Zacks Small-Cap Research

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GeneNews Limited

(GEN-TO, GNWSF-OTC)

GEN.TO: Revenue from IDL is ramping up quickly and expected to accelerate in 2014; new product added to offering menu, PT raised to $3.00--- Outperform.

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	05/30/2013
Current Price (03/04/13)	$0.94
Twelve- Month Target Price	**$3.00**

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

52-Week High	**$1.03**
52-Week Low	**$0.42**
One-Year Return (%)	**N/A**
Beta	**1.73**
Average Daily Volume (sh)	**16,706**
Shares Outstanding (mil)	**34.1**
Market Capitalization ($mil)	**$31**
Short Interest Ratio (days)	**3.50**
Institutional Ownership (%)	**39**
Insider Ownership (%)	**23**
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 2012 Estimate	**N/A**
P/E using 2013 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**N/A**
Type of Stock	**N/A**
Industry	**Med Instruments**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	0.05 A	0.01 A	0.04 A	0.04 A	0.13 A
2014	0.04 E	0.04 E	0.04 E	0.04 E	0.16 E
2015					1.67 E
2016					5.83 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.05 A	-$0.06 A	-$0.04 A	-$0.03 A	-$0.17 A
2014	-$0.03 E	-$0.03 E	-$0.03 E	-$0.03 E	-$0.11 E
2015					-$0.09 E
2016					-$0.03 E

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

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WHAT'S NEW

- **Revenue from IDL is ramping up quickly;**
- **New test added to its offering menu;**
- **Revenue growth will accelerate in 2014 and beyond;**
- **Maintain Outperform rating, raise price target to $3.00 from previous $2.00 per share;**

Revenue from IDL Is Ramping Quickly

On March 4, 2014, GeneNews Limited reported operational and financial results for the three-month and full-year periods ended December 31, 2013.

Revenues earned by IDL for 2013 were $0.3 million (US$0.3 million) with costs incurred of approximately $2.6 million (US$2.5 million), resulting in a start-up net loss of approximately $2.3 million (US$2.2 million). As GeneNews has joint control of IDL with its American partners, the Company accounts for its interest in IDL using the equity method. As such, GeneNews reflects its share of the total revenues less total expenses in its consolidated statements of loss and comprehensive loss, which was $0.7 million (US$0.7 million) for the year ended December 31, 2013.

Research and Development expenses were $1.7 million for the year 2013, compared to $1.9 million for the year 2012. Sales, General and Administrative expenses were $3.9 million for 2013, compared to $2.7 million for 2012.

Net loss for the year 2013 was approximately $9.4 million or $0.31 loss per common share, as compared to a net loss of approximately $5.1 million, or $0.28 loss per common share for the year 2012. The increased 2013 loss of $4.3 million was primarily due to costs associated with the Company's August strategic restructuring ($1.4 million), the Company's share of loss from IDL ($0.7 million) and non-cash costs associated with the Company's December debenture conversion ($1.1 million).

The Company's cash and cash equivalents at December 31, 2013 were approximately $3.0 million.

With the completed restructuring, the full rollout of ColonSentry and new test added, **we expect** revenue from IDL will accelerate in 2014 and beyond. Specifically, we estimate revenue from IDL will be $2.6 million, and reach 10 million in 2015. IDL will become profitable in 2015 with $5 million in profit and GeneNews' share of the profit will be approximately $1.67 million. Revenue from IDL will reach $75 million in 2018, which will provide approximately $20 million revenue for GeneNews.

The Restructuring Has Taken Effect

For 2013, the Company's key priority was to direct its efforts toward launching ColonSentry(R) broadly across the United States and establishing a reimbursement strategy to demonstrate the value and utility of ColonSentry to the public and commercial payers in the US. To support this focus, the Company restructured its operations mid-way through the year, enhancing its commercial capabilities and reducing its overall cost structure, primarily through a reduction in personnel and the closure of its laboratory operations in Richmond Hill.

Key achievements included the July 2013 creation of a joint venture with two private American companies, Health Diagnostic Laboratory, Inc. (HDL) and a specialized diagnostic sales organization with national capabilities in the diagnostic space, to establish an accredited clinical laboratory, Innovative Diagnostic Laboratory, LLP (IDL), the August 2013 restructuring of its laboratory operations, and the successful December 2013 debenture conversion.

IDL operates from a single facility in Richmond, Virginia, capable of servicing its entire territory. Start-up operations began during the third quarter of 2013, including set-up and validation of lab facilities, technology transfer, training of laboratory personnel, application for and receipt of CLIA and other regulatory licenses, development of marketing materials, sales planning and the development of a comprehensive ColonSentry(R) reimbursement strategy.

The restructuring implemented in 2013 has laid the foundation for a successful 2014. According to management, doctor and patient interest in the ColonSentry(R) test has been high. The company continues to work on a consistent reimbursement profile, and has made significant progress in building IDL's sales force and scaling-up to a full U.S. launch. In a January business update, GeneNews reported that full operation of the Richmond, Virginia lab facility has been established. We expect that ColonSentry(R) will be commercially available across the U.S. before the end of 1Q14.

Also, according to management, through IDL, sales of ColonSentry(R) have ramped up considerably in January. Therefore, we expect to see continued growth throughout the rest of 2014. As the R&D and new product development component of IDL, GeneNews is in discussions with several entities with respect to in-licensing their products. New test offerings for 2014, including EarlyCDT(R)-Lung and the planned addition of other tests to the menu during the first and second quarters of 2014, are expected to significantly enhance IDL's revenue generation capabilities.

IDL Adds Important New Test to Offering Menu

On Jan. 21, 2014, GeneNews announced the addition of EarlyCDT(R)-Lung - a simple blood test that aids physicians in risk assessment and the early detection of lung cancer in high-risk, asymptomatic patients -- to IDL's offering.

Representing the initial expansion of the IDL offering, GeneNews' joint venture partner, Health Diagnostic Laboratory, Inc., has granted IDL a license to distribute and perform the EarlyCDT(R)-Lung test in the United States.

Lung cancer is the second most common cancer in both men and women (not counting skin cancer) and is the leading cause of cancer-related death worldwide and in the United States. Lung cancer accounts for about 13% of all new cancers. The American Cancer Society estimates that there will be about 224,210 new cases of lung cancer, and 159,260 deaths from lung cancer in the US in 2014.

Normal cells often produce aberrant or mutated proteins (antigens) which the body identifies as 'self' and does not attempt to eliminate. Abnormal antigens produced by cancer cells will be recognized by the immune system as 'non-self' and elicit the production of antibodies against them ('autoantibodies'). Autoantibodies arise in the early stages of lung cancer development, as well as later stages, and are measureable in blood even when the tumor may be small and/or localized. An elevated level of autoantibodies beyond a pre-determined cutoff is indicative of disease (whereby EarlyCDT(R)-Lung test indicates increased risk of lung cancer), necessitating follow-up tests (e.g., spiral CT).

Like the ColonSentry(R) test, EarlyCDT(R)-Lung has the potential to lead to earlier cancer detection, improved patient outcomes and reduced healthcare costs.

We believe this is only the beginning of LDL expansion. As ColonSentry and EarlyCDT-Lung advance to their full rollout, more new tests will be added to its offering menu. IDL is working to assemble, through a combination of internal pipeline development, third-party licenses and potential acquisitions, a robust menu of advanced cancer assays to be offered by it throughout the United States.

Valuation Is Attractive

We maintain our Outperform rating on GeneNews Limited and **raise** our 12-month price target to $3.00 per share from previous $2.00 per share.

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 191% compound annual growth rate (CAGR) from fiscal 2013 to 2018 according to our financial model. We model that the Company will break even in fiscal 2017 based on total revenue of $15.5 million. We forecast EPS will grow to $0.10 per share based on revenue of $24.0 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 $0.90 per share which values the Company at $31 million in terms of market cap based on 34.1 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 173% CAGR from 2013 to 2018. We estimate GeneNews will become profitable in 2017, one year earlier than we previously estimated. We think GeneNews shares should trade at 25 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 $0.12 in 2018, discounted at 25% for four years, we come up with a price target of $3.00 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.

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.

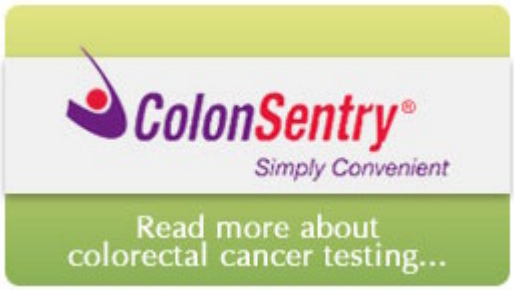
- Cancer is primarily a disease of the elderly and now that the baby boomer generation has started to turn sixty, the U.S. is experiencing a significant increase in the number of senior citizens. The American Cancer Society estimates that one in four senior citizens will develop some form of cancer during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

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.

Table 2. Colorectal cancer (CRC) biomarker gene list and differential expression in the training set (112 CRC and 120 controls)

Gene symbol[5]	Gene name	Sequence accession ID	Fold change[1]	Fold change *p* value[2]	Expression ratio[3]	Expression ratio *p* value[2]	Expression ratio AUC[4]
ANXA3	Annexin A3	NM_005139	1.67	<0.001	1.71	<0.001	0.71
CLEC4D	C-type lectin domain family 4, member D	NM_080387	1.39	0.002	1.50	<0.001	0.66
IL2RB	Interleukin 2 receptor, beta	NM_000878	0.84	0.01	–	–	–
LMNB1	Lamin B1	NM_005573	1.31	<0.001	1.37	<0.001	0.68
PRRG4	Proline rich Gla (G-carboxyglutamic acid) 4 (transmembrane)	NM_024081	1.58	<0.001	1.72	<0.001	0.76
TNFAIP6	Tumor necrosis factor, alpha-induced protein 6	NM_007115	1.50	<0.001	1.58	<0.001	0.66
VNN1	Vanin 1	NM_004666	1.48	<0.001	1.53	<0.001	0.67

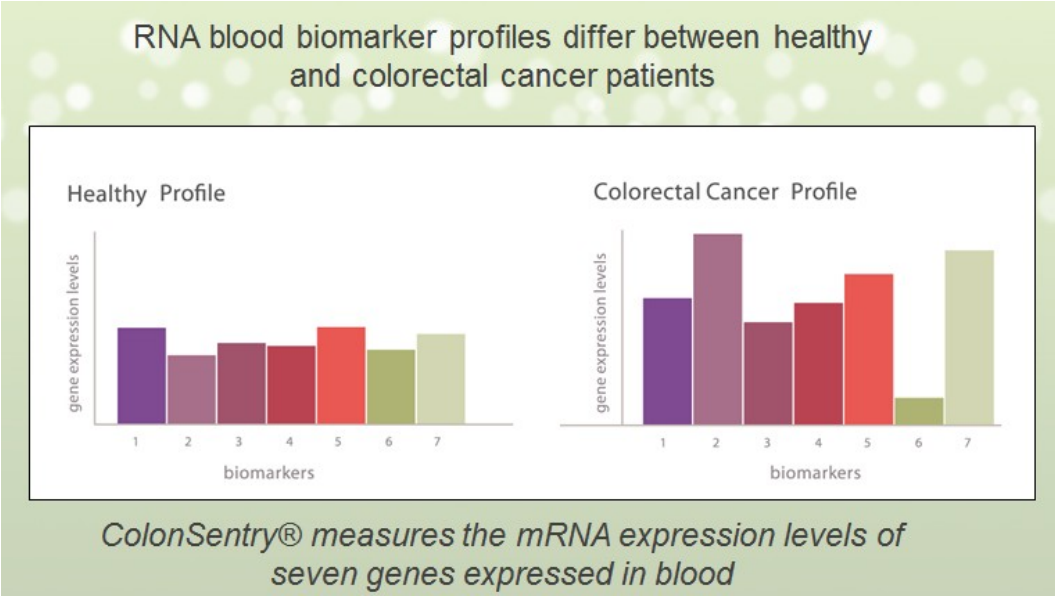
[1]Determined by qRT-PCR analysis using ACTB (reference) gene as denominator. [2]Calculated by Mann–Whitney test. [3]Determined by qRT-PCR analysis using IL2RB (underexpressed) gene as denominator. [4]Area under receiver-operating-characteristic curve. [5]Biomarker candidates were screened by microarray (5 μg of total blood RNA extracted from blood collected into EDTA tubes was hybridized to U133Plus2.0 GeneChip, Affymetrix).

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;

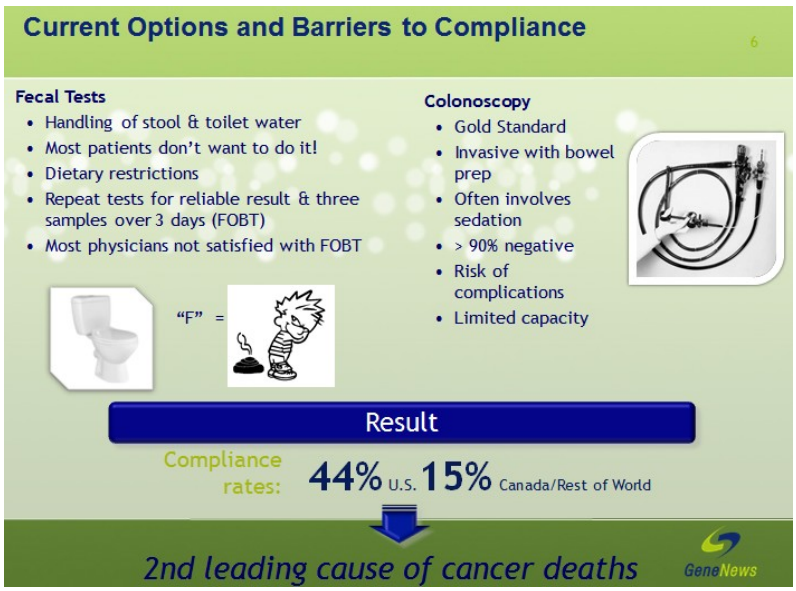
ColonSentry Advantages

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.

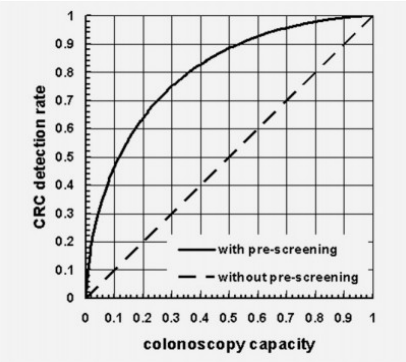


GeneNews' **ColonSentry** is a blood-based test which can provide clinically actionable CRC risk information. ColonSentry will likely enhance screening compliance and facilitate clinical decision making. The 7-gene ColonSentry test can be incorporated into CRC decision making in several ways.

- 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.

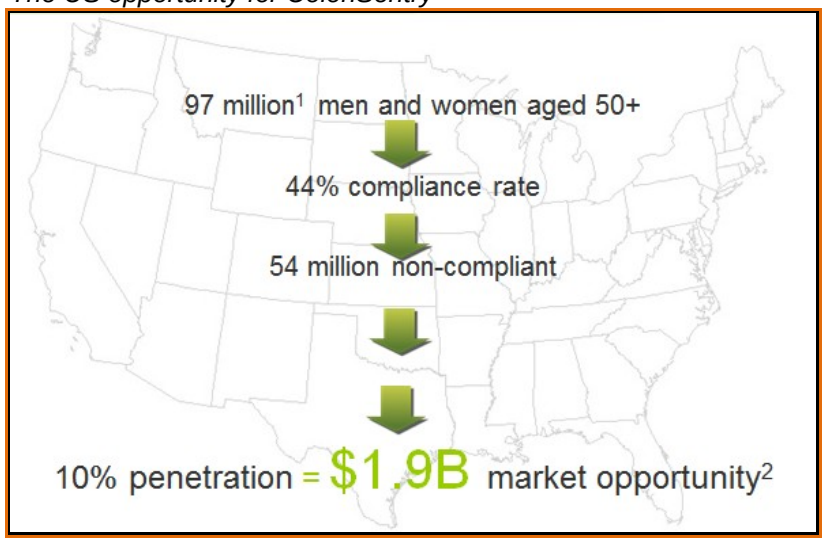
A health economic analysis on ColonSentry demonstrated that screening with the ColonSentry test lowered the costs associated with CRC by increasing early-stage CRC detection and extending survival. From the private payer perspective, ColonSentry was dominant (produced better patient outcomes at lower 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



PROJECTED INCOME STATEMENT

	2013					2014					2015	2016	2017	2018
Cdn$ in millions except per share data	Q1	Q2	Q3	Q4	FY	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE	FYE
Milestone	$0.00	$0.00	$0.04	$0.04	$0.07	$0.04	$0.04	$0.04	$0.04	$0.16	$0.00	$0.00	$0.00	$0.00
Royalty	$0.05	$0.01	$0.00	$0.00	$0.05	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
YOY Growth	-	*-85.6%*	*-100.0%*	*-100.0%*	*-79.3%*	*-100.0%*	*-100.0%*	*#DIV/0!*	*#DIV/0!*	*-100.0%*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*
LDL revenue (loss)	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$1.67	$5.83	$13.33	$20.00
YOY Growth	*-85.9%*	*-43.0%*	*-72.7%*	*-100.0%*	*-71.0%*	*-100.0%*	*-100.0%*	*-100.0%*	*#DIV/0!*	*-100.0%*	*#DIV/0!*	*250.0%*	*128.6%*	*50.0%*
Total Revenues	**$0.05**	**$0.01**	**$0.04**	**$0.04**	**$0.13**	**$0.04**	**$0.04**	**$0.04**	**$0.04**	**$0.16**	**$1.67**	**$5.83**	**$13.33**	**$20.00**
YOY Growth	*646.5%*	*-82.2%*	*-76.5%*	*-38.4%*	*-52.8%*	*-17.3%*	*299.2%*	*8.1%*	*8.9%*	*21.1%*	*941.7%*	*250.0%*	*128.6%*	*50.0%*
CoGS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Income	**$0.05**	**$0.01**	**$0.04**	**$0.04**	**$0.13**	**$0.04**	**$0.04**	**$0.04**	**$0.04**	**$0.16**	**$1.67**	**$5.83**	**$13.33**	**$20.00**
Gross Margin	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*
R&D	$0.50	$0.6	$0.5	$0.1	$1.7	$0.1	$0.1	$0.1	$0.1	$0.2	$0.5	$0.8	$1.0	$1.5
% R&D	*1039.9%*	*5715.7%*	*1326.2%*	*290.4%*	*1266.2%*	*125.0%*	*125.0%*	*125.0%*	*125.0%*	*125.0%*	*30.0%*	*12.9%*	*7.5%*	*7.5%*
SG&A	$0.89	$1.2	$1.0	$0.9	$3.9	$0.9	$0.9	$1.0	$1.1	$3.9	$4.5	$6.0	$7.5	$10.0
% SG&A	*1830.9%*	*11544.3%*	*2711.0%*	*2455.2%*	*2987.7%*	*2250.0%*	*2250.0%*	*2500.0%*	*2750.0%*	*2437.5%*	*270.0%*	*102.9%*	*56.3%*	*50.0%*
Others	$0.0	$0.0	$0.0	$4.0	$4.0	($0.1)	($0.1)	($0.1)	($0.1)	($0.3)	$0.0	$0.0	$0.0	$0.0
% Other	*0.0%*	*0.0%*	*-5162.4%*	*10796.9%*	*3002.9%*	*-125.0%*	*-208.3%*	*-208.3%*	*-208.3%*	*-187.5%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Operating Income	**($1.3)**	**($1.7)**	**($1.5)**	**($4.9)**	**($9.5)**	**($0.9)**	**($0.8)**	**($0.9)**	**($1.0)**	**($3.6)**	**($3.3)**	**($0.9)**	**$4.8**	**$8.5**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	*42.5%*
Other Income (Net)	($0.2)	($0.2)	($1.9)	$2.3	$0.0	($0.2)	($0.2)	($0.2)	($0.2)	($0.8)	($0.8)	($0.8)	($0.8)	($0.8)
Pre-Tax Income	**($1.5)**	**($1.9)**	**($3.4)**	**($2.6)**	**($9.4)**	**($1.1)**	**($1.0)**	**($1.1)**	**($1.2)**	**($4.4)**	**($4.1)**	**($1.7)**	**$4.0**	**$7.7**
Net Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($1.5)**	**($1.9)**	**($3.4)**	**($2.6)**	**($9.4)**	**($1.1)**	**($1.0)**	**($1.1)**	**($1.2)**	**($4.4)**	**($4.1)**	**($1.7)**	**$4.0**	**$7.7**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Weighted avg. Shares Out	*33.7*	*33.7*	*33.7*	*35.2*	*34.1*	*35.4*	*35.6*	*45.0*	*45.0*	*40.3*	*48.0*	*55.0*	*60.00*	*65.00*
Reported EPS	**($0.05)**	**($0.06)**	**($0.10)**	**($0.07)**	**($0.28)**	**($0.03)**	**($0.03)**	**($0.03)**	**($0.03)**	**($0.11)**	**($0.09)**	**($0.03)**	**$0.07**	**$0.12**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	$0.00	$0.00	$1.91	$1.63	$3.54	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Non GAAP Net Income	**($1.5)**	**($1.9)**	**($1.5)**	**($1.0)**	**($5.9)**	**($1.1)**	**($1.0)**	**($1.1)**	**($1.2)**	**($4.4)**	**($4.1)**	**($1.7)**	**$4.0**	**$7.7**
Non GAAP EPS	**($0.05)**	**($0.06)**	**($0.04)**	**($0.03)**	**($0.17)**	**($0.03)**	**($0.03)**	**($0.03)**	**($0.03)**	**($0.11)**	**($0.09)**	**($0.03)**	**$0.07**	**$0.12**

LDL revenue	$0.30	$0.35	$0.50	$0.75	$1.00	$2.60	$10.00	$25.00	$50.00	$75.00
LDL expense	$2.60	$0.50	$0.75	$1.00	$1.25	$3.50	$5.00	$7.50	$10.00	$15.00
LDL profit (loss)	($2.30)	($0.15)	($0.25)	($0.25)	($0.25)	($0.90)	$5.00	$17.50	$40.00	$60.00
GeneNews Share	($0.77)	($0.05)	($0.08)	($0.08)	($0.08)	($0.30)	$1.67	$5.83	$13.33	$20.00

Source: Company filing and Zacks estimates

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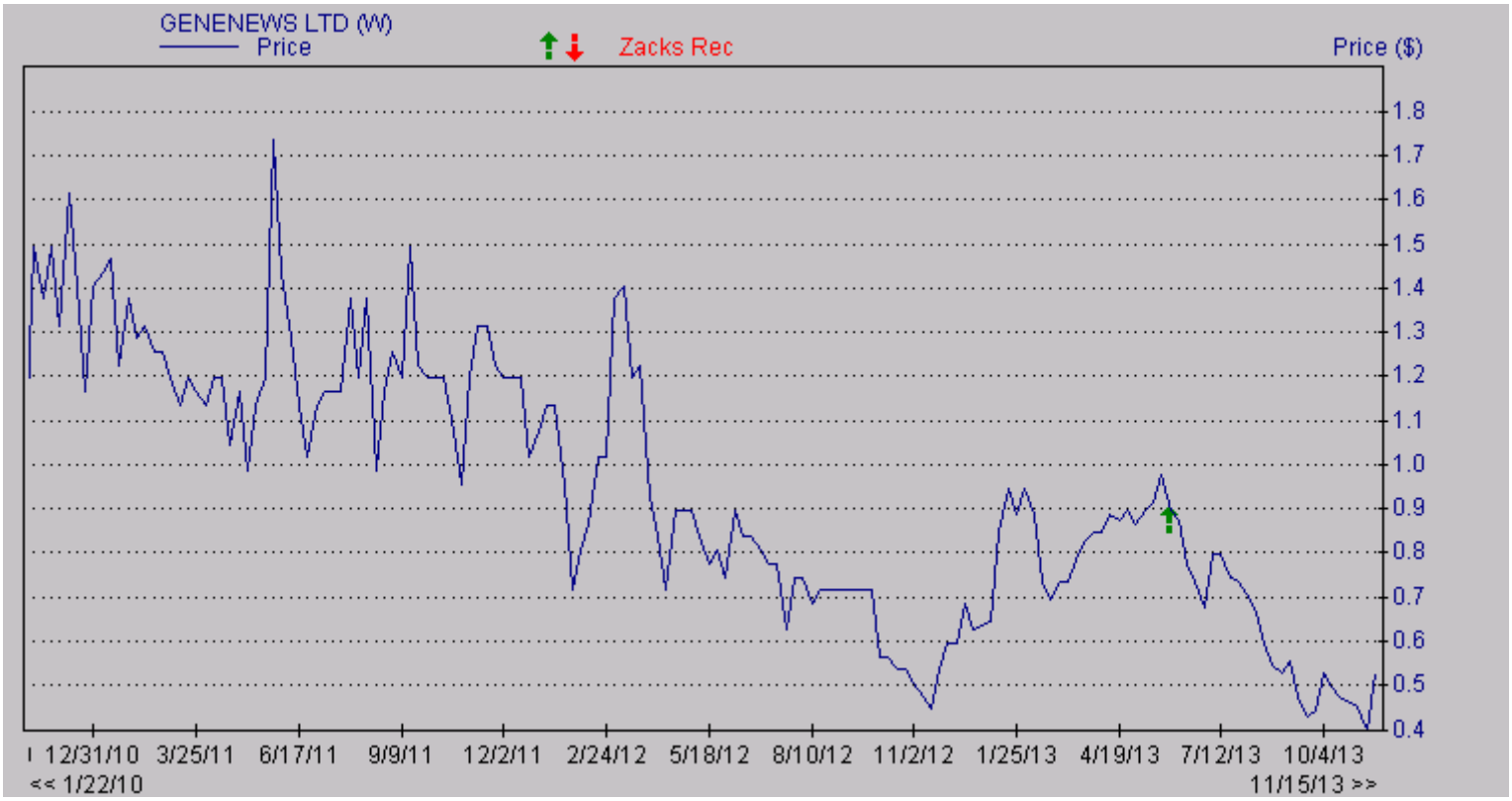

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