GeneNews Limited

GEN.TO: Focus has shifted to commercialization of ColonSentry in the US---Outperform.

OUTLOOK
GeneNews is a molecular diagnostics company with focus on cancer testing. The Company has developed Sentinel Principle platform technology by using functional genomics. The lead product ColonSentry to facilitate compliance with early colon cancer screening is already available in the US, Canada, China and Malaysia. Current focus is market expansion in the US.

Revenue will accelerate in the coming years due to focused marketing strategy and new product offering. Valuation is attractive now, and we rate the shares Outperform.

SUMMARY DATA

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Zacks Estimates

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<tr>
<th>Revenue (in millions of $)</th>
<th>Q1 (Mar)</th>
<th>Q2 (Jun)</th>
<th>Q3 (Sep)</th>
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<th>Earnings per Share (EPS)</th>
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Zacks Projected EPS Growth Rate - Next 5 Years % | N/A
WHAT’S NEW

GeneNews Exits 2Q 2013 With Strong Balance Sheet

On Aug. 9, 2013, GeneNews Limited (GEN.TO) reported operational and financial results for the three-month and six-month periods ended June 30, 2013.

There was no revenue for the three months ended June 30, 2013.

R&D expenses were $0.6 million for 2Q13 compared to $0.4 million for 2Q12.

SG&A expenses were $1.2 million for the three months ended June 30, 2013 compared to $0.7 million for the three months ended June 30, 2012.

Net loss was $1.9 million ($0.06 per share) for the three months ended June 30, 2013 compared to net loss of $1.3 million ($0.07 per share) for the same period of 2012.

For the six months ended June 30 2013, the Company reported a net loss of approximately $3.4 million, or $0.11 loss per common share, as compared to a net loss of approximately $2.5 million, or $0.16 loss per common share for the same six-month period in 2012.

As of June 30, 2013, the Company’s cash and short-term investments amounted to approximately $6.4 million. Current cash balance will last into 2Q14 according to our model.

Current Focus On ColonSentry® Commercialization In The US

GeneNews recently shifted its focus to market ColonSentry throughout the US, the most important market for ColonSentry.

The Company currently expects to launch ColonSentry® test into regions of the U.S. beyond New York and New Jersey, through IDL, during the third and fourth quarters.

As a reminder, On April 10, 2012, the Company announced the commercial launch of its lead product, ColonSentry®, by its first U.S. marketing partner, Enzo Clinical Labs (a division of Enzo Biochem, Inc.), into the New York and New Jersey region.

On July 2, 2013, GeneNews formed a joint venture with two private American companies, Health Diagnostic Laboratory and a sales organization with national capabilities, to establish an accredited clinical laboratory called Innovative Diagnostic Laboratory, LLP (IDL). IDL will initially focus on the development and broader US commercialization of ColonSentry and is functional and certified under the Clinical Lab Improvement Amendments Act (CLIA).

GeneNews has granted IDL an exclusive license for certain technology related to the ColonSentry test for immediate development and commercialization throughout the United States, excluding NJ and NY. Each party to the JV will receive a share of the revenues and profits generated by IDL.

The launch of ColonSentry in the US and the establishment of IDL are important to GeneNews. It provides the Company with a US commercialization platform for the introduction of ColonSentry into the US market. IDL is also being developed as a full diagnostic laboratory focused on the early detection and treatment of cancer and, with GeneNews as the driving scientific force, will add other complementary products to enhance the product offering. We believe revenue growth will be accelerated in the coming quarters.
Currently, the Company's activities have been primarily focused on U.S. ColonSentry® commercialization initiatives that include the development of a reimbursement strategy, the planning and initiation of additional clinical studies, and evaluation of potential technology platforms to reduce costs for next generation ColonSentry® and pipeline products.

We are encouraged by the positive response to the recent launch of ColonSentry® into New York and New Jersey by the Company's first U.S. partner.

**Strategic Restructuring Announced To Prepare For The Countrywide Launch of ColonSentry**

In order to prepare for the commercial launch of ColonSentry in the US beyond NJ and NY, GeneNews recently announced a strategic restructuring, including senior management changes and staff reductions.

This strategic restructuring is designed to further position its recently formed joint venture, Innovative Diagnostic Laboratory LLP (IDL) to become a leader in molecular diagnostics and personalized medicine, with a primary focus on cancer-related indications.

The commercial launch of ColonSentry® test into regions of the U.S. beyond NY and NJ will be done through IDL. The Company has also begun the work of assembling a robust menu of other advanced cancer tests to be offered by IDL. GeneNews has initiated the strategic restructuring both to sharpen its focus on commercialization and to improve its overall cost structure, extending the Company's cash runway so that it adequately supports IDL's commercial success.

In connection with the restructuring, GeneNews announced the departure of Gailina J. Liew, its President and Chief Operating Officer. Ms. Liew has also resigned from the Company's Board of Directors.

GeneNews also announced that it expects to reduce staffing levels by approximately 60% between August 20 and November 30, 2013. The Company noted that the planned staff reductions will be focused on reducing its internal effort behind pure research, while maintaining its scientific competence and enhancing support for its business development, commercialization and regulatory functions.

Earlier in July, GeneNews announced that Dr. Heiner Dreismann has stepped down as GeneNews' Interim CEO, but continues as the Company's Lead Director. In that capacity, he will leverage his wealth of experience and contacts in the diagnostics industry to advance GeneNews' business development activities. Specifically, Dr. Dreismann intends to help assemble a robust menu of advanced cancer assays to be offered by IDL in the United States through third party licenses and potential acquisitions.

At the same time, James R. Howard-Tripp has been appointed Executive Chair of GeneNews’ Board, succeeding Rory Riggs, who has stepped down as Chair, but remains a Director. Mr. Riggs has been a member of GeneNews' Board since inception, is a large shareholder and will continue to actively support the Company.

Mr. Howard-Tripp, who will now lead the company as Chairman and CEO, brings a track record of successfully developing and commercializing products and of building out new businesses.

**INVESTMENT HIGHLIGHTS**

- We maintain our Outperform rating on GeneNews Limited (GEN.TO). Our 12-month price target is $3.50 per share.
- GeneNews is an emerging molecular diagnostics company with a focus on cancer testing services, which has been growing rapidly in recent years due to rapid advancement in genomics
and proteomics research. This market continues to grow dramatically due to the rapid growth of personalized medicine.

- GeneNews has developed a unique Sentinel Principle platform technology which utilizes functional genomics to enable early diagnosis and personalized health management. Based on this platform technology, GeneNews has recently launched its lead product ColonSentry®, a blood test to determine an individual's current risk for having colorectal cancer (CRC).

- ColonSentry was launched in April 2012 in NJ and NY in the US. For 2013, the Company's two key priorities are to successfully launch ColonSentry into the broader US market and to execute reimbursement strategy to demonstrate the value and utility of ColonSentry® to public and commercial U.S. payers. The Company has recently formed a joint venture of Innovative Diagnostic Laboratory (IDL), with two private US companies, to commercialize ColonSentry throughout the US excluding NJ and NY, will provide a platform for additional products and expansion into a full diagnostics laboratory focused on early detection and treatment of cancer.

- On the global front, GeneNews' growth strategy is to establish alliance with appropriate partners to bring ColonSentry to people around the world. Currently, ColonSentry is also available in Canada, China and Malaysia.

- GeneNews holds numerous patents approved or pending and has built a strong portfolio which provides long term growth potential in the years to come.

- We think revenue growth will accelerate in the coming years thanks to the focused marketing strategy and continued new products/services offering. We model the top line growing from $0.20 million in 2013 to $28.5 million in 2018, an impressive CAGR of 170%. We model GeneNews will become profitable in 2017 with EPS of $0.05, which will grow to $0.16 per share in 2018.

- GeneNews has an appropriate growth strategy in place. Recent developments within the Company have made us believe this strategy will be well executed and we have a high confidence in management's ability to lead GeneNews to the next level of growth in the next five years.

- Based on the Company's strong fundamentals, we think its shares are undervalued. We think downside risk is low and upside potential is high at this point. We encourage investors to accumulate GeneNews shares at current level.

OVERVIEW

GeneNews Limited (GEN-TO, GNWSF-OTC) is a molecular diagnostics company focused on developing and commercializing proprietary blood-based diagnostic tests for early disease detection, determining the stage of disease and monitoring its progression, treatment or recurrence.
The Company has developed a powerful approach to identify unique RNA-based signatures from whole blood, the Sentinel Principle®, which has the ability to detect and stage virtually any disease or medical condition from a simple blood sample. The Sentinel Principle® is a platform technology which utilizes functional genomics to enable early diagnosis and personalized health management. Sentinel Principle is proprietary and protected by broad pioneering foundational patents. GeneNews has applied the Sentinel Principle in major areas with unmet clinical needs such as cancer, arthritis, cardiovascular disease and neurological disorders.

The Company’s current efforts are primarily focused on the commercialization of its lead product ColonSentry® and development of new products in collaboration with research and development partners.

ColonSentry is a blood test to determine an individual's current risk for colorectal cancer (CRC). ColonSentry is already available in the US, Canada, Malaysia and China. The Company is actively in discussions with potential partners to establish a global ColonSentry marketing and distribution network that will make this innovative product available to patients in Asia, Europe, and additional regions of the U.S. and Canada.

GeneNews Limited (formerly ChondroGene Limited) was formed in 1998 and the Sentinel Principle was originally developed by its founder Dr. C.C. Liew, an internationally recognized leader in the area of tissue-specific functional genomics.

Going forward, GeneNews plans to use its Sentinel Principle and Discovery Funnel to generate various biomarkers, which will enable development of a broad range of molecular diagnostic tests and related applications. These gene expression-based tests and the genomic information gained from the Company’s discovery pipeline will provide a continuing stream of novel information or "news" across a broad range of diseases and clinical questions.

The Company’s corporate headquarters and primary discovery research, product development and clinical laboratory facilities are located near Toronto in Richmond Hill, Canada. Research and development activities are also conducted in Penang, Malaysia, and in Shanghai, China, in collaboration with Shanghai Biochip.

The Company’s common shares are listed on the Toronto Stock Exchange (TSX) under the stock symbol "GEN". Its shares are also listed over-the-counter (OTC) in the US under the symbol “GNWSF”

**INVESTMENT THESIS**

**GeneNews Targets the Large Medical Diagnostics Market**

GeneNews is a medical testing service provider specifically focused on molecular/genetic (GM) testing. Recent advances in the genomic and proteomic research, combined with the complete sequencing of the human genome, have made sophisticated new scientific testing tools to diagnose and treat diseases possible, and therefore boosted the lab testing market dramatically.

Currently, the medical diagnostic/testing market consists of three primary segments:

- Clinical Pathology (CP) lab testing,
- Anatomic Pathology (AP) testing, and
- Genetic/Molecular Diagnostic (GM) testing

**CP testing** is typically engaged in high volume, highly automated, lower complexity tests on easily procured specimens such as blood and urine. Clinical lab tests often involve testing of a less urgent
nature such as cholesterol testing and testing associated with routine physical exams. CP testing yields relatively low average revenue per test.

**AP testing** involves the diagnosis of cancer and other medical conditions through the examination of tissues (biopsies) and the analysis of cells (cytology) taken from patients. Generally, the anatomic pathology process involves the preparation of slides by trained histo-technologists or cytologists and the review of those slides by anatomic pathologists. AP testing usually seeks to answer the question: is it cancer? The most widely performed AP procedures include the preparation and interpretation of pap smears, skin biopsies, and tissue biopsies. AP tests are typically more labor and technology intensive than CP lab tests and have higher average revenue per test than clinical lab tests.

**GM testing** typically involves analyzing chromosomes, genes or DNA/RNA sequences or expression profiles for abnormalities. The past decade has witnessed the rapid progress in this emerging market due to the tremendous advances made in genomics and proteomics research, as well as the completion of human genome project. New tests continue to be developed at an accelerated pace in recent years, thus this segment continues to expand rapidly. Genetic and molecular testing requires highly specialized equipment and credentialed individuals (typically MD or PhD level) to certify results and typically yields the highest reimbursement levels of the three market segments. GM testing represents one of the fastest growing segments of the clinical lab diagnostics market.

The clinical medical testing industry consists primarily of three types of providers: hospital-based laboratories, physician office laboratories and independent clinical laboratories. The total medical testing market is a multi-billion dollar business with estimated total revenue of about $57 billion in 2010 and hospital affiliated labs account for 50% of the market share.

GeneNews is an independent lab testing provider and it targets the GM segments with a current focus on cancer diagnostics. It is estimated that the genetic/molecular testing segment is growing 20% to 25% per year as new applications are developed and commercialized. The market for cancer testing is also growing rapidly due to the following key factors:

- Cancer is the leading cause of death in the US (it overtakes heart disease as number one killer in 2011), and one in 4 deaths in the United States is due to cancer. A total of 1,638,910 new cancer cases and 577,190 deaths from cancer are estimated to occur in the United States in 2012 according to American Cancer Society.

- Cancer is primarily a disease of the elderly and now that the baby boomer generation has started to turn sixty, the U.S. is experiencing a significant increase in the number of senior citizens. The American Cancer Society estimates that one in four senior citizens will develop some form of cancer during the rest of their lifetime;

- Every year more and more genes are implicated in development and/or clinical course of cancer. These associations fuel the development of new genetic or molecular tests.

The total cancer testing market is about $10 billion to $12 billion in the US, and grows very rapidly. This market is expected to grow at a healthy compound annual rate of 5.4% despite the present economic uncertainty, impending healthcare reform, and cost/reimbursement issues. GeneNews currently addresses approximately $2 billion of the colon cancer testing market.

**The Unique Sentinel Principle® Platform Technology**

The key asset of GeneNews is its Sentinel Principle® Platform Technology, a novel approach to identifying biomarkers of body state using blood. This unique blood biomarker approach has been modified and refined with time, but is based on the scientific observation that circulating blood reflects, in a detectable way, what is occurring throughout the body.
The Principle

The Sentinel Principle® technology is based on the concept that all clinical conditions and body states, including those resulting from disease or in response to treatment, generate characteristic gene expression signatures in the blood as a result of the constant and dynamic physiological interaction of blood with the cells, tissues and organs of the human body. This technology is the basis of GeneNews’ first product, ColonSentry® the world’s first blood test for colorectal cancer, and the SentinelGx™ suite of services for drug development.

According to the principle:

- As blood circulates communication occurs between cells in blood and tissue;
- Subtle changes that occur in cells due to injury or disease trigger detectable, specific changes in blood cell gene expression;
- Profiling these changes generates unique molecular signatures reflecting disease activity;
- These molecular signatures can be used to identify disease-specific blood biomarkers;

These biomarkers are the foundation for GeneNews' highly sensitive and specific molecular diagnostic assays which are currently under development.

One of the strengths of the Sentinel Principle is its flexibility. Applying it to different disease areas enables GeneNews’ scientists to generate specific combinations of biomarkers for numerous applications, indeed theoretically virtually any medical condition. This enables GeneNews to focus on the clinical questions and diseases with the greatest unmet need and largest commercial opportunities.

The Utilities

The Sentinel Principle has a broad range of applications. Below are the major usages:

- early diagnosis
- determining stage of disease
- identifying responders/non-responders to a specific therapy
- monitoring progression/recurrence of disease
- monitoring the effects of treatment
- monitoring treatment compliance

GeneNews has demonstrated the power of the method in over a dozen diseases and is developing molecular diagnostic tests to address specific clinical needs with a near term focus on cancer.

**The Process**

The process GeneNews uses to develop molecular diagnostics is called **Discovery Funnel™**, a genomics technology. Molecular signatures obtained from the blood RNA assessed by microarrays represent hundreds to thousands of genes. Using rigorous statistical analysis, GeneNews is able to generate from the complex microarray data a small set of clinically useful biomarkers, which can be used to develop specific molecular diagnostics, such as the Company’s ColonSentry.

The end result of the Discovery Funnel is that a broad molecular signature of disease is narrowed from thousands or hundreds of genes to a small panel of about half a dozen genes. GeneNews’ Sentry products are small panels designed to run on a platform ubiquitous in the clinical molecular diagnostics laboratory: real time (or kinetic) polymerase chain reaction (RT-PCR).
The Sentinel Principle applies advanced functional genomic microarray technology to identify molecular signatures that are applied to the Company’s proprietary Discovery Funnel. At the “bottom” of the funnel, practical biomarker sets are identified that may be used in the clinical laboratory. Using this approach GeneNews has shown that readily obtained blood samples may be used to test for biomarkers that diagnose the presence of disease in the body, for example, solid tumors. The Sentinel Principle enables blood based-molecular diagnostics for occult disease detection and represents an important advance to complement solid tissue-based diagnostic methods and for the detection of diseases for which there are not appropriate laboratory tests.

- Cancer diagnosis often requires an **invasive biopsy** to diagnose or stage disease. Biopsies can be painful and difficult and are invasive. Blood test represents an attractive alternative.
- Cancer diagnostics, such as **colonoscopy** for colon cancer screening can be **unpleasant** and as a result many people avoid them, delaying diagnosis and treatment. Blood samples can be obtained quickly and easily as part of the routine checkup or at any time and are highly likely to improve compliance.

**Target Diseases**

The Sentinel Platform targets many of the most critical and costly problems currently facing patients, providers and reimbursers of healthcare. GeneNews has identified **four major disease groups** where advanced diagnostics technology can make a fundamental difference.

**Cancer diagnostics** is a key area GeneNews is targeting. GeneNews' Sentry products will enable earlier and broader detection of cancer. For example, few adults undergo regular screening for colorectal cancer because traditional screening methods are generally inconvenient, uncomfortable and time-consuming. The development of convenient and accurate blood tests for cancer detection and to facilitate compliance with established screening practices would certainly have a positive impact on public health.

GeneNews is utilizing Sentinel Principle Technology to generate content for a new class of molecular oncology tests. Once developed, the Company's blood based biomarker diagnostics tests may replace or supplement current technology for conditions in which:

- early testing can lead to prevention or cure;
- current diagnostic and staging tests are painful, invasive and/or disliked by patients;
- current tests fail to provide information about patient prognosis or outlook;
- more patient-friendly tests will encourage more people to be tested;
- definitive diagnosis will lead to more appropriate choice of treatment;
- early stage identification will reduce suffering, morbidity and health care costs;

In addition to cancer, GeneNews has also applied its technologies to **cardiovascular disease**, **central nervous system** disease, and **arthritis**.

In short, GeneNews is developing and commercializing tests that generate actionable results for physicians to better manage their patients' illnesses.
ColonSentry®: World's First Blood Test To Determine Risk of Colon Cancer

ColonSentry® is GeneNews' first commercial product which is developed based on the Company's Sentinel Principle Technology.

ColonSentry is a sophisticated blood test that can assess a person's current risk of having colorectal cancer. The test is not considered a replacement for colonoscopy, but rather a more convenient step in detecting early warning signs of colon cancer.

ColonSentry does not require a patient to provide a stool sample, nor does it require any dietary restrictions like fasting or refraining from certain foods or medications prior to taking the test. The ColonSentry test is easy to perform and blood can be drawn at the same time as other blood tests with no advanced preparation.

The ColonSentry test measures the expression of seven genes which serve as biomarkers (biological indicators) to detect colorectal cancer risk. The science behind the ColonSentry test is based on the Sentinel Principle®, a breakthrough approach that identifies biomarkers for disease in circulating blood to detect what is occurring throughout a person's body.

The 7-gene biomarker panel was developed from the training set of 232 samples (112 CRC and 120 controls), and validated from the test set of 410 samples (202 CRC/208 controls). The Company analyzed 196 gene expression profiles from the above 642 samples to select candidate CRC biomarkers. Seven genes were selected for the development of CRC biomarker panel. Six of them (ANXA3, CLEC4D, LMNB1, PRRG4, TNFAIP6 and VNN1) were overexpressed (1.31- to 1.67-fold), and 1 (IL2RB) was under-expressed (0.84-fold) in CRC when compared with controls.
Panel performance characteristics and disease prevalence (0.7%) were then used to develop a scale assessing an individual's current relative risk (CURR) of having CRC based on his/her gene signature. Individual gene profiles were compared against the population results and used to calculate the current relative risk for CRC.

Bayes' theorem was used to calculate an individual's CURR, defined as the ratio of the probability of having CRC to the CRC prevalence, based on their blood-sample gene expression profile. At CURR=1, a subject has the same CRC risk as the unstratified average-risk population. At CURR=10, the subject has a 10-fold risk increase. Similarly, at CURR=0.1, the subject has a 10-fold risk decrease.

The performance of the predictive model on the training set had the following characteristics: 73% accuracy, 82% sensitivity, 64% specificity, 68% positive predictive value (PPV) and 79% negative predictive value (NPV). The performance of the predictive model on the test set had the following characteristics: 71% accuracy, 72% sensitivity, 70% specificity, 70% PPV and 73% NPV.

The differentiated expression of the 7 genes forms the basis of the ColonSentry test. The 7-gene panel can stratify subjects according to their current relative risk across a broad range in an average-risk population. Across the continuous spectrum of risk as defined by the current relative risk scale, it is possible to identify clinically meaningful reference points that can assist patients and physicians in CRC screening decision making.
Colorectal cancer is the number two cause of cancer death in men and women. Because this deadly disease shows no symptoms in its most curable stages, early detection can increase a patient's chances of survival.

The ColonSentry test applies to the following people who
- are 50 years of age or older
- have not had a colonoscopy or have been avoiding it
- do not want to handle stool or toilet water that is required for fecal tests like FOBT or FIT
- want to monitor their colorectal cancer risk between colonoscopies
- are elderly and at increased risk of complications from invasive procedures

**Huge Market for ColonSentry**

**The CRC Background**

According to National Cancer Institute (NCI), colorectal cancer (CRC) is the third most common malignant neoplasm and the second leading cause of cancer deaths (irrespective of gender) in the United States. It is estimated that there will be 142,820 new cases diagnosed in the United States in 2013 and 50,830 deaths due to this disease. About 5% of Americans are expected to develop the disease within their lifetimes.

Worldwide, CRC also ranks the third most common cancer according to Cancer Research UK. An estimated 1.24 million people worldwide were diagnosed with colorectal cancer in 2008, accounting for 10% of the total. CRC is the fourth most common cause of cancer death worldwide, estimated to be responsible for almost 610,000 deaths in 2008.

The risk of CRC begins to increase after the age of 40 years and rises sharply at ages 50 to 55 years. The risk doubles with each succeeding decade, and continues to rise exponentially. Despite advances in surgical techniques and adjuvant therapy, there has been only a modest improvement in survival for patients who present with advanced neoplasms. Hence, effective primary and secondary preventive approaches must be developed to reduce the morbidity and mortality from CRC.

CRC incidence and mortality rates have been declining for the past 2 decades in the US in both men and women, which is largely attributable to the contribution of screening to prevention and early detection.
However, there are still about 56% of people at high risk of CRC who don't get screened. And about 60% of CRCs are detected too late.

**CRC Screening**

Colorectal cancer (CRC) screening can detect cancer; polyps; nonpolypoid lesions, which are flat or slightly depressed areas of abnormal cell growth; and other conditions. Nonpolypoid lesions occur less often than polyps, but they can also develop into colorectal cancer.

If CRC screening reveals a problem, diagnosis and treatment can occur promptly. In addition, finding and removing polyps or other areas of abnormal cell growth may be one of the most effective ways to prevent CRC development. Also, CRC is generally more treatable when it is found early, before it has had a chance to spread.

Current recommended CRC screening tests are grouped into 2 categories:

- Tests that primarily detect cancer, which include both the guaiac-based fecal occult blood test (gFOBT) and fecal immunochemical test (FIT, also called immunochemical fecal occult blood test) and testing stool for exfoliated DNA;
- Tests that can detect cancer and advanced lesions, which include the *endoscopic examinations* and radiological examinations including flexible sigmoidoscopy (FSIG), colonoscopy, double-contrast barium enema (DCBE), and computed tomography colonography (CT colonography or virtual colonoscopy).

But the most often used CRC screenings are FOBT and colonoscopy. Both have advantages and disadvantages.

**Fecal Occult Blood Test (FOBT)**

**Advantages:**
- No cleansing of the colon is necessary;
- Samples can be collected at home;
- Cost is low compared with other colorectal cancer screening tests;
- Does not cause bleeding or tearing/perforation of the lining of the colon;

**Disadvantages:**
- Fails to detect most polyps and some cancers;
- False-positive results (the test suggests an abnormality when none is present) are possible;
- Dietary restrictions may be needed before the test;
- Additional procedures, such as colonoscopy, may be needed if FOBT indicates an abnormality;

**Colonoscopy**

**Advantages:**
- Allows the doctor to view the rectum and the entire colon;
- Doctor can perform a biopsy and remove polyps or other abnormal tissue during the test, if necessary;

**Disadvantages:**
- May not detect all small polyps, nonpolypoid lesions, and cancers, but is one of the most sensitive tests currently available;
- Thorough cleansing of the colon is necessary before this test;
- Some form of sedation is used in most cases;
- Although uncommon, complications such as bleeding and/or tearing/perforation of the lining of the colon can occur;
- 0.5% incidence of colonoscopy-associated morbidity;

**ColonSentry Advantages**
Colon Cancer is one of the most preventable and treatable forms of cancer when detected early. According to the American Cancer Society:

- The 5-year relative survival rate for people whose colorectal cancer is treated in an early stage is better than 90%
- The 5-year relative survival rate if cancer has spread to distant organs (i.e., the liver or lung) is less than 10%
- Only 40% of colorectal cancers are found in early treatable stages.

Therefore, early diagnosis and treatment is the key to improve CRC survival. Unfortunately, since traditional tests for colorectal cancer including FOBT and colonoscopy are often perceived to be inconvenient and uncomfortable, people avoid or delay being tested until symptoms appear which usually means the cancer is in its late stages.

CRC screening saves lives, but patient compliance with faecal testing and endoscopy remains low. Although colonoscopy is considered a CRC diagnostic “gold standard,” as a screening tool the technology has limitations. Many are averse to the procedure, and most healthcare systems have limited capacity. Even in the United States, colonoscopy capacity is insufficient to adequately screen the entire average-risk population. Furthermore, the 0.5% incidence of significant colonoscopy-associated morbidity is of concern given low CRC prevalence (0.7%) in the over 50, average-risk population.

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<th>Current Options and Barriers to Compliance</th>
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<td><strong>Fecal Tests</strong></td>
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<tr>
<td>- Handling of stool &amp; toilet water</td>
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<tr>
<td>- Most patients don’t want to do it!</td>
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<tr>
<td>- Dietary restrictions</td>
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<tr>
<td>- Repeat tests for reliable result &amp; three samples over 3 days (FOBT)</td>
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<tr>
<td>- Most physicians not satisfied with FOBT</td>
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<tr>
<td><strong>Colonoscopy</strong></td>
</tr>
<tr>
<td>- Gold Standard</td>
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<tr>
<td>- Invasive with bowel prep</td>
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<tr>
<td>- Often involves sedation</td>
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<tr>
<td>- &gt; 90% negative</td>
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<tr>
<td>- Risk of complications</td>
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<tr>
<td>- Limited capacity</td>
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</table>

GeneNews’ ColonSentry is a blood-based test which can provide clinically actionable CRC risk information. ColonSentry will likely enhance screening compliance and facilitate clinical decision making. The 7-gene ColonSentry test can be incorporated into CRC decision making in several ways.

- A blood-based ColonSentry test would benefit patients who desire information about their CRC status but refuse screening due to dislike of screening options. In particular, identification of increased current CRC risk may facilitate colonoscopy decision making for these patients, who would otherwise refuse colonoscopy.
- Second, in healthcare systems with limited colonoscopy capacity, blood-based ColonSentry could help prioritize patients at greatest current risk for CRC, similar to the proposed breast cancer...
stratification strategy. Combining ColonSentry testing in advance of colonoscopy can detect 2.1–4.7 times more cancers, when colonoscopy capacity is between 10% and 40%, which is the case in most countries.

- Furthermore, identifying patients with diminished current CRC risk with ColonSentry can help enhance physician and patient decision making. Provision of this type of novel, decreased-risk information can help facilitate subsequent screening decision making that is tailored to a patient’s individual circumstances. It can also help ensure that finite colonoscopy resources are directed to those with greatest risk.

In sum, the blood-based 7-gene biomarker test ColonSentry provides enriched information about an individual’s CURR for having CRC. As a blood test, it addresses one of the greatest challenges currently limiting CRC screening effectiveness: lack of compliance. Additionally, by identifying patients with enhanced CURR and with diminished CURR, ColonSentry can help healthcare providers assess need for increased monitoring or further workup, and help tailor the use of invasive and expensive procedures to those most likely to benefit.

A health economic analysis on ColonSentry demonstrated that screening with the ColonSentry test lowered the costs associated with CRC by increasing early-stage CRC detection and extending survival. From the private payer perspective, ColonSentry was dominant (produced better patient outcomes at lower costs) over no screening and FOBT. From the healthcare perspective, the ColonSentry test is cost-effective compared with the generally accepted oncology ICER benchmark. Screening is even more cost-effective for all perspectives when patients have the option of either FOBT or the ColonSentry test.

Although launched recently, ColonSentry is already moving patients toward colonoscopy compliance.

**The Market Potential**

The annual expenditure for colorectal cancer treatment in the US was conservatively estimated at $14 billion in 2010 by the National Institutes of Health (NIH) and that is estimated to increase to $17 billion by 2020. ColonSentry is targeting the huge CRC early screen market with $2 billion market opportunity.

*The US opportunity for ColonSentry*
Going Global, the Ultimate Marketing Strategy

GeneNews is a Canadian company, but it is working with its partners in other countries to make ColonSentry available to as many people as possible.

This marketing strategy has made ColonSentry® now available in Canada, USA, Malaysia and China.

The most important market is in the US for ColonSentry. On April 10, 2012, the Company announced the commercial launch of its lead product, ColonSentry®, by its first U.S. marketing partner, Enzo Clinical Labs (a division of Enzo Biochem, Inc.), into the New York and New Jersey region.

On July 2, 2013, GeneNews formed a joint venture with two private American companies, Health Diagnostic Laboratory and a sales organization with national capabilities, to establish an accredited clinical laboratory called Innovative Diagnostic Laboratory, LLP (IDL). IDL will initially focus on the development and broader US commercialization of ColonSentry and is expected to be functional and certified under the Clinical Lab Improvement Amendments Act (CLIA) in the third quarter.

GeneNews has granted IDL an exclusive license for certain technology related to the ColonSentry test for immediate development and commercialization throughout the United States, excluding NJ and NY. Each party to the JV will receive a share of the revenues and profits generated by IDL.

The launch of ColonSentry in the US and the establishment of IDL are important to GeneNews. It provides the Company with a US commercialization platform for the introduction of ColonSentry into the US market. Revenue growth will be accelerated in the coming quarters.

Currently, the Company's activities have been primarily focused on U.S. ColonSentry® commercialization initiatives that include the development of a reimbursement strategy, the planning and initiation of additional clinical studies, and evaluation of potential technology platforms to reduce costs for next generation ColonSentry® and pipeline products.

We believe reimbursement will prove to be challenging as the reimbursement environment in the U.S. remains in transition due to changes in coding methodology that became effective on January 1, 2013. Currently, the value assigned by the Centers for Medicare and Medicaid (CMS) to the new reimbursement codes that would be applicable to the ColonSentry® test has not been determined and is not expected to be published until January 2014. As such and while these changes in reimbursement, coding practice and payment processing further evolve, revenues to be earned from the sale of ColonSentry® in the U.S., generally, and more specifically in New York and New Jersey, are expected to
be constrained until these various issues reach resolution. However, revenue in the US will accelerate from 2014 onward when the progress in reimbursement will be made.

We are also encouraged by the positive response to the recent launch of ColonSentry® into New York and New Jersey by the Company’s first U.S. partner.

**China** is the second most important market for ColonSentry in our view.

In September 2012, GeneNews entered into a strategic alliance with Shanghai Biochip Co. Ltd. (SBC). Shanghai Biochip is a national engineering center for advanced microarray and gene expression profiling technologies in China that specializes in genetics, protein and other micro-organism detection with a dedicated clinical diagnostics institute that provides molecular examination services for early diagnosis and personalized treatment of certain diseases.

GeneNews and SBC will establish the first **Sentinel Centre for Personalized Medicine**, based in Shanghai, to co-develop and commercialize additional products based on GeneNews’ Sentinel Principle® Technology. For 2013, the Company has targeted the initiation of a program to develop a test to facilitate the early detection of lung cancer and expects to define the study protocol and commence sample accrual from multiple centers in China.

Under the terms of the agreement, SBC also obtains **non-exclusive rights to market and sell ColonSentry® test** in China.

With an annual GDP growth rate over 7.5% in the past 30 years, China has been one of the major pharmaceutical markets in the world. One of the focuses of Chinese government is to enhance and improve health standards for its 1.3 billion people population, particularly with respect to the prevention, early detection and personalized treatment of diseases such as cancer, diabetes and mental disorders.

The cooperation with SBC represents a significant milestone for the commercialization of ColonSentry, opens the door to the large Chinese market. Going forward, China will be a significant revenue source for GeneNews’ ColonSentry and other pipeline products based on the Sentinel technology.

The ColonSentry test is available **in Ontario and Quebec, Canada**. The ColonSentry test must be ordered by a doctor. It can be ordered on its own or in conjunction with other tests as part of a routine physical examination. Doctors may refer patients to a participating laboratory service provider where a blood sample can be drawn. Test results will be mailed to the doctor within 5-7 business days.

**Gamma-Dynacare** has the non-exclusive rights to market and sell ColonSentry® test in Canada.

ColonSentry is available **in Malaysia** through GeneNews Diagnostics, a private Malaysian incorporated company. GeneNews Diagnostics is the sole Malaysian provider of ColonSentry™. GeneNews Diagnostics has licensed the right to market ColonSentry from GeneNews Limited. GeneNews Diagnostics was incorporated in Malaysia on 14 July 2009 and was awarded BioNexus status by Malaysia Biotechnology Corporation (BiotechCorp) on 11 September 2009. BiotechCorp is an agency under the purview of Ministry of Science, Technology and Innovation of Malaysia.

**Strong Intellectual Property**

GeneNews’ patent portfolio presently encompasses 41 issued international patents, including 21 issued U.S. patents; issued patents in major European countries, Canada, China and other countries; and over 50 additional pending patent applications in a range of international jurisdictions.

These patents cover a broad range of applications which includes foundational patents in the U.S. and Canada. These patent applications cover general applications of GeneNews’ core Sentinel Principle® technology relating to blood-based gene expression profiling. The first of these foundational patents
issued in 2009, followed by additional issuances in 2010 and 2011. In 2012, the Company has been granted an additional six related U.S. patents. These foundational patents and applications are directed towards an innovative and novel concept that essentially any disease, condition or body state is characterized by distinct gene expression signatures in blood, due to its pervasive, ongoing and close physiological interaction with cells and tissues throughout the body.

In addition to the foundational patents, the Company's patent portfolio includes a broad range of disease-specific patent application families including colorectal cancer, schizophrenia, infectious disease, osteoarthritis, prostate cancer, diabetes, heart failure, Alzheimer's disease, melanoma, lung cancer, ovarian cancer, breast cancer and cervical cancer.

This strong IP position provides the Company with long term growth potential.

**VALUATION AND RECOMMENDATION**

We maintain our Outperform rating on GeneNews Limited. Our 12-month price target is $3.50 per share.

GeneNews is a commercial stage molecular diagnostics company with a current focus on cancer detection. GeneNews has developed a unique Sentinel Principle platform technology based on functional genomics. Based on this technology, the Company has recently launched its lead product ColonSentry for early screening of colorectal cancers (CRC) and SentinelGx services.

GeneNews holds 41 issued international patents and over 50 additional pending patent applications in a range of international jurisdictions. These patents cover a broad range of applications which includes foundational patents in the U.S. and Canada. This strong IP position provides the Company with long term growth potential.

We think revenue will accelerate in the coming years thanks to its focused marketing strategy and continued new products/services offering. Currently, ColonSentry is the main driver for revenue growth. We see total revenue growing at an impressive 170% compound annual growth rate (CAGR) from fiscal 2013 to 2018 according to our financial model. We model that the Company will become profitable in fiscal 2017 with earnings per share (EPS) of $0.05 based on total revenue of $19.00 million. We forecast EPS will grow to $0.16 per share based on revenue of $28.5 million in fiscal 2018. This is impressive considering the relatively short history of the operations and the small size of the Company.

Based on GeneNews' strong fundamentals, we think the Company is undervalued. Currently, GeneNews shares are trading at about $0.55 per share which values the Company at $19 million in terms of market cap based on 33.7 million shares outstanding. This is a deep discount compared to its peers in our view. Based on our financial model, revenue will grow at amazing 170% CAGR from 2013 to 2018. GeneNews will become profitable in 2017. We think GeneNews shares should trade at 45 x P/E multiple which is similar to the biotech industry average P/E ratio. This P/E is justified because GeneNews will experience a high growth in the next five years. If we use this P/E multiple, coupled with our estimated EPS of $0.16 in 2018, discounted at 20% for four years, we come up with a price target of $3.50 per share.

One wild card for GeneNews valuation is that the Company could be an acquisition target for big players. The clinical lab testing industry is quite fragmented currently, and merger & acquisition activity is looming. We have noticed that big players LabCorp and Quest Diagnostics are increasingly acquiring smaller players in this field. Qiagen NV, a research service company based in Netherland, entered into molecular diagnostics market in 2007 by acquiring Digene Corp. Since then, Qiagen has been quite aggressive in acquisition of other small genetic/molecular testing companies.

With the increased activity in M&A in the industry, GeneNews could be an easy target for acquisition. If acquired by big players, share price of GeneNews may soar.
We are optimistic about the Company's prospect. With a rapidly growing cancer testing market worldwide, combined with its unique technology and broad range of product offering, the Company is well positioned to boost its top line and bottom line in the coming years. We think at this time, downside risk for GeneNews is relatively low while upside potential is high.
## PROJECTED INCOME STATEMENT

<table>
<thead>
<tr>
<th>Cdn$ in millions except per share data</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Milestone</strong></td>
<td>$0.00</td>
<td>$0.00</td>
<td>$0.00</td>
<td>$0.00</td>
<td>$0.08</td>
<td>$0.01</td>
<td>$0.01</td>
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<tr>
<td><strong>Royalty</strong></td>
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<td>$0.05</td>
<td>$0.15</td>
<td>$0.06</td>
<td>$0.06</td>
<td>$0.01</td>
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<td><strong>CoGS</strong></td>
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<td>$0.00</td>
<td>$0.00</td>
<td>$0.00</td>
<td>$0.00</td>
<td>$0.00</td>
<td>$0.00</td>
</tr>
<tr>
<td><strong>Total Revenues</strong></td>
<td>$0.05</td>
<td>$0.01</td>
<td>$0.02</td>
<td>$0.12</td>
<td>$0.20</td>
<td>$1.75</td>
<td>$4.50</td>
</tr>
<tr>
<td><strong>Gross Income</strong></td>
<td>$0.05</td>
<td>$0.01</td>
<td>$0.02</td>
<td>$0.12</td>
<td>$0.20</td>
<td>$1.65</td>
<td>$4.25</td>
</tr>
<tr>
<td><strong>R&amp;D</strong></td>
<td>$0.45</td>
<td>$0.4</td>
<td>$0.6</td>
<td>$0.5</td>
<td>$1.9</td>
<td>$0.5</td>
<td>$0.5</td>
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<tr>
<td><strong>SG&amp;A</strong></td>
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<td>$0.7</td>
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<td>$0.5</td>
<td>$2.7</td>
<td>$0.89</td>
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<tr>
<td><strong>Others</strong></td>
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<td>$0.0</td>
<td>$0.0</td>
<td>$0.0</td>
<td>$0.0</td>
<td>$0.0</td>
</tr>
<tr>
<td><strong>Operating Income</strong></td>
<td>($1.1)</td>
<td>($1.1)</td>
<td>($1.2)</td>
<td>($0.9)</td>
<td>($4.4)</td>
<td>($1.3)</td>
<td>($1.7)</td>
</tr>
<tr>
<td><strong>Net Taxes (benefit)</strong></td>
<td>$0.0</td>
<td>$0.0</td>
<td>$0.0</td>
<td>$0.0</td>
<td>$0.0</td>
<td>$0.0</td>
<td>$0.0</td>
</tr>
<tr>
<td><strong>Reported Net Income</strong></td>
<td>($1.3)</td>
<td>($1.3)</td>
<td>($1.4)</td>
<td>($1.1)</td>
<td>($5.1)</td>
<td>($1.5)</td>
<td>($1.9)</td>
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<tr>
<td><strong>Reported EPS</strong></td>
<td>($0.08)</td>
<td>($0.07)</td>
<td>($0.07)</td>
<td>($0.06)</td>
<td>($0.27)</td>
<td>($0.05)</td>
<td>($0.05)</td>
</tr>
<tr>
<td><strong>Non GAAP Net Income</strong></td>
<td>($1.3)</td>
<td>($1.3)</td>
<td>($1.4)</td>
<td>($1.1)</td>
<td>($5.1)</td>
<td>($1.5)</td>
<td>($1.9)</td>
</tr>
<tr>
<td><strong>Non GAAP EPS</strong></td>
<td>($0.08)</td>
<td>($0.07)</td>
<td>($0.07)</td>
<td>($0.06)</td>
<td>($0.27)</td>
<td>($0.05)</td>
<td>($0.05)</td>
</tr>
</tbody>
</table>

**Source:** Company filing and Zacks estimates

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