition the market remains largely untapped with about 50% (~2.5k) of these target hospitals yet to adopt molecular testing and roughly 80% (~3.9k) yet to adopt a sample-to-result molecular platform. The adoption curve is expected to accelerate, however, as smaller hospitals look to upgrade from legacy testing methods to lower cost molecular systems such as GBSN's Portrait technology. Per IVDMarketReach molecular diagnostics of hospital acquired infections is expected to grow at an annual rate of 20% which they say will be catalyzed "by the emergence of new low cost, simple to use MDx platforms that are likely to help drive adoption of HAI testing into more of the small hospitals that have not yet adopted MDx testing." [4]

Figure 3




SOURCE: IVDMarketReach

***Analyzer placements….***

The company tailors their specific revenue model to the territories where they operate. Their current international footprint is characterized by relatively more liberal hospital capital equipment budgets but tighter variable spending. As such, in these countries GBSN can expect that utilization may be lower and therefore, unlike the U.S. market, the company does not place the analyzer free of charge. Instead, the analyzer is sold at cost which shifts some of the capital risk to the hospitals and provides them with some incentive to use the instrument (i.e. purchase GBSN's assays). And by being able to purchase at cost, the hospitals' investment still remains relatively low (particularly relative to competitors' instruments, most of which are sold at mark-up). Title is transferred to the customer upon sale and GBSN has no warranty obligations or servicing revenue opportunities. Many of the analyzers placed overseas are refurbished instruments that had at one time been used in the U.S.

In the U.S., where capital budgets can be more influential in dictating which instrument platforms a particular hospital will run, GBSN places their analyzers free of charge (GBSN has used sale-leasebacks to finance the cost of some of the analyzers). The company believes that the benefit of having no upfront cost has been a catalyst in facilitating initial interest in their platform from hospitals and helped speed adoption decisions.

For U.S. system placements GBSN retains title to the analyzer and can reclaim installed instruments. While U.S. customers are under no obligation to use the instruments (i.e. purchase consumables), just because the analyzers are offered at no cost does not mean a particular hospital will necessarily accept one. New instruments require staff to be trained and a location for the machine to reside. Hospitals use space and resources efficiently and get little or no benefit from having dormant or little-used equipment occupying valuable space. As such, if a hospital elects to accept GBSN's analyzer, it is likely that they plan on using it. Typically a hospital will evaluate the diagnostic platform prior to adopting it. GBSN notes that ~ 75% - 80% of potential customers that evaluate their system eventually adopt it.

**Analyzer Accounting Treatment**

The analyzers are carried on the balance sheet under property, plant and equipment (PP&E). The accounting treatment differs depending on whether the analyzers are sold (international territories) or placed free of charge (U.S.)

- **International territories:** sold at cost. When sold, title of the analyzer is transferred to the buyer. The sale is accounted for as a fixed asset sale and gain/loss on sale is recorded on the income statement. The gain/loss is included as an operating expense (i.e. "above the line")
- **U.S. market:** placed free of charge. GBSN retains title of the analyzer. Cost of the analyzer is depreciated straight-line over five years. Depreciation runs through cost of goods sold

***Consumables dictate margins and help drive demand….***
GBSN sells their assays through a direct sales force in the U.S. and through third-party distributors OUS. The current direct sales force consists of five reps which are supported by technical specialists and other support personnel.

The analyzers represent the razor and the assays the razor blade. While the consumables are what will generate the totality of the margin, the company's longest commercialized "razor blade", their C. diff. test, has been only moderately profitable. This is due to relatively pricey reagents required to produce the assay as well as a 14% royalty paid to IDT and BioHelix for use of their aforementioned technologies. This royalty, which is paid on net sales, applies only to the C. diff assay.

Gross profit, while improving, has remained negative as sales volumes, while increasing, have not yet reached a level where the margin covers analyzer depreciation and fixed manufacturing costs. This is reflective of the manual, hands-on production process and low materials purchasing volume (i.e. lack of substantive volume discounts). However, gross margin is expected to continue to improve with growth in sales providing greater economies of scale. In addition, as pipeline tests begin to make a contribution, including the just-launched GBS test, this should further benefit margins as these will not be subject the 14% royalty and are manufactured with less expensive reagents as compared to the C. diff assay.

And finally, in terms of GBSN's focus on reaching a point of sustainable positive gross profit, the company will use some of the recent $22M additional financing to begin automating their manufacturing processes. Currently the test cartridges are all hand-built. GBSN recently began automating some of the manufacturing processes. Automation is expected to progress over the next several years, over which time gross margins should experience a consistent and significant widening.

**Consumables are also what help drive demand for a particular diagnostic platform.** Accuracy, speed, cost and ease-of-use are all important customer considerations. As we detailed above, GBSN's platform appears to be highly competitive on all of these measures. But another important consideration is the size and quality of the testing menu that runs on a particular instrument. Hospitals are typically loathe to run several diagnostic platforms due to requisite additional training, the need and dis-economics of dealing with several vendors, and the clutter factor. As such, all else equal, a system with a larger testing menu will be more appealing.

So while GBSN has had early success with adoption of their system with just the C. diff assay, we think interest in and demand for their platform will significantly increase as their pipeline tests come to market. This should have a multiplier-type affect to revenue as the additional tests provide incremental sales and overall demand for their platform increases.

***$22.5M raise facilitating growth initiatives….***
In addition to upgrading manufacturing efficiency, GBSN is using some of the proceeds from the March 2015 financing (preferred plus warrants) to accelerate growth initiatives. This includes a goal of increasing the number of FDA-cleared tests from two today to seven by the first half of 2016. Another seven tests are currently in earlier stages of development. The company has been aggressive in increasing their installed base in order to fully capitalize on the soon-to-be much larger testing menu.

The company has already begun **ramping up analyzer manufacturing** to build the installed base and to meet growing demand. 150 analyzers have been built since closing of the company's IPO in October 2014 and a batch of another 250 are currently in production and expected to be completed by mid-2015. Management noted on the Q4 call (March 18$^{th}$) that 61 of the initial 150 analyzers had either been placed at hospitals for evaluation or were scheduled to be placed and expected that all 150 will have been shipped by mid-April. Evaluations for the next 250 instruments were expected to begin in July.

As of the end of May GBSN had 112 **customers in the U.S**. which were purchasing their assays ("result reporting customers"), up from 101 at the end of March. Another 40+ customers were either actively evaluating or scheduled to evaluate the system. Historically, each customer has on average used approximately two analyzers. Another 20+ international customers are purchasing assays (as U.S. customers represent ~97% of total revenue we confine our discussion to the domestic market). By the current year-end the company hopes to have 170 – 180 U.S. customers and another 40 – 45 in evaluation.

The **evaluation process** typically consists of a head-to-head comparison of GBSN's system with a hospitals' current testing method. Historically 75% - 80% of evaluations eventually convert to using customers. The

evaluation process is typically rigorous and can be somewhat drawn out, which coupled with the high conversion rate suggests that the vast majority of potential customers see value in the system after doing significant due diligence. It also indicates that "value" is determined by much more than the ability to receive an analyzer at no cost. As noted earlier, hospitals prefer to use as few diagnostic platforms as possible and, as such, if they choose GBSN system, they are likely to use it.

## INVESTMENT CONSIDERATIONS

- **Small-Medium Sized Hospitals, Infectious Diseases Driving MDx Demand:** while the global MDx market is forecast to grow at about 11% over the next several years, even more outsized growth is expected in certain specific segments. The pinnacle of growth is expected to come from infectious diseases (which is also, by far, the largest MDx segment) and be catalyzed from the accelerating adoption of MDx by small-to-medium sized hospitals. Industry research forecasts infectious disease MDx to experience 20% annual growth and predicts simple-to-use MDx technologies will fuel greater adoption by smaller hospitals. GBSN, with a sample-to-result platform running on novel technology and a specific focus on both infectious diseases and smaller hospitals, has positioned itself to capitalize on the fastest growing segments in molecular diagnostics.

- **Competitive Position:** while the molecular diagnostics market is mostly dominated by just a handful of much larger companies (with much more established marketing and distribution capabilities), these relative behemoths largely service the major hospital segment which require platforms that cover all molecular diagnostic categories, generate a high volume of tests and are less cost-conscious. As such these companies are not direct competition to GBSN.

  We think GBSN can be competitive against direct competitors such as Meridian, GenMark and Cepheid (and others focused on GBSN's targeted segment) given the totality of the benefits of the Portrait technology including low cost, both low-plex and multiplexing abilities, ease-of-use and quick turnaround time which are a combination of features that are not shared by its direct competitors. GBSN has already had early success with taking market share as approximately 50% of recent customer wins have come at the expense of competing molecular diagnostic platforms.

- **Installed Base Expected To More Than Double By Year-End:** the $30M+ raised from the IPO in October and follow-on offering in March 2015 have allowed GBSN to begin streamlining manufacturing, fund the late-stage pipeline and ramp analyzer production. 150 new analyzers have already been built and another 250 are expected to be completed by mid-year. Hospitals appear to be highly receptive to the technology with all of the first 150 batch expected to be either under evaluation by prospective customers or already being used by purchasing customers by the end of April. The next 250 would then begin rolling out to evaluation sites in the summer. Management aims to have 170 – 180 U.S. purchasing customers by the current year end, up from 84 at the end of 2014 (over 100% growth).

- **Bigger Testing Menu and Installed Base Should Be Major Revenue Catalyst:** Until very recently C. diff had been the company's only commercialized test which generates approximately $20k per customer per year. The GBS test launched in July and the company has indicated that it has received a very warm reception. With the recent acceleration in pipeline development management anticipates five other new tests to launch in the U.S. by 1H 2016. All of these pipeline assays have market sizes similar to or larger than C. diff and, as such, GBSN could see significant growth in per-customer revenue as the pipeline is commercialized. We think this could be particularly true if and when the MRSA-related tests (S. aureus and nasal screen) come to market given the relatively enormous size of this market and a burgeoning interest from hospitals to reduce the cost of hospital-acquired infections.

  A larger testing menu should also help drive overall demand for the Portrait platform from hospitals. Growth in revenue per customer and in the installed base should have a multiplier-effect to total revenue which could significantly steepen the sales growth curve as new tests come to market.

- **Industry Consolidation:** the molecular diagnostics space has experienced fairly rapid consolidation over the recent past as IVD companies looking to enhance their portfolio pick up smaller MDx players with novel technologies. The space as become highly competitive as the larger MDx companies look for new technologies in order to edge out their competition. Kalorama Information put it more bluntly in an August 2014 report noting

that, “Molecular diagnostic companies are partnering to survive.” Recent acquisitions by the MDx “majors” include;

- in 2013 France-based bioMerieux bought BioFire Diagnostics for BioFire’s multiplex PCR technology
- in 2012 Thermo Fisher acquired One Lambda for that company’s MDx transplant technology and already established firms look to enhance their molecular diagnostics portfolio
- Qiagen has made several recent MDx-related acquisitions including Scandinavian Gene Synthesis (2012), AmniSure (2012), SABiosciences (2009), CLC bio (2013) and Ingenuity Systems (2013)
- Becton Dickinson bought GeneCell Biosystems (2014) and Alverix, Inc (2014)
- Hologic acquired Gen-Probe (2012)
- Roche bought Ariosa Diagnostics (2015), IQuum (2014) and Genia Technologies (2014)

The recent consolidation in the industry could bode well for companies such as GBSN with novel technologies and which are exploiting a rapidly growing portion of the market. While we have no indication that GBSN could be a take-out target, success could very well beget interest from the MDx majors.

❖ **Financials – Will Require Significant Ramp in Volume to Reach Profitability:** the company is still very much in the early stages of commercialization. Their first assay, C. diff, launched in late 2012 which has had early success, with sales growing from $761k in 2013 to $1.6M in 2014 (+111%). The GBS test just launched in July, making it the company's second commercialized product and, per management, also enjoying significant early customer interest. As indicated earlier, we think the combination of ramping analyzer placements and monetization of the pipeline can push revenue significantly higher. And given that the pipeline should begin bleeding into the market as soon as early next year with as many as five new tests coming to the U.S. by the end of 2016, GBSN could see sales ramp in fairly short order.

But while revenue grew $845k from 2013 to 2014, gross profit fell $937k over that same period, ending 2014 at ($2.4)M. As explained earlier, depreciation of the U.S.-placed analyzers runs through cost of goods sold as does the 14% royalty paid to IP licensors on C. diff sales. But, even stripping out the depreciation and royalty, gross profit still would have been well in the red in both 2013 (-$832k, or negative 109%) and 2014 (-$1.4M, or negative 86%). Part of the reasons for the poor gross margin is the high cost of reagents used in the C. diff test as well as relatively costly and inefficient manually hand-building the assays.

| | 2013 A | 2014 A |
|---|---|---|
| Total Revenues | $760.6 | $1,606.3 |
| *YOY Growth* | - | *111.2%* |
| 14% royalty | $106 | $225 |
| Depreciation of analyzers | $486 | $755 |
| Non-deprec / Non-royalty COGS | $1,593 | $2,988 |
| Cost of Revenues | $2,186.0 | $3,968.2 |
| Gross Income | ($1,425.3) | ($2,361.9) |
| *Gross Margin* | *-187.4%* | *-147.0%* |
| *Non-deprec / Non-royalty margin* | *-109.4%* | *-86.0%* |

Some of the inherent costs running through COGS should dissipate as GBSN implements more automated manufacturing. And the recently launched GBS assay and pipeline tests should have significantly lower reagent costs and will also not be subject to the 14% IP royalty. But analyzer depreciation, which is a significant portion of COGS (equal to 22% and 19% of 2013 and 2014 COGS, respectively), will continue to pressure margins as will fixed costs such as facility expenses unless and until revenue reaches a sufficient level to dilute these costs.

❖ **Modeling Accelerating Revenue Growth w/ Pipeline Launch, Rapid Improvement to Profitability:** utilization per customer averaged 916 tests during 2014 (or ~230/quarter) and average revenue per test was approximately $21. Our model incorporates the assumption that these averages tick up slightly in the second half of 2015, incrementally benefitting from the launch of the GBS in early July.

As of the end of May there were 112 assay purchasing customers, up from 84 at the end of 2014. Management is guiding for 170 – 180 by 2015 year-end. We (slightly more conservatively) assume an installed base servicing 130 customers by the close of Q3 and 160 at current year-end. Incorporating the utilization and price/test averages from the prior year, with an incremental benefit from the GBS assay introduction, results in 2015 total revenue of approximately $2.5M (+ 55% from 2014). We forecast some improvement in GM during 2015 but, given the representative slim margins of the C. diff test and expectations that implementation of production automation (and the cost-saving benefits of) will still be in the early stages, that GM will remain well in the red. We also think that despite expectations of revenue growth that operating loss may actually worsen compared to 2014 as a result of increased spend on R&D for clinical trials and regulatory submissions related to the late-stage pipeline as well as additional investments in SG&A (i.e. new hires, additional overhead, etc) as the company prepares for the next stage of growth, that being commercialization of their deep pipeline.

***Model inflection beginning in 2016…***
Corresponding with the initial introduction of the late-stage pipeline, we think the beginning of a much more substantial inflection in both revenue growth and improvement in profitability will materialize in 2016. Management aims to have five new tests on the market by 1H 2016. Incorporating a cushion for potential delays, we more conservatively model just the Staph ID/R and STEC products to reach the market by 2016 and the remaining three (SA nasal screen, Candida and food-borne) assays to launch in 2017.

We have the user base growing at about a mid-40% rate over the next several years. This is arguably conservative given that management's forecast is that it will more than double in 2015 (we have it increasing by 91%) and the fact that they expect to begin detailing the next 250 analyzer batch this Summer. Assuming management can hit their goal of ~175 customers by current year-end and extrapolating the customer win rate of ~7/month, results in total user base of ~260 by 2016 year-end and 340 by the close of 2017. Our model more assumes approximately 160 (YE 2015), 230 (YE 2016) and 335 (YE 2017).

But even with our more conservative outlook, we model significant revenue growth beginning in 2016: 230% in 2016 (to $8.2M), 103% in 2017 (to $16.6M) and 119% in 2018 (to $36.3M). Our assumed utilization for each test roughly mirrors that of the C. diff product with relatively low initial orders incrementally growing over time. However, we think certain of the pipeline candidates, particularly the MRSA-related tests (S. aureus and nasal screen), could have tremendous upside given their respective relatively enormous markets and blossoming demand in these areas of infectious disease molecular diagnostics.

A steepening revenue curve, flattening of OpEx from deceleration in R&D activity and leverage in SG&A, coupled with healthier margins from the pipeline should result in fairly rapid improvement in profitability which we think begins to materialize in 2016. We model gross profit to turn positive in year 2017 (although we note that this is difficult to predict given various unknowns related to cost and pricing of the pipeline products) and continue to rapidly widen over the next several years as higher margin pipeline-related revenue further dilutes that of the relatively low-margin C. diff product. We think operating income turns positive by late 2019, or potentially earlier depending on level of sales growth and how rapidly GM improves.

❖ **Additional Capital May Be Required:**
Combined cash used in operating and investing activities was $12.1M in 2014 on operating loss of $12.2M. Another $945k and $435k was used for principal payments on capital leases (related to financing analyzer construction) and notes payable, respectively. At Q1 2015 quarter-end $3.0M and ~$700k were outstanding under the capital lease and notes payable, respectively.

We estimate operating loss and cash burn of almost $16M in 2015, including ~$12M in the last nine months. In addition, ~$800k in capital lease principal remains due during the year. For 2016, we estimate cash burn plus financing / capital lease maturities (including $1.3M in capital leases) of approximately $17M.

Pro forma for issuance of common shares subsequent to the end of the quarter, cash balance at Q1 quarter-end was approximately $22 million. Assuming our cash burn estimates are accurate, GBSN will exit 2015 with approximately $9M in cash (assuming no additional capital raises during the year) and need to raise additional capital by sometime in 2016. Our modeled outstanding share count incorporates the assumption that future capital raises come in the form of common equity (or convertible debt which is subsequently converted to equity).

## VALUATION / RECOMMENDATION

We value GBSN using a combination of 10-year DCF and industry P/S comparables. We note that our model does not yet incorporate any contribution from early-stage pipeline candidates which the company has alluded to but which there is currently little information about.

We model revenue of $2.5M in 2015, consisting mostly of sales of the C. diff test with a small contribution from Group B, growing to $36M in 2018, driven by the recent big push to significantly expand the user base and initial contribution from the late-stage pipeline. We assume all five late-stage candidates are on the market by 2017. We model the user base to expand from the current 112 customers to almost 500 by 2018 year-end, a customer acquisition/conversion rate which is commensurate with near-term expectations.

We assume the installed base grows at about 15% per year from 2018 to 2025, facilitated by the ongoing shift from legacy testing methods to molecular diagnostics, particularly in GBSN's target customer market of small-to-medium sized hospitals. In addition, as we detailed earlier, the company has noted that approximately 50% of recent account wins have come from customers switching from a competitor's diagnostic platform to GBSN's. We see this as an additional catalyst to expanding the user base.

The company has indicated that they think revenue per customer, which currently stands at approximately $20k, can increase to more than $250k with full commercialization of the late-stage pipeline (excluding Candida). We take a much more conservative stance and model just better than $70k per customer by year 2018 and approximately $110k per customer by 2025 with revenue increasing at a CAGR of approximately 25% over that period.

Our 10-year DCF values the company at $6.59/share which is similar to P/S comparables of competitors GNMK, VIVO and CPHD which values the stock at about $6.30/share. We use the approximate average and recommend investors accumulate up to our $6.50/share target price. We are initiating coverage of GBSN with a Buy recommendation.

| | TICKER | | | | Implied |
|---|---|---|---|---|---|
| Price/ Sales | GNMK | VIVO | CPHD | Average | GBSN pps |
| 2014 | 12.6 | 4.3 | 9.6 | 8.8 | $2.20 |
| 2015 | 10.1 | 4.1 | 8.1 | 7.4 | $2.87 |
| 2016 | 7.4 | 4.0 | 6.9 | 6.1 | $7.76 |
| 2017 | 5.9 | 3.1 | 5.3 | 4.8 | $12.30 |
| | | | | **Avg.** | **$6.28** |

## FINANCIAL MODEL

### Great Basin Scientific, Inc.

| | 2014 A | Q1A | Q2E | Q3E | Q4E | 2015 E | 2016 E | 2017 E | 2018 E |
|---|---|---|---|---|---|---|---|---|---|
| Total Revenues | $1,606.3 | $458.7 | $541.2 | $664.0 | $823.7 | $2,487.6 | $8,202.9 | $16,635.0 | $36,343.9 |
| *YOY Growth* | *111.2%* | - | - | *62.2%* | *85.0%* | *54.9%* | *229.8%* | *102.8%* | *118.5%* |
| Cost of Revenues | $3,968.2 | $966.6 | $1,119.6 | $1,241.2 | $1,368.8 | $4,696.2 | $9,093.6 | $14,896.4 | $23,753.4 |
| Gross Income | ($2,361.9) | ($507.9) | ($578.4) | ($577.2) | ($545.1) | ($2,208.6) | ($890.7) | $1,738.6 | $12,590.4 |
| *Gross Margin* | *-147.0%* | *-110.7%* | *-106.9%* | *-86.9%* | *-66.2%* | *-88.8%* | *-10.9%* | *10.5%* | *34.6%* |
| R&D | $4,609.9 | $1,503.6 | $1,615.0 | $1,487.0 | $1,502.0 | $6,107.6 | $5,114.0 | $4,818.0 | $4,510.0 |
| *% R&D* | *287.0%* | *327.8%* | *298.4%* | *223.9%* | *182.4%* | *245.5%* | *62.3%* | *29.0%* | *12.4%* |
| Selling/Mktg | $2,301.6 | $806.1 | $824.0 | $848.0 | $855.0 | $3,333.1 | $4,815.1 | $6,005.2 | $9,231.3 |
| *% S&M* | *143.3%* | *175.7%* | *152.3%* | *127.7%* | *103.8%* | *134.0%* | *58.7%* | *36.1%* | *25.4%* |
| G&A | $2,928.2 | $1,060.7 | $1,021.0 | $1,035.0 | $1,040.0 | $4,156.7 | $4,515.0 | $5,044.0 | $5,412.0 |
| *% G&A* | *182.3%* | *231.2%* | *188.7%* | *155.9%* | *126.3%* | *167.1%* | *55.0%* | *30.3%* | *14.9%* |
| (Gain)/loss on asset sales | ($8.2) | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| Operating Income | ($12,193.5) | ($3,878.2) | ($4,038.4) | ($3,947.2) | ($3,942.1) | ($15,805.9) | ($15,334.8) | ($14,128.6) | ($6,562.9) |
| *Operating Margin* | *-759.1%* | *-845.4%* | *-746.2%* | *-594.5%* | *-478.6%* | *-635.4%* | *-186.9%* | *-84.9%* | *-18.1%* |
| Interest expense, net | ($1,132.9) | ($301.3) | ($325.0) | ($330.0) | ($335.0) | ($1,291.3) | ($1,400.0) | ($844.0) | ($208.0) |
| Chge in value of deriv liability | ($8,396.2) | ($66,994.1) | $0.0 | $0.0 | $0.0 | ($66,994.1) | $0.0 | $0.0 | $0.0 |
| Total Other Income | ($9,529.0) | ($67,295.4) | ($325.0) | ($330.0) | ($335.0) | ($68,285.4) | ($1,400.0) | ($844.0) | ($208.0) |
| Pre-Tax Income | ($21,722.5) | ($71,173.6) | ($4,363.4) | ($4,277.2) | ($4,277.1) | ($84,091.4) | ($16,734.8) | ($14,972.6) | ($6,770.9) |
| Taxes | $5.3 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| *Tax Rate* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* |
| Preferred Dividends | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| Net Income | ($21,727.8) | ($71,173.6) | ($4,363.4) | ($4,277.2) | ($4,277.1) | ($84,091.4) | ($16,734.8) | ($14,972.6) | ($6,770.9) |
| *YOY Growth* | *79.6%* | - | - | *-75.2%* | *-384.6%* | *287.0%* | *-80.1%* | *-10.5%* | *-54.8%* |
| *Net Margin* | *-1352.7%* | *-15515.4%* | *-806.2%* | *-644.2%* | *-519.3%* | *-3380.4%* | *-204.0%* | *-90.0%* | *-18.6%* |
| EPS (continuing ops) | ($17.32) | ($13.99) | ($0.67) | ($0.57) | ($0.39) | ($11.18) | ($0.39) | ($0.27) | ($0.11) |
| Diluted Shares O/S | 1,254 | 5,087 | 6,500 | 7,500 | 11,000 | 7,522 | 43,250 | 55,000 | 64,000 |

*Brian Marckx, CFA*

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## LEADERSHIP

### Management

**Ryan Ashton**
***President , Chief Executive Officer***
Mr. Ashton has extensive experience in driving successful marketing, sales, IPO and M&A strategies for advanced-technology companies. His experience includes serving as a senior vice president, sales and marketing at Megahertz—a publicly-held company with annual sales in excess of $150 Million; as a senior officer at Inari, a pre-IPO technology start-up; and as CEO of Printelligent Corporation. Ashton has a proven track record in successfully managing diverse teams of personnel—scientists, marketing, sales and administrative resources—in high-growth technology companies.

**Jeffrey Rona**
***Chief Financial Officer***
Mr. Rona is a seasoned executive in the healthcare and biotech industry with over 20 years of experience in originating, structuring and executing corporate transactions and financings. Most recently, he has served as a financial consultant to Great Basin since 2012 in his role as the managing director of Rona Capital, LLC, a life sciences-focused transactional advisory consultancy, founded in 2011. From 2006 to 2011, Mr. Rona was the Chief Business Officer of GlobeImmune, a private biopharmaceutical company developing treatments for cancer and infectious diseases. Prior to joining GlobeImmune, Mr. Rona was Vice President of Corporate Development for Corgentech, Inc., following the merger between Corgentech and AlgoRx Pharmaceuticals in 2005. At AlgoRx, he was CFO and responsible for the execution of the merger with Corgentech. Mr. Rona was in the investment banking department at UBS Warburg from 2000 to 2002. Prior to this, he was Director of Finance and Corporate Development at Antigenics Inc., now Agenus, taking the company public in 2000. Mr. Rona began his career in 1990 with Coopers and Lybrand and its wholly-owned subsidiary, Coopers & Lybrand Securities, where he held positions with increasing responsibility. Mr. Rona received a B.S. in Accounting from Case Western Reserve University in 1990.

**Robert D. Jenison**
***Senior Vice President, R&D and Chief Technology Officer***
Mr. Jenison joined Great Basin Corporation from BioStar, an Inverness Medical Innovations Inc. company (formerly Thermo Electron), where he served as associate director of Research and Development. At BioStar, Jenison directed a team in developing rapid nucleic acid diagnostic assays, created and then executed the go-to-market strategy for the platform, and was nominated for the Thermo Electron Life and Laboratory sector′s Innovation Award for development of the CF genotyping test. Jenison has been awarded four patents based on his work with nucleic acid ligands and arrayed elements; furthermore his work has been published in numerous scientific journals. Jenison holds a bachelors degree in Chemistry from Revelle College, University of California at San Diego.

**Laurence Rea**
***Chief Engineer***
Mr. Rea brings to Great Basin more than 20 years of engineering and manufacturing experience, of which eight years were spent managing a Good Manufacturing Practice (GMP) facility for BioStar, an Inverness Medical Innovations Inc. company (formerly Thermo Electron), with revenues that exceeded $30 million during Rea′s tenure. As general manager at BioStar, Rea oversaw the pre-clinical and clinical trials at hospitals and clinics, including institutional review board (IRB) approvals from multiple organizations; and was responsible for FDA regulatory requirements– seeing multiple diagnostic products through the 510K approval process–and the overall performance of the business unit. Rea holds a Bachelor of Science degree in Physics from University of Colorado, Boulder, Colo.

**Sandra Nielsen**
***Vice President, Sales and Marketing***
Ms. Nielsen is a seasoned executive with extensive success in building and executing customer acquisition programs for high–growth technology start–ups. Nielsen joins Great Basin from Pearson PLC where she served as senior director of marketing for the Data Solutions business unit (formerly Edustructures). During her tenure at Edustructures, she created and implemented aggressive marketing and customer acquisition programs that positioned the company for purchase by Pearson. Prior to Pearson, Nielsen served as the senior director of marketing for Omniture where she executed programs that contributed to the company′s record–setting (100 percent year–over–year) revenue growth in preparation for the company′s 2006 IPO. Nielsen spearheads the company′s global sales and marketing efforts, managing both the direct sales team as well as the distributor network and leads the customer/technical support operations. Nielsen also oversees product management and user experience, as well as corporate communications and public relations efforts.

**Wesley C. Lindsey, Ph.D., MBA**
***Vice President, Product Development***
Dr. Lindsey joins from Nanosphere, Inc. where he was the associate director of Assay Development, Infectious Disease. At Great Basin Corporation, Dr. Lindsey is responsible for the development of IVD (In Vitro Diagnostics) assays from feasibility to FDA 510(k) clearance and market, and for directing reagent manufacturing and quality control. He received his Ph.D. in Genetics and Molecular Biology from Emory University, Atlanta, Ga., and an MBA from Georgia State University.

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**Walter Hammond**
***Vice President, Manufacturing***
Mr. Hammond has over 20 years of experience in operations executive management directing the worldwide functional aspects of diverse manufacturing, planning and scheduling, distribution, quality control, purchasing and supply chain management, logistics and inventory management, support services and sales administration, e-commerce systems, facilities and fleet management. He has served as served as vice president of Operations in his last three companies and in those postions has implemented effective and efficient business and process solutions, while providing positive, sound leadership, and continuously striving for improvement based on Lean Six Sigma, and other best practices. Mr. Hammond holds an MBA from Utah State University and a BA from Brigham Young University.

## Board of Directors

**David Spafford**
***Chairman of the Board***
Mr. Spafford is a founding investor of Great Basin and has served as Chairman of our Board of Directors since its inception. Mr. Spafford was a co-founder, director and senior executive officer of Megahertz Corporation. Megahertz Corporation completed an initial public offering in 1993 and was acquired by U.S. Robotics in 1995 in a transaction valued at approximately $450 million. Since 1994 Mr. Spafford has focused on angel investing and philanthropic work.

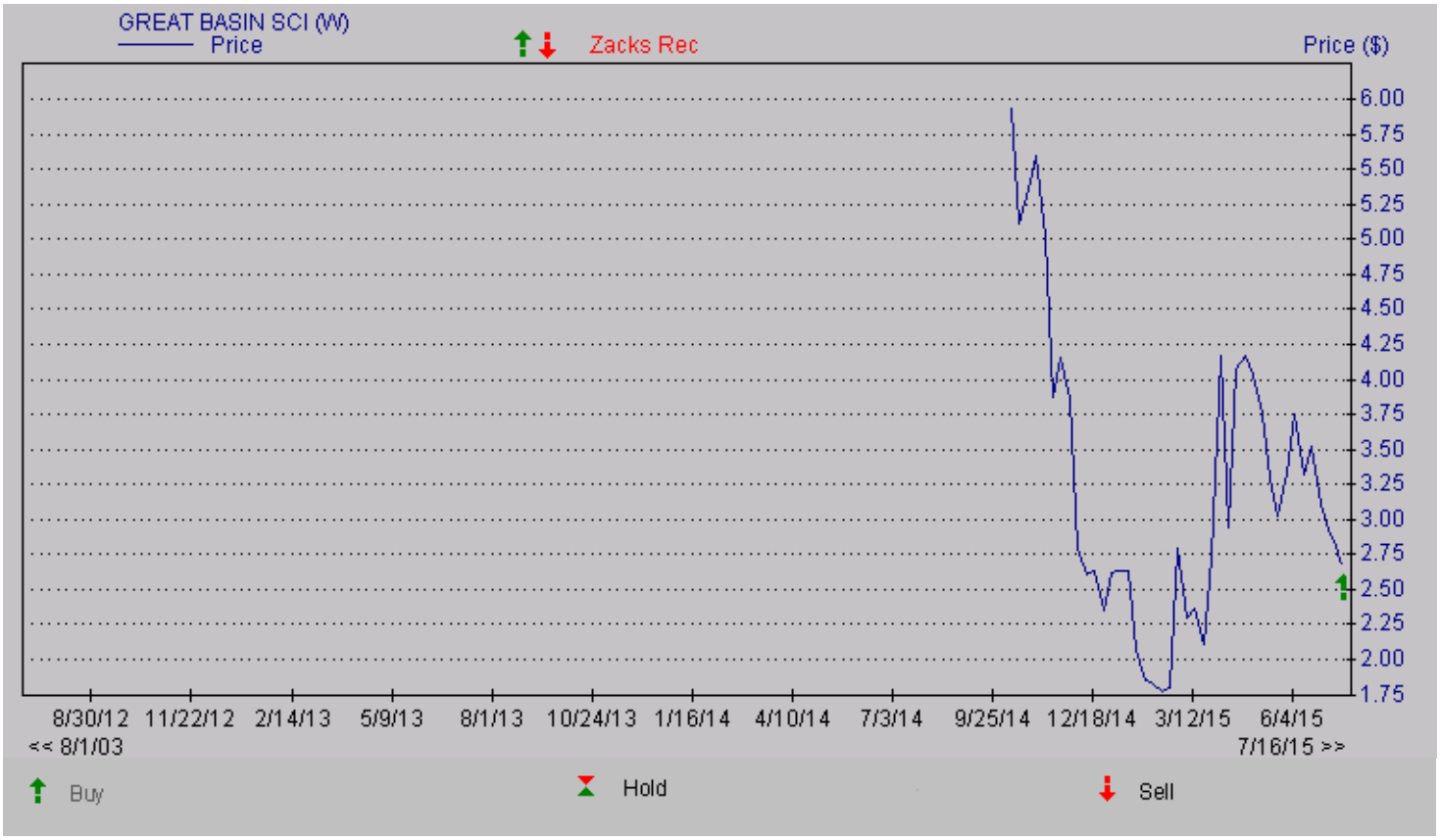
**Ryan Ashton**
(see bio above)

**Sam Chawla**
***Independent Director***
Mr. Sam Chawla is a Portfolio Manager at Perceptive Advisors LLC. He is also on the Board of Directors at Response Genetics, Inc.
Prior to joining Perceptive Advisors in August 2013, Mr. Chawla was employed as a Managing Director by UBS Securities LLC, a Director by Credit Suisse Securities (USA) LLC, and a Project Manager by Bloomberg LP.
Mr. Chawla received his undergraduate degree from The Johns Hopkins University and his MBA in Management from Georgetown University - The McDonough School of Business.

**Stephen Aldous**
***Independent Director***
Mr. Aldous has been one of our directors since 2010. Mr. Aldous was a co-founder of Megahertz Corporation. He served as director and chief technology officer from 1986 to 1995. Since the acquisition of Megahertz, Mr. Aldous has focused on angel investing and philanthropic work. Mr. Aldous received his BS in electrical engineering from the University of Utah in 1985.

**Ronald K. Labrum**
***Independent Director***
Mr. Ronald K. Labrum is Independent Director at Great Basin Scientific, Inc., Chairman at Suture Express, Inc., and Independent Director at Wright Medical Group, Inc. He is on the Board of Directors at Great Basin Scientific, Inc., ProCure Treatment Centers, Inc., Aptalis Holdings, Inc., Wright Medical Group, Inc., and Aptalis Pharma, Inc.
Mr. Labrum was previously employed as Chief Executive Officer by Fenwal, Inc., Chief Executive Officer-Healthcare Supply Chain Se by Cardinal Health, Inc., President-Allegiance Manufacturing & Distribution by American Hospital Supply Corp., President by Allegiance Healthcare Corp., and a Principal by Baxter International, Inc.
He received his undergraduate degree from Utah State University.

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The current distribution is as follows: Buy/Outperform- 27.7%, Hold/Neutral- 51.3%, Sell/Underperform – 17.9%. Data is as of midnight on the business day immediately prior to this publication.