June 7, 2011

Zacks Small-Cap Research

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Transgenomic Inc. (TBIO-OTC)

TBIO: Initiating Coverage at Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	01/12/2011
Current Price (06/07/2011)	$1.63
Target Price	**$4.00**

OUTLOOK

Near-term growth comes from a December 2010 acquisition which bolts on about $13MM in revenue and is already providing synergies.

Long-term growth will come from TBIO's transition away from instruments and into the high-growth market of companion diagnostics. The company is just in the infancy of this transformation and early indications already suggest their novel, ultra-sensitive testing technology is garnering significant interest from pharma companies.

TBIO is sufficiently capitalized and could continue to generate positive cash flow for the foreseeable future.

We are initiating on TBIO with an Outperform rating and $4.00 price target.

SUMMARY DATA

52-Week High	**$1.71**
52-Week Low	**$0.30**
One-Year Return (%)	**189.47**
Beta	**2.05**
Average Daily Volume (sh)	**72,448**
Shares Outstanding (mil)	**49**
Market Capitalization ($mil)	**$81**
Short Interest Ratio (days)	**0.22**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**2**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-2.5**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2011 Estimate	**N/A**
P/E using 2012 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med Instruments**

ZACKS ESTIMATES

Revenue
(in '000 of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	5,442 A	5,095 A	4,419 A	5,092 A	20,048 A
2011	7,480 A	8,947 E	8,894 E	9,265 E	34,586 E
2012					38,744 E
2013					46,319 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$0.01 A	-$0.02 A	-$0.02 A	-$0.02 A	-$0.06 A
2011	-$0.06 E	-$0.03 E	-$0.03 E	-$0.03 E	-$0.15 E
2012					-$0.11 E
2013					-$0.00 E

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

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INVESTMENT THESIS

- Transgenomic is on the front-end of transitioning away from mostly an instrument supplier to a companion diagnostics company.

- Near-term revenue growth will be mostly driven by the late-2010 acquisition of Clinical Data's genetics business, which included the FAMILION line of genetics tests and another CLIA-certified lab. Transgenomic has already begun to wring out synergies from the acquisition and managed to eke out positive cash flow in Q1 2011.

- Longer-term growth will be fueled by the company's companion diagnostics business. Recent interest in companion diagnostics has surged, with most of the activity focused in the area of oncology. This has resulted in increased demand from cancer drug manufacturers for more sensitive, lower cost genetic testing technologies.

- Transgenomic is beginning to capitalize on this through the recent introduction their novel, ultra-high sensitivity genetic testing technology. Ice COLD-PCR affords the earlier detection of mutations, is compatible with the industry standard Sanger sequencing equipment, allows for use of less-invasive samples types such as blood and urine (versus requiring sampling directly from the tumor itself) and affords multiple mutant detections with a single test. The compilation of these benefits also means Ice COLD-PCR may be a significantly lower cost alternative to competing testing technologies.

- Transgenomic has indicated over the past few months that they have received significant interest in their testing technology from drug manufacturers including a "major oncology pharmaceutical partner". Growing interest in Ice COLD-PCR should significantly ramp Transgenomic's revenue over the next few years.

- The acquired FAMILION tests have insurance coverage spanning 280 million covered. Transgenomic should have an opportunity to leverage this coverage base which could be key in growing their clinical lab business, especially as they convert some of the Ice COLD-PCR based tests from the research-lab into specific assays.

- The recent acquisition also brought with it two biomarker assays; an Fc gamma receptor oncology test and a test to determine whether an individual is suited for treatment with Plavix. Both of which could provide additional opportunity to accelerate revenue growth over the long-term.

- We model revenue of $34.6MM in 2011. This implies growth of 73%, which is mostly a result of inclusion of the acquired FAMILION tests. And while this is on the low end of management's $34MM - $38MM guidance, we think Transgenomic could continue to generate positive cash flow and do not anticipate a need for additional financing in the near-term.

- We look for revenue to grow to $55.4MMin 2014. This, again, could be conservative and will likely depend on the adoption rate of Ice COLD-PCR.

- Based on comp valuations, TBIO trades at a discount to fair value. We value the company at $4.00/share and are initiating coverage of the company with an Outperform rating.

BUSINESS

Transgenomic, Inc. (Transgenomic) provides high-sensitivity genetic variation analysis instrumentation, consumables and services related to the diagnosis of cancer, Mitochondrial and hematological disorders, and cardiovascular and inherited diseases. Transgenomic greatly expanded its laboratory services offerings through the December 2010 acquisition of Clinical Data's genetics businesses, which included the FAMILION line of genetic tests. The acquisition bolts-on approximately $13 million in additional revenue, brings another CLIA-certified lab, and is already offering synergies and the opportunity to trim redundant expenses. The company is also focused on growing organically and just recently began offering Ice COLD-PCR, a novel ultra-high sensitivity testing technology through its pharmacogenomics business. If all goes well, Transgenomic will develop and commercialize assay kits using this technology which could provide a significant boost to revenue in the coming years.

Customers include hospitals, medical clinics, clinical labs, pharmaceutical / biotech companies and academic institutions. International sales (largely in Europe) accounted for 56% of revenue in 2010. Headquartered in Omaha, Nebraska, Transgenomic also maintains facilities in California, Scotland and Connecticut. As of December 31, 2011 the company had 162 employees.

PRODUCTS / SERVICES

Transgenomic reports revenue from two general business lines; Instrument Related Businesses and Laboratory Services. **Instrument Related Businesses** includes revenue from sales of proprietary and OEM molecular diagnostic instruments and related consumables. **Laboratory Services** includes clinical lab testing at Transgenomic's CLIA-certified lab for oncology, cardiology, hematology and inherited disorders. It also includes the company's pharmacogenomics research business which provides services such as biomarker development for pharmaceutical and biotech companies.

Laboratory Services accounted for 25% of total revenue (Instrument Related Business the other 75%) in 2010 but we expect this to grow to about 60% in 2011 as a result of the December 2010 acquisition and a continued slide in instrument sales. 2011 will mark the front-end of Transgenomic's shift from mostly an instruments related business to, ultimately, a companion diagnostics company. Going forward, this transformation will be in large part driven by growth in Transgenomic's oncology diagnostics capabilities as a result of the recent introduction of, and demand for, their COLD-PCR/Ice COLD-PCR technology. The pharmacogenomics lab business should be the initial beneficiary as a result of increasing interest in this technology from pharmas and biotechs which have been greatly expanding their cancer research efforts. The clinical lab and consumables segments should be secondary beneficiaries as Transgenomic converts some of the COLD-PCR/Ice COLD-PCR based tests from the research-lab into specific assays and companion diagnostics.

LABORATORY SERVICES

The **Clinical Laboratories** portion of Laboratory Services relates to tests performed in Transgenomic's CLIA labs on patient specimens from tests ordered by their doctors. Insurance reimbursement is generally available for these tests and the acquired FAMILION tests have insurance coverage spanning 280 million covered lives. Transgenomic's Clinical Labs business was greatly expanded with the purchase of PGxHealth's (a subsidiary of Clinical Data) FAMILION cardiology genetic tests in late 2010. Revenue related to these tests was approximately $13 million in revenue in 2009, compared to $3.5 million (16% of total revenue) for Transgenomic's legacy molecular lab business.

The FAMILION product line includes 11 genetic tests for the detections of mutations than can cause cardiac channelopathies and cardiomyopathies - rare but potentially deadly heart conditions. Channelopathies are diseases caused by defects in cell proteins and can result from a mutation in the encoding genes. FAMILION

channelopathy tests include long QT syndrome (LQTS), Catecholaminergic polymorphic ventricular tachycardia (CPVT) and Brugada syndrome (BrS). Cardiomyopathy, is defined as deterioration of the function of the heart muscle. People suffering from the disease are often at risk of suffering sudden cardiac death. The FAMILION cardiomyopathy tests include hypertrophic cardiomyopathy (HCM), arrhythmogenic right ventricular cardiomyopathy (ARVC) and dilated cardiomyopathy (DCM).

The FAMILION tests meet guidelines established by the ACC/AHA/ESC (American College of Cardiology/American Heart Assocaition/European Society of Cardiology) which recommends genetic testing for inherited cardiac diseases in order to help prevent sudden cardiac death.

The $15.4 million acquisition, which closed on December 29, 2010, also included a CLIA lab located in New Haven, CT and pipeline genetic tests. The acquired pipeline includes a test to determine whether cardiac patients will respond favorably to treatment with clopidogrel (Plavix - the second largest selling drug worldwide) and an Fc gamma receptor test to determine whether patients will respond to certain cancer drugs.

Outside of the FAMILION family of tests, Transgenomic's clinical lab services tests include those for mitochondrial disease, inherited disorders and oncology.

Clinical Data's Genetics Business Acquisition

- **$15.4 million acquisition price**
  - Paid with $6MM cash, an $8.6MM 3-year 10% note and $1.0MM 1-year 6.5% note to Clinical Data
  - $6MM cash portion financed with sale of 2,586,205 shares of newly created Series A convertible preferred stock to Third Security - attached were warrants allowing purchase of 1,293,102 shares of the Series A preferred stock at $2.32 / share
  - Clinical Data will also receive milestones and royalties upon development and commercialization of new products

- **Acquired assets include:**
  - 11 currently commercialized proprietary genetic tests for cardiac channelopathies and cardiomyopathy and related intellectual property
  - A fully-staffed CLIA lab in New Haven, CT
  - Contracts with public (Medicare/Medicaid) and private insurers (including BCBSA, United, Aetna, Cigna, Humana) with access to 280MM covered lives
  - Pipeline tests including Fc gamma receptor oncology test and metabolism genetic test for clopidogrel (Plavix)
  - Marketing team

- **Acquired assets generated:**
  - Approximately $13MM in revenue ($7.5MM net loss) in 12 months ending March 31, 2010, an increase of 25% from the same period in 2009.
  - Gross margin was 57% through 3/31/10 which compares favorably to TBIO's GM of 49% in FY 2010
  - TBIO management expects the acquisition to be accretive very quickly. Cost synergies are expected to be found in sales/marketing, facilities and related personnel, and administration. Leveraging insurance reimbursement contracts offers opportunity for revenue synergies

The **Pharmacogenomics Services** business provides services such as biomarker development and clinical trial support to pharmaceutical and biotech companies. Genetics can be a significant determinant of tumor response to certain cancer drugs - a major focus for Transgenomic is aiding drug companies in the validation and detection of new genetic markers to increase the predictive value of genetics in response to these oncology drugs.

Transgenomic's research services includes the use of their WAVE instrumentation for mutation detection, biomarker development, design of custom assays and testing for pre-clinical and clinical trials. Revenue from pharmacogenomics research increased 34% in 2010 to $1.4 million (7% of total revenue), from $1.0 million (5% of total revenue) in 2009. The business is characterized by somewhat choppy revenue as it relies on project-based work which can be highly variable from period to period.

Transgenomic expects the recent addition of COLD-PCR/Ice COLD-PCR to benefit demand for its pharmacogenomics services, especially as a result of life science companies expanding their research and development on high potential cancer markers and companion diagnostics to include analysis of non-invasive patient samples such as serum and plasma.

INSTRUMENT RELATED BUSINESSES

The **WAVE System** comprises Transgenomic's line of proprietary instruments. The WAVE instruments are used for detection of genetic variation and are largely used for genetic research and molecular diagnostics purposes. Running proprietary Navigator Software, which provides assay design capabilities, users of the WAVE instruments can compare data from several projects and hundreds of samples against each other, allowing for user-friendly comparison of wild type (i.e. - normal) and mutant genes. Deliverable capabilities include comprehensive report generation in table as well as three dimensional scatter graph format.

Transgenomic also acts as a distributor for HANABI Metaphase Chromosome Harvesters and Spreaders (OEM instruments) which are manufactured by ADSTEC Corporation. The instruments are largely used by cytogenetic labs and are designed for automation and high throughput.

The WAVE System installed base through the end of 2010 was approximately 1,500 units in over 50 countries. Transgenomic sells new as well as refurbished WAVE Systems and also offers service contracts and parts for both the proprietary and OEM equipment. Instrument sales were $8.3 million in 2010 (42% of total revenue), down 18% from 2009 ($10.2 million, 46% of total revenue). Transgenomic sold 25 WAVE and 10 OEM instruments during 2010, compared to 32 and 11, respectively, for 2009. The company has noted that demand for the WAVE Systems has been impacted by competitive and novel technologies.

WAVE System 4500



TRANSGENOMIC INC.

Transgenomic also manufactures and sells **consumables** used in these instruments including buffers and mutation detection kits. Transgenomic's proprietary SURVEYOR Scan Mutation Detection Kits are used for detection of DNA mutations with applications in oncology. The SURVEYOR kits are compatible with the WAVE System as well as other platforms. Transgenomic launched SURVEYOR kits for the analysis of the BRAF and PIK3CA genes in April 2011. A K-RAS gene kit was launched in late 2009 in the U.S. and is also available as a CE IVD version in Europe. Mutations of these three genes (K-RAS, BRAF and PIK3CA) have shown to be a strong predictor of resistance to epidermal growth factor receptor (EGFR) inhibitors. EGFR inhibitors are a widely used class of cancer drugs but have been shown to be ineffective in lung and colon cancer patients expressing certain gene mutations.

Transgenomic also hopes to launch a kit for the TP53 gene (another cancer drug resistance marker) and introduce the BRAF and PIK3CA kits to the European market. Transgenomic continues to forge ahead with progress on development EGFR markers and on May 26, 2011 announced that they had acquired an exclusive worldwide license from Montefiore Medical Center's (Bronx, NY) patent application for "Method of Determining the Sensitivity of Cancer Cells to EGFR Inhibitors including cetuximab (Erbitux), panitumumab (Vectibix) and erlotinib (Tarciva)". The invention relates to the discovery by Montefiore scientists and collaborators that tumor-specific mutations in the genes PIK3CA and PTEN can aid in predicting patient non-response to EGFR inhibitors.

Mutation of the K-RAS gene has been predictive of a very poor response to Vectibix and Erbitux in colon cancer. Roughly 40% of colon cancers are believed to have this mutation which has prompted the FDA to require testing for the mutation prior to treatment. Frequency of BRAF gene mutations are estimated to be about 80% in melanomas, 3% in lung cancers and 5% in colon cancer. While the American Society of Clinical Oncology has recommended that colorectal cancer patients who are candidates for anti-EGFR therapy receive testing for mutations in the K-RAS gene, no recommendation currently exists for the PIK3CA and PTEN genes. This is despite studies (from Montefiore Medical Center and elsewhere) which demonstrated that mutations in PIK3CA and PTEN can also cause anti-EGFR therapies to be ineffective. As such, a test that could detect mutations in all three of these genes (PIK3CA, PTEN, K-RAS) could have significant utility.

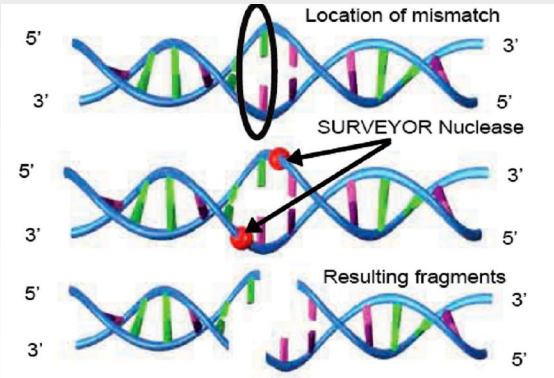
The SURVEYOR Scan kits were built on Transgenomic's proprietary SURVEYOR nuclease technology that utilizes an endonuclease (in this case specialized enzymes that cut the DNA specifically at the site of mutations) that can identify both the presence and location of a mutation. The kits are designed to allow analysis of standard research and diagnostic lab DNA isolates that are prepared by the use of a method known as the polymerase chain reaction (PCR) that greatly amplifies the very low quantities of DNA found in clinical samples. The SURVEYOR nuclease technology affords Transgenomic's kits very high sensitivity and specificity with a user-friendly format and can be used on a variety of instrument platforms. Transgenomic's kit technology enables identification of all mutations (known and unknown mutations) in a particular sample - this is important as new biologically relevant mutations are still being discovered and competitorsômutation specific assays will fail to detect novel variants. Transgenomic is currently developing a next-generation line of kits that is expected to offer even higher sensitivity through the use of recently in-licensed COLD-PCR and Ice COLD-PCR technology.

Consumables revenue was $6.8 million (34% of total revenue) in 2010, a decrease of 7% from 2009 ($7.3 million, 33% of total revenue).

A Quick Primer On PCR

PCR uses thermal cycling (repeated heating and cooling) of the DNA fragments to execute amplification. Denaturing (or "DNA melting") is the initial step in thermal cycling whereby high temperatures are used to break the hydrogen bonds between double-stranded DNA strands and separates them into single-stranded DNA. The temperature is then lowered to a temperature that allows short, artificial DNA molecules, known as primers, to bind to the melted DNA strands (this is called "annealing"). The final step uses an enzyme that recognizes the primer-melted DNA complex and copies the DNA. The whole procedure repeats itself many times. As PCR progresses, the copied DNA molecules are themselves copied, doubling the yield with each cycle; this is known as exponential replication.

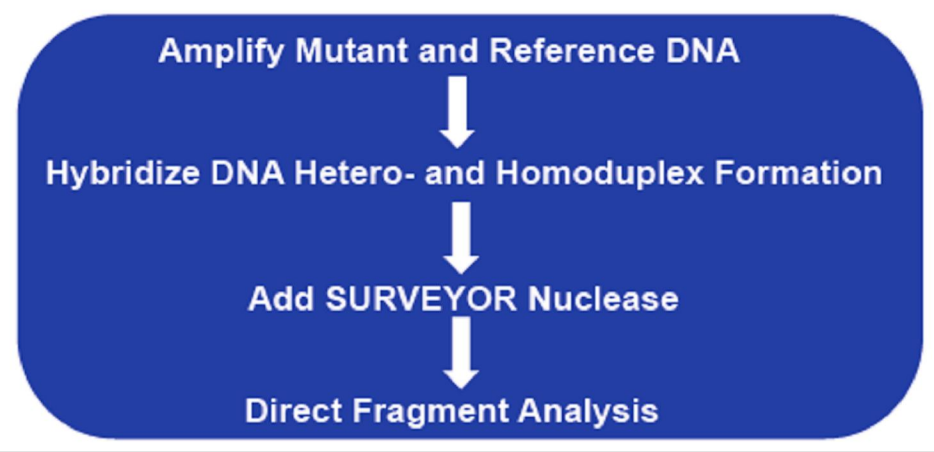
Scanning DNA with SURVEYOR



Transgenomic

DNA scanning is the use of an endonuclease to "scan" the length of a DNA molecule following replication. The SURVEYOR Scan kits were built on Transgenomic's proprietary SURVEYOR nuclease technology that utilizes an endonuclease (in this case specialized enzymes that cut the DNA specifically at the site of mutations) that can identify both the presence and location of a mutation. Once cut, the DNA molecule breaks into fragments.

Mutant Detection via SURVEYOR



Transgenomic

PIPELINE

Transgenomic has somewhat of a multi-project pipeline consisting of the development of their recently in-licensed COLD-PCR/Ice COLD-PCR technology, adding new tests using existing PCR technology and commercializing the pipeline assets that came with the Clinical Data assets acquisition. Many of these pipeline tests are expected to be used in the company's clinical and pharmacogenomics labs as well as be made available as kits to bioconsumable customers.

ONCOLOGY KITS

The oncology kit menu is expected to be expanded on a continuing basis. Demand for new tests should be largely driven by the recent introduction of novel cancer drugs and pharmaceutical / biotech companies' greater focus on personalized medicine and companion diagnostics. The escalating cost of drug development, cost containment measures through healthcare reform and demand for more efficacious drugs means drug companies are looking to develop more effective medicines while at the same time controlling costs. Patent cliffs of blockbuster chemical drugs has also meant drug manufacturers have a greater focus on biologics development - this should also create demand for genetic tests - in both the development and companion diagnostic areas.

Transgenomic expects to add a cancer kit for the TP53 gene, complementing the already commercialized oncology tests for K-RAS, BRAF and PIK3CA. TP53 functions as a cell tumor suppressor but if mutated, its suppression ability can be compromised, exposing the cell to cancer growth. Mutations in the TP53 gene are the most commonly observed genetic mutation in human cancers. The recent licensing agreement with Montefiore also offers the potential for development of a K-RAS/PIK3CA/PTEN panel.

ICE COLD-PCR

COLD-PCR (co-amplification at lower denaturation temperature-PCR) is a modified form of PCR which allows for detection of very low concentrations of DNA mutations. COLD-PCR has been shown to be up to 100 times more sensitive than PCR. Greater sensitivity affords the earlier detection of mutations and also allows for use of less-invasive samples types such as blood and urine (versus requiring sampling directly from the tumor itself). Since COLD-PCR does not require biopsy of the tumor (unlike conventional technologies) it is also less costly.

COLD-PCR works by forming heteroduplexes which melt at a lower temperature than wild type homoduplexes. By using critical denaturation temperatures, COLD-PCR preferentially amplifies mutant DNA. In essence, COLD-PCR significantly reduces the size of the "haystack" (i.e. - normal DNA), leaving the "needles" (i.e. - mutant DNA) in plain sight.

A key application of COLD-PCR is in the early detection of serious and progressive diseases such as cancer. The greater sensitivity afforded by COLD-PCR means that effective treatments can be determined at an earlier stage. And unlike conventional PCR which requires sampling directly from the tumor, serum, plasma or urine (as well as tumor samples) samples can be used with COLD-PCR, making it a more practical early screening and monitoring tool. COLD-PCR can be used on standard Sanger Sequencing equipment, a widely used sequencing protocol and one that the FDA requires pharmaceutical companies to use when submitting gene mutation data.

Transgenomic began licensing the COLD-PCR/Ice COLD-PCR technology from the Dana-Farber Cancer Institute in September 2010. Transgenomic has been working on further enhancing COLD-PCR and recently completed studies using Ice COLD-PCR. Ice COLD-PCR affords even higher sensitivity and faster throughput than COLD-PCR. Another key benefit is that Ice COLD-PCR exposes all the mutations that occur in a particular region. This is important as it allows a single test to pick up multiple mutations, in contrast to competing technologies that require a different test for detection of each mutation. In March 2011 Transgenomic also announced discovery of a novel sequencing technology called BLOCker-Sequencing (BLocking Olignucleotides in Cycle sequencing) which affords standard Sanger sequencing higher detection. In April 2011 the company presented study results in the analysis in mutations of the K-RAS gene which showed an 8-fold increase in sensitivity with BLOCker-Sequencing compared to standard Sanger sequencing.

Transgenomic has been busy making presentations on Ice COLD-PCR at industry conferences and has indicated there has been significant interest in the technology from current or prospective pharma customers. The company

currently has several oncology-related discovery projects utilizing Ice COLD-PCR underway for pharmacogenomics customers. The hope is that some of these small projects eventually turn into larger contracts and clinical trials. Transgenomic has also noted that they are working with Dana-Farber as well as a "major oncology pharmaceutical partner" (the name of the company has not been disclosed) in the development of assays utilizing Ice COLD-PCR and BLOCker-Sequencing. .

The current game plan is to validate several cancer genetic marker tests (including K-RAS, PIK3CA, BRAF, NRAS and TP53) using Ice COLD-PCR in the pharmacogenomics lab and then convert assays with broad demand over to specific assay kits. The versatility afforded by Ice COLD-PCR (can be used on Sanger sequencing instruments) means the potential market for these kits could be substantial.

PERSONALIZED MEDICINE PIPELINE

The recent Clinical Data assets acquisition brought with it two biomarker assays; an Fc gamma receptor oncology test and a test to determine whether an individual is suited for treatment with Plavix.

Fc gamma

Fc receptors are part of the immune system and bind to antibodies to help protect the body from disease. There are several types of Fc receptors and Fc gamma receptors bind to the most common type of antibodies (called IgG). Clinical studies have shown that differences in Fc gamma receptor genes can be predictive of the efficacy of certain monoclonal antibody oncology drugs in cancer patients.

Clinical Data had already been out-licensing an Fc gamma test for research testing. Transgenomic now earns the royalties from this licensing agreement (approximately $500k per year). Transgenomic also retains the rights to offer these services as well and has recently begun to do so to its pharmaceutical customers. Work is in process to fully validate the test. Following validation, Transgenomic would likely look to present and publish findings, hopefully increasing visibility and interest in the marker from pharmaceutical customers.

Transgenomic hopes to broaden the applicability of this technology to other tumor types and to other monoclonal antibody drugs. If the technology has applicability to EGFR inhibitors such as Erbitux and Vectibix, this could significantly broaden the market for the test, potentially opening it up to use with patients with colon as well as head and neck cancers. The ultimate plan is to commercialize the Fc gamma tests as companion diagnostic tests (assuming sufficient demand, and insurance reimbursement, exists) - launch of which, while not likely to be a near-term event, could happen within the next couple of years.

Plavix

Plavix (generic name, clopidogrel) is anti-blood clotting drug sold by Bristol-Myers and Sanofi-Aventis. Prescribed to patients to reduce the risk of heart attack, stroke or cardiovascular death, it is the second biggest selling drug, with worldwide sales over $9 billion in 2010.

The FDA added a warning to the Plavix label in May 2009 but "upgraded" it to black-box in March 2010. Black-box warnings are FDA's most serious warning and are typically only issued when the agency believes the drug could carry potentially serious adverse risks. The warning notes that Plavix may be less effective in certain people (those with reduced functioning of their CYP2C19 liver enzyme) and therefore these "poor metabolizers" may remain at risk of suffering from heart attack, stroke or death. Roughly 2% to 14% of the U.S. population is estimated to fit into this "poor metabolizer" category. The FDA recommended testing to determine which individuals are susceptible to less response to Plavix.

Transgenomic's acquired Plavix response test is based on the ABCB1 (or MDR1) gene. The company has not provided specific guidance on when they may introduce the test - our best guess is that the test may launch sometime during 2012. While the test will compete against several other Plavix response tests already on the market, Transgenomic should have an opportunity to leverage its FAMILION network to help spark sales of its test. Plavix also loses U.S. exclusivity in 2012 - once generic, uptake of the drug will grow even more which should expand the overall market for Plavix response testing.

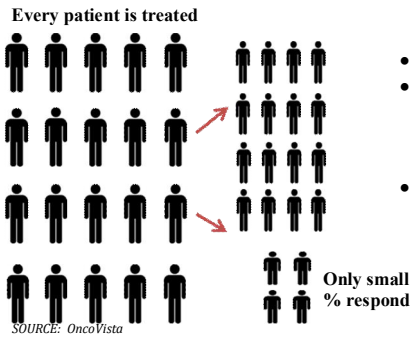
MARKET TRENDS

COMPANION DIAGNOSTICS

Companion diagnostics refers to the use of a diagnostic test to determine optimal treatment for a particular individual. As opposed to the common "one size fits all" approach, companion diagnostics accounts for differences in a person's or a particular population's biological make-up. This helps guide drug development and dispensing decisions, providing for more effective therapies.

Recent interest in companion diagnostics has surged, with most of the activity focused in the area of oncology. A report by Roche and Boston Biomedical Consultants on the in-vitro diagnostics market estimates that sales of molecular diagnostics (specific to tests that analyze the DNA or RNA of an organism) will grow from $2.6 billion in 2007 to $5.0 billion in 2012. We expect the recent and expected continued strong growth of companion diagnostics to benefit both Transgenomic's lab services and instrument/consumables businesses.

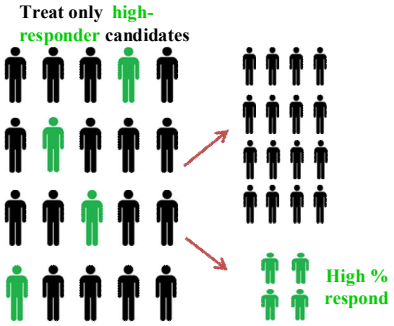
Oncology drug manufacturers such as Genentech, Bristol-Myers, Amgen and AstraZeneca commonly use companion diagnostics during clinical trial enrollment. Clinical trials can be extraordinarily expensive which is especially true for biological drug candidates. One way to control the cost of clinical trials is to include only individuals expected to benefit most from the drug being tested. COLD-PCR/Ice COLD-PCR, which sample directly from blood or plasma and do not require tumor biopsy, could also provide significant savings in patient enrollment.



SOURCE: OncoVista

TRADITIONAL TRIAL DESIGN

- All patients with a common diagnosis (e.g. - colon cancer) are included.
- Every patient receives treatment although a high percentage will likely show no response to the drug being tested. This means the treated patient population has to be large in order to increase likelihood of meeting statistical significance.
- Costly



SOURCE: OncoVista

TARGETED TRIAL DESIGN

- Through the use of a companion diagnostic, identify those patients most likely to respond to drug being tested (e.g. - tumors expressing K-RAS mutations).
- Treat only these high-responder candidates.
- Smaller treated patient population required to meet statistical significance
- Lower cost

Pharma companies also commonly partner with diagnostic companies for development of companion tests used after the drug has launched. A companion diagnostic test helps ensure that a patient receives the most effective treatment at the earliest point in time, thereby improving the chances for the best possible care. An example would be a colorectal cancer patient being tested with Transgenomic's K-RAS mutation kit in order to determine the effectiveness of Erbitux.

For both applications (i.e. - pre- and post-commercialization) relative sensitivity is an important differentiating characteristic among that various companion diagnostic tests. All else equal, demand will be driven towards those tests that provide the highest sensitivity. Transgenomic hopes to capitalize on this through its ultra-high sensitivity Ice COLD-PCR and BLOCker technologies.

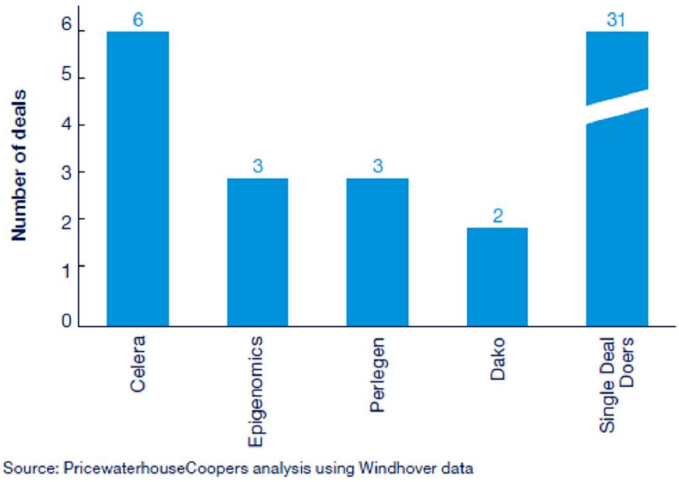
Pharmacogenomics Dominated By Smaller Companies...

While a number of large life sciences companies have in-vitro diagnostic testing divisions (including Roche, J&J, Abbott and Inverness), the majority of these do not participate in companion diagnostic development. A recent industry study by PricewaterhouseCoopers titled, "Diagnostics 2009: Moving Towards Personalized Medicine" examined recent activity and significant events for personalized medicine (which includes companion diagnostics).

It notes that the majority of partnerships (from 2004 to 2008) were with pharmaceutical companies related to the development of a companion diagnostic were with relatively small diagnostic companies. The authors cite that the risk and time to market associated with drug candidates make development of a companion diagnostic unattractive to larger IVD companies compared to their clinical lab businesses. Of the 45 companion diagnostic deals penned between 2004 and 2008, 21 (47%) were related to cancer.

The report also notes that most of these pharma/diagnostic partnerships were dispersed amongst several companion diagnostic companies, suggesting no single company has much of a foothold. This may also suggest technological advancements (such as COLD-PCR) may have an influence in garnering new business (in both the pharmacogenomics as well as instrument/bioconsumable businesses) from these large pharmas.

Companion Diagnostic Deals w/ Big Pharma by Diagnostic Partner (2004-2008)



Source: PricewaterhouseCoopers analysis using Windhover data

The FDA's Involvement...

The FDA recently started compiling a list of genomic biomarkers which the agency believes are useful to guide decision-making in the use of certain drugs. The vast majority of the almost 30 biomarkers that the agency currently considers "valid" relate to oncology. While the FDA recommends that testing for all of these biomarkers be completed prior to the commencement of drug therapy, it requires the use of diagnostic testing for only five of these markers. Four of these markers (EGFR, K-RAS, Philadelphia chromosome and Her2/neu) relate to cancer drugs Erbitux, Tarceva, Iressa, Tykerb, Vectibix, Herceptin, Sprycel and Tasigna. The EMEA (European regulatory body) also maintains a list of valid biomarkers - 11 of which are currently require testing for (9 of which relate to cancer).

Based on the trends favoring development of targeted therapies and the FDA's recent involvement in product labeling related to companion diagnostics, its clear this list of required biomarkers will continue to grow which should drive demand of companion diagnostic tests.

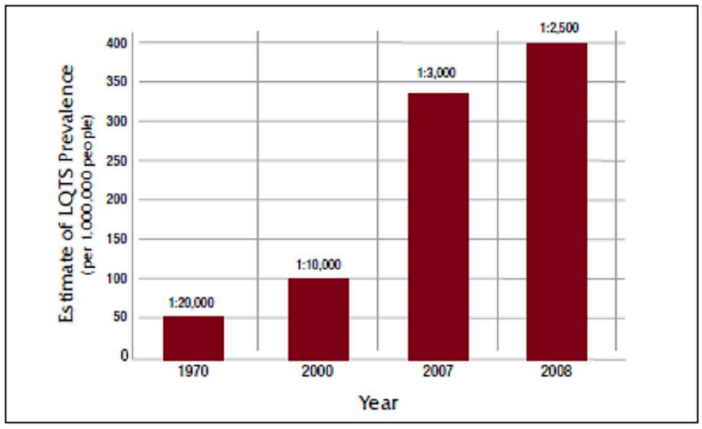
Trends Point to Growth...
The authors of the PWC study cited above concluded that, "We expect the annual number of diagnostic partnerships between pharmaceutical and diagnostic companies to increase over the next five years. One key factor will be increased pressure on pharmaceutical companies from regulators and payers to provide a diagnostic alongside pharmaceuticals to guide their use."

Another factor will almost certainly be a greater shift towards development of less patent-exposed drugs. Patent cliffs of blockbuster chemical drugs has meant big pharma turning to a much greater focus on biological drugs, including cancer therapies. A recent example is Bristol-Myers' purchase of ImClone in order to gain rights to Erbitux to help offset impending generic competition to Plavix, which contributed 34% of the company's revenue in 2010. Plavix faces generic competition next year when the drug's U.S. patent expires. Currently lacking a clear regulatory pathway to genericize biologics, these drugs do not face the same patent cliff risks as do chemical compounds. Although U.S. regulators are investigating a potential pathway to get biosimilars to market, it does not appear this will be in place in the near-term. It is estimated there are currently over 400 new cancer drug candidates being studied in clinical trials. As big pharma continues its push into cancer biologics, this should help further spur demand for companion diagnostics.

INHERITED CARDIAC DISEASE

The majority of revenue generated through Transgenomic's clinical lab will now come from sales of the FAMILION tests for inherited cardiac diseases. These are relatively rare diseases with the actual incidence rates not known for some of these conditions - such as Brugada Syndrome and Short QT Syndrome. Long QT Syndrome is believed to be one of the most common inherited cardiac disease but even it is relatively rare, afflicting only about 1 in 2,500 people. As the true prevalence of these diseases are unknown, it is impossible to gauge with any certainty whether incidence rates are on the rise. Although there has been a significant increase in the number of people diagnosed with these diseases over the last several decades, this is due mostly due to advances in testing.

Advances in Genetic Testing Reveals Increase in Prevalence of LQTS



SOURCE: familion.com / Crotti L, et el. Congenital long QT syndrome. Orphanet Journal of Rare Diseases

Increasing Sensitivity Offers Growth Opportunities...
The clinical utility of genetic testing (in general, not specific to FAMILION) for some of these rare diseases can be somewhat uncertain due to their relatively low sensitivity. As such, a large part of activity in this segment will likely surround research of novel genetic markers in order to increase sensitivity. And while the FAMILION tests clearly do not suffer from lack of reimbursement (i.e. - 280MM covered lives), greater clinical utility can only help increase interest from health care providers and insurers. Transgenomic continues to advance its current line-up of tests and in early May 2011 announced enhancements to its Brugada Syndrome FAMILION test, adding two new genes and broadening the indication to cover other diseases in a larger category called J-wave syndromes. The company noted that this enhancement marked the fourth test launched or expanded within the last six months. We expect this to be an ongoing theme in order to grow the FAMILION franchise.

Transgenomic will continue development on their already widely used FAMILION franchise, enhancing sensitivity of current tests through the inclusion of novel markers and launching new tests. Enhanced sensitivity means even more clinical utility (with an ever greater percentage of test results categorized as Class I Mutation and Class III Variants from the table below) which should help further drive demand.

FAMILION Tests Interpretation Guide

Related to Disease ← → Not Related to Disease

	Class I Mutation (Deleterious or Probable Deleterious)	Class II Mutation (Variant of Uncertain Significance)	Class III Variants (Not Expected to Cause Disease)
Clinical Interpretation	• Result strongly suggests an inherited cardiac disease.	• Mutation may be disease-causing or benign.	• Class III variants are not expected to be disease-causing. A report with only Class III variants is considered negative.
Reasons for Classification	• Strong evidence of deleteriousness. • "Probable," if included, indicates that variant is predicted, but has not been demonstrated, to cause disease. • Typically absent from a healthy control population.	• Evidence is insufficient to determine whether the mutation is deleterious. • Typically absent from a healthy control population.	• Evidence indicates variant is not disease-causing. • Typically common in a healthy control population.
Recommendations	• Genetic testing of all first-degree relatives is recommended to identify those at risk for disease. Genetic counseling should be considered.	• Genetic testing and clinical screening in family members may elucidate the significance of the mutation. Genetic counseling should be considered.	• Genetic testing of family members for Class III variants is not advised.

SOURCE: familion.com

FINANCIAL CONDITION

Balance Sheet

As of their most recent reporting period (3/31/11) Transgenomic had $3.2 million in cash and equivalents. $9.4 million in debt owed to PGxHealth consists of $741k remaining under in a one-year, 6.5% senior secured note (due December 31, 2011) and a three-year, 10% senior secured note (due December 30, 2013).

Terms of the one-year note call for monthly principal and interest payments. The three-year note pays only interest through March 2012, then principal and interest through the December 2013 maturity.

Transgenomic also issued 2.6 million shares of convertible preferred stock (along with warrants to purchase additional preferred stock) in order to fund a portion of the Clinical Data assets purchase. The preferred stock is accounted for as a liability as the holders, by majority vote, have the option of redeeming it at any time. The shares are convertible at a rate of 4 shares of common stock for every preferred share. The preferred stock accrues cumulative dividends at 10% annually. Transgenomic's level of distributable cash flow (as defined in the prospectus) determines whether these dividends will be paid out in any given quarter.

Cash Flow

Cash used in operations was $1.7 million through the 12 months ending 12/31/2010. Q1 2011 cash from operations was positive $51k. It appears management has already been successful in finding synergies from the recent acquisition - which, according to audited carve out financial statements (prepared by Clinical Data), used $6.1 million in cash from operations through the 12 month period ending March 31, 2010.

Transgenomic generated $51k in cash from operations in the most recent period despite posting a net loss of $3.0 million. The reason for the large difference is mostly due to $494k in depreciation/amortization and a $2.0 million non-cash expense related to revaluation of embedded options in the outstanding preferred stock (i.e. - conversion

option in the preferred stock gained value due to TBIO's common stock price increasing). The company made $248k in principal payments on the one-year note.

Based on our current model (which there could be significant changes to over the next few quarters) we believe Transgenomic could possibly generate positive operating cash flow for the foreseeable future. Based on management's comments on the Q1 call, they also believe the company will continue to generate cash throughout the remainder of 2011. The $741k principal remaining on the one-year note is payable monthly up to December 2011 - we expect this to be manageable through cash on hand and cash from operations.

$3.7 million and $4.9 million of principal on the three-year note (paid quarterly beginning April 2012) is due in 2012 and 2013, respectively. Based on our current model, Transgenomic may be able to just manage the 2012 principal payments with cash on hand and operating funds but may need additional capital to make the 2013 principal payment. It is possible that sufficient capital could come from the exercise of warrants (o/s are 400k warrants @ $1.13 strike expiring 2011 and 5.2MM warrants @ $0.58 strike expiring 2015). We also note that our current model should be viewed as the first of potentially many iterations and may change significantly over the next several quarters. Depending on the success in growing the pharmacogenomics business, it is possible Transgenomic could meet all its cash needs through operating cash flow and cash on hand.

FINANCIAL RESULTS: Q1 2011

Revenue

Q1 2011 was the first full quarter with the FAMILION assets included. Q1 revenue came in at $7.5 million, while this is up $2.1 million (37%) from the $5.4 million generated in Q1 2010, approximately $2.7 million of the current period's revenue came from FAMILION tests (i.e. - comparable revenue fell 12%). Bioconsumables, which experienced revenue growth of about 4% in the quarter, was the only comparable segment not experiencing a y-o-y decline (clinical lab ex-FAMILION fell ~17%, pharmacogenomics fell ~18% and instruments fell ~22%).

	Q1 2010	Full Year 2010	Q1 2011
FAMILION			$2,700
YOY Growth			-
Legacy TBIO Molecular Lab	$942	$3,606	$787
YOY Growth	*-1.2%*	*1.8%*	*-16.5%*
Clinical Lab	$942	$3,606	$3,487
% of Lab revenue	74.1%	72.4%	92.8%
YOY Growth	*-1.2%*	*1.8%*	*270.2%*
Pharmacogenomics Research Svcs.	$329	$1,373	$270
% of Lab revenue	25.9%	27.6%	7.2%
YOY Growth	*8.6%*	*34.0%*	*-17.9%*
Laboratory Services	$1,271.0	$4,979.0	$3,757.0
% of total revenue	23.4%	24.8%	50.2%
YOY Growth	*1.2%*	*9.0%*	*195.6%*
Bioinstruments	$2,352	$8,320	$1,837
% of Instrument revenue	56.4%	55.2%	49.3%
YOY Growth	*23.0%*	*-18.2%*	*-21.9%*
Bioconsumables	$1,819	$6,749	$1,886
% of Instrument revenue	43.6%	44.8%	50.7%
YOY Growth	*-0.1%*	*-7.3%*	*3.7%*
Instruments	$4,171.0	$15,069.0	$3,723.0
% of total revenue	76.6%	75.2%	49.8%
YOY Growth	*11.7%*	*-13.7%*	*-10.7%*
Total Revenues	$5,442.0	$20,048.0	$7,480.0
YOY Growth	*9.1%*	*-9.0%*	*37.4%*

Gross Margin

Q1 GM was 55.5%, the highest of any quarter since Q1 2009. Prior to the FAMILION assets acquisition, Transgenomic's gross margins had been narrowing due to the fairly consistent decline in revenue from the instruments business, which has historically carried higher margins compared to lab services. Despite revenue

from the instruments segment falling 11% y-o-y in Q1, gross margin managed to tick up 250 b.p. from Q1 2010, which is largely due to the addition of the FAMILION business (also partly due to favorable instrument product sales mix). According to Clinical Data's income statement carve-outs, FAMILION's gross margins had been running around 57%. Inclusion of FAMILION pushed lab services margin up to almost 48% in Q1 2011, a level also not realized since Q1 2009.

Our thesis, as we explain in our Outlook section below, is that gross margins should benefit over the next few years as a result of significant revenue growth in the pharmacogenomics business - which should be a fairly scalable.

	Q1 2010	Full Year 2010	Q1 2011
Cost of Clinical Lab	$462	$2,125	$1,587
Molec Lab margin	*51.0%*	*41.1%*	*54.5%*
Cost of Pharmacogenomics Svcs.	$326	$1,416	$383
Pharmaco. Svcs.margin	*0.9%*	*-3.1%*	*-41.9%*
Laboratory Services	$788.0	$3,541.0	$1,970.0
Lab Svcs margin	*38.0%*	*28.9%*	*47.6%*
Cost of Bioinstruments	$932	$3,560	$522
Bioinstruments margin	*60.4%*	*57.2%*	*71.6%*
Bioconsumbales	$838	$3,183	$834
Bioconsumbales margin	*53.9%*	*52.8%*	*55.8%*
Instruments	$1,770.0	$6,743.0	$1,356.0
Instruments margin	*57.6%*	*55.3%*	*63.6%*
Cost of Revenues	$2,558.0	$10,284.0	$3,326.0
Gross Income	$2,884.0	$9,764.0	$4,154.0
Gross Margin	*53.0%*	*48.7%*	*55.5%*

Operating Expenses

Q1 operating expenses were $4.9MM. At 65% of revenue, this is roughly in-line with both Q1 2010 and the full year 2010. There are a couple of things that are worth noting, however. One is that almost $9MM of the purchase price of the recent acquisition was allocated to intangible assets which means a significantly greater portion of operating expense in the current period is non-cash. The other thing to note is that the expectation is that revenue, especially in the more scalable pharmacogenomics segment, will grow faster than operating expenses beginning in Q2 2010.

Cash Flow

Q1 cash flow from operations was $51k, compared to $392k in Q1 2010 and ($1,718k) for the full year 2010. Excluding changes in working capital (a better gauge of cash generated from the business), cash flow was $207k in Q1 2011, ($185k) in Q1 2010 and ($2,440k) for the full year 2010. The improvement in cash flow appears to be a result of cutting superfluous costs from integration of FAMILION. Part of this includes combining clinical lab operations into the lab acquired through the acquisition and utilizing Transgenomic's Omaha-based lab for pharmacogenomics.

EPS

EPS came in at ($0.06) compared to ($0.01) in Q1 2010 and ($0.06) for the full year 2010. Important to note is that Q1 2011 EPS includes the aforementioned $2,027k non-cash derivative revaluation expense - there was no such expense in the earlier periods. The recent period also includes $231k in income from a federal QTDP grant ($630k in QTDP income was also recorded in Q3 2010). If we strip out the derivative revaluation expense and QTDP income, EPS in Q1 2011 was approximately($0.025).

OUTLOOK

Laboratory Services accounted for 25% of total revenue (Instrument Related Business the other 75%) in 2010 but we expect this to grow to about 60% in 2011 as a result of the December 2010 acquisition and a continued slide in instrument sales. 2011 will mark the front-end of Transgenomic's shift from mostly an instruments related business to, ultimately, a companion diagnostics company. Going forward, this transformation will be in large part driven by growth in Transgenomic's oncology diagnostics capabilities as a result of the recent introduction of, and demand for, their COLD-PCR/Ice COLD-PCR technology. The pharmacogenomics lab business should be the initial beneficiary as a result of increasing interest in this technology from pharmas and biotechs which have been greatly expanding their cancer research efforts. The clinical lab and consumables segments should be secondary beneficiaries as Transgenomic converts some of the COLD-PCR/Ice COLD-PCR based tests from the research-lab into specific assays and companion diagnostics.

BUSINESS SEGMENTS:

Bioinstruments
WAVE instrument sales have likely peaked and will continue to experience an annual decline to increased demand for competing technologies. Sales of OEM HANABI instruments may show moderate growth but since they account for a relatively small percentage of overall instrument sales, will not be enough to offset the aggregate decline in WAVE sales. The net result we expect will be revenue from instrument sales continuing to fall.

Bioconsumables
We expect sales of bioconsumables, which eked out a slight gain in the most recent quarter, to remain somewhat lackluster over the near-term. While recent launches of new kits incorporating additional cancer markers may provide some incremental revenue, Transgenomic may not see much in the way of significant growth in their bioconsumables business until the after introduction of COLD-PCR/BLOCker into specific test kits - which may not be until sometime in 2012. Ice COLD-PCR, adaptable to a broad range of instruments, means bioconsumables revenue should grow over the long-term despite the expected continuing declining sales of Transgenomic's proprietary WAVE systems.

Clinical Lab
While the recent acquisition will provide an immediate boost to the top-line in 2011, we do not view FAMILION's current menu of tests as holding outsized opportunities for long-term growth or profitability. Instead gaining access to 280 million covered lives and the pipeline assets (i.e. - Fc gamma) that came with the acquisition may prove significantly more valuable to Transgenomic. Leveraging access to the 280 million covered lives could be key for Transgenomic in growing its clinical lab business, especially as more tests are developed on the COLD-PCR/Ice COLD-PCR platform. Similar to bioconsumables, we think revenue growth in the molecular lab business should show acceleration upon validation and conversion of new COLD-PCR/Ice COLD-PCR - BLOCker based cancer assays into specific test kits.

Pharmacogenomics Lab
In the near-term to mid-term we model the vast majority of Transgenomic's revenue growth to come from the pharmacogenomics segment as a result of snowballing interest from large pharmaceutical companies in its COLD-PCR/Ice COLD-PCR technologies. While revenue from this segment fell to just $270k in Q1 2011 (the lowest since Q4 2009), this is not expected to be indicative of the future. Pharmacogenomics revenue is inherently choppy and management has indicated they are seeing ever-increasing interest in COLD-PCR/Ice COLD-PCR and BLOCker sequencing. On the Q1 earnings call management noted that they expect revenue from pharmacogenomics to be at least $1.5 million in Q2 as a result of contracting a number of high value projects. We model this to be a continuing theme going forward and for the pharmacogenomics segment to account for most of Transgenomic's revenue growth over the next several years. We forecast pharmacogenomics revenue to grow from $1.4MM in 2010 to $4.6MM in 2011 and to $19.4MM in 2014. But, as noted, forecasting revenue in this segment is inherently very difficult due to the nature of short-term contracts and little in the way of anything to anchor on to use to estimate revenue growth. As such, our estimates may change significantly over short periods.

GROSS MARGIN:

Historically, Transgenomic's laboratory services businesses have generated significantly lower gross margins compared to the instruments businesses (lab ~42% vs. instruments ~58%). And as a result of also contributing about 80% of total revenue, the instruments business has accounted for the vast majority (~85%) of gross profit. While we expect revenue from the instrument segment to show a slight incremental decline on an annual basis for the foreseeable future and account for a much smaller portion of total revenue (initially this will mostly be due a spike in lab services revenue as a result of the addition of FAMILION), this should not prevent the aggregate gross margin from expanding. This is due to a combination of the FAMILION business carrying relatively beefy (~57%) margins and expectations that pharmacogenomics will become significantly more profitable (in gross profit as well as gross margin) as revenue ramps.

While it's yet to be proven to be the case, we expect the pharmacogenomics business to be fairly scalable from a gross margin standpoint. Pharmacogenomics has historically contributed relatively little (~5% - 7%) revenue and slim gross margins (negative 3% in 2010 and +20% in 2009). As the majority of costs in this business are fixed (facility) or at least semi-fixed (lab personnel), we expect there will be an opportunity to significantly expand gross margins in this segment as demand and utilization increases.

We model gross margins to expand from 48.7% in 2010 to 56.1% in 2011 to 60.3% in 2014.

OPERATING EXPENSES:

As previously noted, Transgenomic already appears to be wringing synergies from the FAMILION acquisition. While the company may look to incrementally add to their sales force or support functions upon the commercialization of new tests and add pharma lab personnel to meet demand, we believe operating expenses growth will trail that of revenue.

OUR 2011 OUTLOOK

We model 2011 revenue of $34.6 million, on the lower end of management's $34MM - $38MM guidance (which was affirmed on the Q1 call). Our revenue estimate implies growth of 73% from 2010 (or about 8% on an organic, ex-FAMILION, basis). We for Laboratory Services and Instruments to generate revenue of $20.8 million and $13.8 million, respectively. We think EPS comes in at ($0.15) in 2011 or about ($0.07) if the preferred stock revaluation expense and QTDP grant income are eliminated.

Laboratory Services
Our $20.8 million revenue estimate for Laboratory Services includes $16.2 million ($3.3MM ex-FAMILION) from the Clinical Lab segment and $4.6 million from Pharmacogenomics. We assume sales of the FAMILION tests, which are seasonally soft in Q1 due to the reset of insurance deductibles at the beginning of the year, show consistent sequential growth over the course of 2011 but on an annual basis remain relatively flat at about $13 million. We model revenue from Transgenomic's legacy clinical lab business, which fell about 17% in Q1, to contract by approximately 8% for the full year. Meanwhile, the pharmacogenomics business should experience strong growth throughout 2011 - we look for $4.6 million in revenue from this segment, implying growth of over 230% ($1.4MM) from 2010. This could actually prove to be conservative - management mentioned on the Q1 call that they expect to have at least $1.5MM in pharmacogenomics revenue in Q2 alone. As noted earlier, revenue from this segment can be very choppy quarter-to-quarter which makes forecasting somewhat difficult.

Instruments
Management noted on the Q1 call that they have been seeing some firming up in CAPEX from hospitals/clinics/labs due to the improving economy and, as a result, expect instrument (equipment) sales for the remainder of 2011 to remain near the $1.8MM sales level hit in Q1. We model the equipment portion of Transgenomic's instrument business to fall 13% in 2011 to $7.2MM (average of ~ $1.8MM/qtr) but revenue from the consumables business to hold up much better due to new cancer kit launches. We model bioconsumables to fall only 3% in 2011 to $6.6MM.

RECOMMENDATION / VALUATION

Given that we model Transgenomic to post negative income and EPS through 2013, valuing the company using a near-term P/E multiple is not reasonable. Instead, we value the company using competitor price/sales multiples, calculated using estimated 2011 revenue. We looked at ten competitors which had at least one analyst estimate for 2011 sales - P/S multiples range from a low of 0.4x to a high of 21x. We removed both the high and low ratio in order to reduce the bias from outliers to the overall averages This left average comp P/S of 5.8x.

We model Transgenomic to post revenue of $34.6MM in 2011. Using the comp P/S ratio values TBIO at approximately $4.00/share. Based on the price that the shares currently trade at ($1.61), we think the stock is undervalued. As such, we are initiating with an Outperfrom rating.

Management Profiles

Craig Tuttle - Chief Executive Officer, President

Craig J. Tuttle has served as President and Chief Executive Officer of Transgenomic since July 2006. Mr. Tuttle was previously the President and COO of Duke Scientific, a specialty particle technology company, and before that he was the President and CEO of Applied Biotech, Inc, a leading point-of-care rapid diagnostics manufacturer in the Apogent Technologies group. He has held management positions at Seradyn, Boehringer Mannheim, Difco Laboratories and Cetus Corporation. Mr. Tuttle holds a B.S. degree in Biochemistry from UCLA, an M.S. degree in Biochemistry from the University of Colorado, and an MBA from St. Mary's College.

Chad Richards - Chief Commercial Officer

Mr. Richards joined Transgenomic in October 2007 as Senior Vice President, Sales and Marketing. Mr. Richards brings 14 years of sales and marketing experience in laboratory services and diagnostics. Before joining Trangenomic, Mr. Richards was the National Sales Director for Anatomic Pathology for Quest Diagnostics, the world's largest laboratory service business. During his career with Quest Diagnostics, Mr. Richards held a variety of sales management roles in both their physician and hospital business segments. Before joining Quest Diagnostics, Mr. Richards held different marketing and sales management roles with Ventana Medical Systems, a world leader in developing and manufacturing immunohistochemistry and in-situ hybridization instruments and reagent systems. Mr. Richards holds a B.S. degree in Biology from the University of Minnesota.

Katrina Fahlin - Vice President of Quality

Katrina Fahlin is the Vice President of Quality for Transgenomic. She holds a B.S. degree in Professional Chemistry from South Dakota State University and has graduate work in chemistry from the University of Nebraska. Ms. Fahlin has more than 30 years of experience in the quality arena including thirteen years with Novartis in Quality Assurance. She is a qualified Lead Auditor and her regulatory experience includes ISO standards, and FDA experience with pharmaceuticals, feed, food, and food and feed additives. She has lead the successful efforts at Transgenomic to attain ISO 9001 certification for their instrument and bioconsumable business and the College of American Pathologist accreditation of the CLIA reference laboratory.

Katherine A. Richardson, Ph. D. - Vice President of Research and Development

Dr. Richardson is Technical Director for Laboratory Services. She holds an S.B. degree in life sciences from the Massachusetts Institute of Technology and a Ph.D. in molecular cellular developmental biology from Iowa State University. Dr. Richardson has more than 25 years of molecular biology laboratory experience. She joins Transgenomic following eight years as a scientist with OSI Pharmaceuticals, where she specialized in molecular biology research and development in the area of oncology. Previously Dr. Richardson was with Eli Lilly and Company for nine years as a senior toxicologist specializing in genetic toxicology and molecular carcinogenesis. Dr. Richardson has to her credit nearly 60 publications, abstracts and presentations at scientific conferences, and she was part of the group at Eli Lilly that identified the link between the BRCA-1 gene and hereditary breast cancer.

Eric Johnson, Ph. D. - Director, CLIA Laboratory Services

Eric Johnson, Ph.D. is the Medical Director for Laboratory Services. Dr. Johnson has nearly 20 years of genetics experience in both research and diagnostics. Most recently he served as the founder of the Neurovascular / Epilepsy Genetics Research Laboratory at the Barrow Neurological Institute in Phoenix, Arizona and has helped to establish and mentor BioBanking efforts for a number of rare disease family groups, both independently and as the founding Director of the DNA and Tissue Archive of the Genetic Alliance BioBank. His experience in the clinic includes being the founding director of the Molecular Diagnostics and BioBanking Laboratories at St. Joseph's Hospital in Phoenix; serving as director of diagnostic testing at Prevention Genetics in Marshfield, Wisc.; and holding the position of Chief Scientific Officer and Clinical Laboratory Director for Iverson Genetic Diagnostics in Seattle, a personalized medicine genetic diagnostics company. Dr. Johnson has authored and co-authored numerous publications on the nature, identity and function of several epilepsy and neurovascular related genes including FEB2, a febrile seizure susceptibility gene, SCN1B, a Febrile seizure "plus" gene, and CCM1, CCM2 and CCM3, three causative genes for cerebral cavernous malformations. He is considered an expert in translational research: moving tests for heritable diseases from the laboratory bench to the clinic, as evidenced by presenting at more than 50 genetic conferences and workshops during his career. Dr. Johnson received a B.A. in biology/chemistry from Boston University and a Ph.D. inNeuropharmacology/Neuroscience from the University of Pennsylvania. He did post-doctoral work in Psychiatry and Neurosurgery at Yale University, and received advanced training genetics at the Jackson Laboratory in Bar Harbor, Maine.

SOURCE: Transgenomic.com

FINANCIAL MODEL

Transgenomic Inc.

	2010 A	Q1A	Q2E	Q3E	Q4E	2011 E	2012 E	2013 E	2014 E
Laboratory Services	$4,979.0	$3,757.0	$5,655.0	$5,554.0	$5,845.0	$20,811.0	$25,980.0	$33,855.0	$42,791.0
% of total revenue	24.8%	50.2%	63.2%	62.4%	63.1%	60.2%	67.1%	73.1%	77.2%
YOY Growth	9.0%	195.6%	355.7%	339.4%	385.9%	318.0%	24.8%	30.3%	26.4%
Instruments	$15,069.0	$3,723.0	$3,292.0	$3,340.0	$3,420.0	$13,775.0	$12,764.0	$12,464.0	$12,625.0
% of total revenue	75.2%	49.8%	36.8%	37.6%	36.9%	39.8%	32.9%	26.9%	22.8%
YOY Growth	-13.7%	-10.7%	-14.6%	5.9%	-12.1%	-8.6%	-7.3%	-2.4%	1.3%
Total Revenues	$20,048.0	$7,480.0	$8,947.0	$8,894.0	$9,265.0	$34,586.0	$38,744.0	$46,319.0	$55,416.0
YOY Growth	-9.0%	37.4%	75.6%	101.3%	82.0%	72.5%	12.0%	19.6%	19.6%
Laboratory Services	$3,541.0	$1,970.0	$2,402.6	$2,342.2	$2,554.8	$9,269.6	$11,035.6	$13,454.8	$16,220.5
Lab Svcs margin	28.9%	47.6%	57.5%	57.8%	56.3%	55.5%	57.5%	60.3%	62.1%
Instruments	$6,743.0	$1,356.0	$1,489.0	$1,386.2	$1,678.2	$5,909.4	$5,770.7	$5,671.3	$5,778.3
Instruments margin	55.3%	63.6%	54.8%	58.5%	50.9%	57.1%	54.8%	54.5%	54.2%
Cost of Revenues	$10,284.0	$3,326.0	$3,891.6	$3,728.4	$4,233.0	$15,179.0	$16,806.3	$19,126.1	$21,998.8
Gross Income	$9,764.0	$4,154.0	$5,055.4	$5,165.6	$5,032.0	$19,407.0	$21,937.7	$27,192.9	$33,417.2
Gross Margin	48.7%	55.5%	56.5%	58.1%	54.3%	56.1%	56.6%	58.7%	60.3%
SG&A	$10,933.0	$4,323.0	$4,595.0	$4,595.0	$4,715.0	$18,228.0	$18,472.4	$21,289.5	$24,110.0
% SG&A	54.5%	57.8%	51.4%	51.7%	50.9%	52.7%	47.7%	46.0%	43.5%
R&D	$2,305.0	$557.0	$684.0	$726.0	$738.0	$2,705.0	$3,300.0	$3,480.0	$3,660.0
% R&D	11.5%	7.4%	10.7%	10.2%	9.1%	7.8%	8.5%	7.5%	6.6%
Restructuring charges	$138.0	$24.0	$0.0	$0.0	$0.0	$24.0	$0.0	$0.0	$0.0
Operating Income	($3,612.0)	($750.0)	($223.6)	($155.4)	($421.0)	($1,550.0)	$165.3	$2,423.4	$5,647.1
Operating Margin	-18.0%	-10.0%	-2.5%	-1.7%	-4.5%	-4.5%	0.4%	5.2%	10.2%
Interest income, net	($4.0)	($238.0)	($230.0)	($230.0)	($220.0)	($918.0)	($800.0)	($780.0)	$10.0
Expense on preferred stock	$0.0	($2,027.0)	($600.0)	($600.0)	($600.0)	($3,827.0)	($4,000.0)	($500.0)	$0.0
Other income	$632.0	$231.0	$0.0	$0.0	$0.0	$231.0	$0.0	$0.0	$0.0
Pre-Tax Income	($2,984.0)	($2,784.0)	($1,053.6)	($985.4)	($1,241.0)	($6,064.0)	($4,634.7)	$1,143.4	$5,657.1
Taxes	$150.0	($6.0)	$32.9	$33.4	$34.2	$94.5	$127.6	$124.6	$126.3
Tax Rate	-5.0%	0.2%	-3.1%	-3.4%	-2.8%	-1.6%	-2.8%	10.9%	2.2%
Preferred dividends	$0.0	($260.0)	($260.0)	($260.0)	($262.0)	($1,042.0)	($1,042.0)	($1,042.0)	($1,042.0)
Net Income	($3,134.0)	($3,038.0)	($1,346.5)	($1,278.8)	($1,537.2)	($7,200.5)	($5,804.3)	($23.3)	$4,488.9
YOY Growth	-63.2%	-837.7%	-17.5%	42.4%	100.7%	-129.8%	-19.4%	-99.6%	-19389.7%
Net Margin	-15.6%	-40.6%	-15.0%	-14.4%	-16.6%	-20.8%	-15.0%	-0.1%	8.1%
EPS	($0.06)	($0.06)	($0.03)	($0.03)	($0.03)	($0.15)	($0.11)	($0.00)	$0.07
YOY Growth	-63.0%	835.7%	17.3%	42.2%	99.8%	129.2%	-22.7%	-99.6%	-15760.1%
Diluted Shares O/S	49,244	49,293	49,308	49,350	49,500	49,363	51,500	53,500	65,900

Brian Marckx, CFA

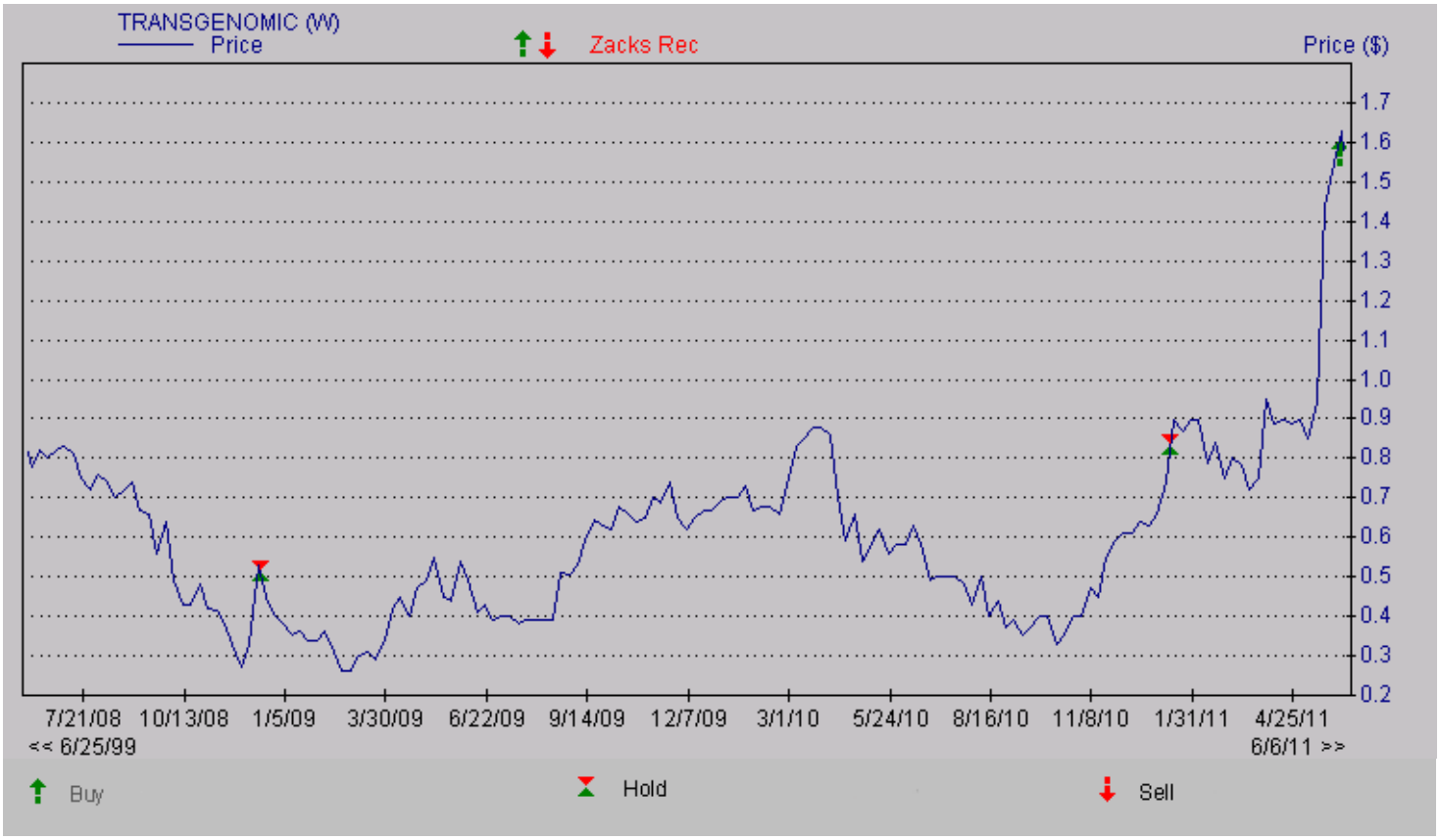
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REVENUE / GM DETAIL

Transgenomic Inc.

	2010 A	Q1A	Q2E	Q3E	Q4E	2011 E	2012 E	2013 E	2014 E
FAMILION		$2,700	$3,250	$3,350	$3,650	$12,950	$13,850	$15,700	$17,850
YOY Growth		-	-	-	-	*-0.4%*	*6.9%*	*13.4%*	*13.7%*
Legacy TBIO Molecular Lab	$3,606	$787	$845	$860	$810	$3,302	$3,880	$4,605	$5,501
YOY Growth	*1.8%*	*-16.5%*	*-9.2%*	*-6.3%*	*-0.6%*	*-8.4%*	*17.5%*	*18.7%*	*19.5%*
Clinical Lab	$3,606	$3,487	$4,095	$4,210	$4,460	$16,252	$17,730	$20,305	$23,351
% of Lab revenue	72.4%	92.8%	72.4%	75.8%	76.3%	78.1%	68.2%	60.0%	54.6%
YOY Growth	*1.8%*	*270.2%*	*339.8%*	*358.6%*	*447.2%*	*350.7%*	*9.1%*	*14.5%*	*15.0%*
Pharmacogenomics Research Svcs.	$1,373	$270	$1,560	$1,344	$1,385	$4,559	$8,250	$13,550	$19,440
% of Lab revenue	27.6%	7.2%	27.6%	24.2%	23.7%	21.9%	31.8%	40.0%	45.4%
YOY Growth	*34.0%*	*-17.9%*	*403.2%*	*288.4%*	*257.0%*	*232.0%*	*81.0%*	*64.2%*	*43.5%*
Laboratory Services	$4,979.0	$3,757.0	$5,655.0	$5,554.0	$5,845.0	$20,811.0	$25,980.0	$33,855.0	$42,791.0
% of total revenue	24.8%	50.2%	63.2%	62.4%	63.1%	60.2%	67.1%	73.1%	77.2%
YOY Growth	*9.0%*	*195.6%*	*355.7%*	*339.4%*	*385.9%*	*318.0%*	*24.8%*	*30.3%*	*26.4%*
Bioinstruments	$8,320	$1,837	$1,780	$1,680	$1,920	$7,217	$6,714	$6,210	$5,840
% of Instrument revenue	55.2%	49.3%	54.1%	50.3%	56.1%	52.4%	52.6%	49.8%	46.3%
YOY Growth	*-18.2%*	*-21.9%*	*-19.7%*	*23.9%*	*-19.8%*	*-13.3%*	*-7.0%*	*-7.5%*	*-6.0%*
Bioconsumables	$6,749	$1,886	$1,512	$1,660	$1,500	$6,558	$6,050	$6,254	$6,785
% of Instrument revenue	44.8%	50.7%	45.9%	49.7%	43.9%	47.6%	47.4%	50.2%	53.7%
YOY Growth	*-7.3%*	*3.7%*	*-7.6%*	*-7.7%*	*0.4%*	*-2.8%*	*-7.7%*	*3.4%*	*8.5%*
Instruments	$15,069.0	$3,723.0	$3,292.0	$3,340.0	$3,420.0	$13,775.0	$12,764.0	$12,464.0	$12,625.0
% of total revenue	75.2%	49.8%	36.8%	37.6%	36.9%	39.8%	32.9%	26.9%	22.8%
YOY Growth	*-13.7%*	*-10.7%*	*-14.6%*	*5.9%*	*-12.1%*	*-8.6%*	*-7.3%*	*-2.4%*	*1.3%*
Total Revenues	$20,048.0	$7,480.0	$8,947.0	$8,894.0	$9,265.0	$34,586.0	$38,744.0	$46,319.0	$55,416.0
YOY Growth	*-9.0%*	*37.4%*	*75.6%*	*101.3%*	*82.0%*	*72.5%*	*12.0%*	*19.6%*	*19.6%*
FAMILION GM		*57.0%*	*58.1%*	*58.1%*	*58.2%*	*57.9%*	*58.5%*	*59.0%*	*60.0%*
Legacy TBIO Molecular Lab GM		*41.0%*	*42.5%*	*46.1%*	*39.0%*	*42.2%*	*44.0%*	*45.0%*	*46.0%*
Cost of Clinical Lab	$2,125	$1,587	$1,848	$1,867	$2,020	$7,322	$7,921	$8,970	$10,111
Clinical Lab margin	*41.1%*	*54.5%*	*54.9%*	*55.6%*	*54.7%*	*54.9%*	*55.3%*	*55.8%*	*56.7%*
Cost of Pharmacogenomics Svcs.	$1,416	$383	$555	$475	$535	$1,948	$3,115	$4,485	$6,110
Pharmaco. Svcs.margin	*-3.1%*	*-41.9%*	*64.4%*	*64.7%*	*61.4%*	*57.3%*	*62.2%*	*66.9%*	*68.6%*
Laboratory Services	$3,541.0	$1,970.0	$2,402.6	$2,342.2	$2,554.8	$9,269.6	$11,035.6	$13,454.8	$16,220.5
Lab Svcs margin	*28.9%*	*47.6%*	*57.5%*	*57.8%*	*56.3%*	*55.5%*	*57.5%*	*60.3%*	*62.1%*
Cost of Bioinstruments	$3,560	$522	$801	$706	$883	$2,912	$2,988	$2,795	$2,657
Bioinstruments margin	*57.2%*	*71.6%*	*55.0%*	*58.0%*	*54.0%*	*59.7%*	*55.5%*	*55.0%*	*54.5%*
Bioconsumbales	$3,183	$834	$688	$681	$795	$2,998	$2,783	$2,877	$3,121
Bioconsumbales margin	*52.8%*	*55.8%*	*54.5%*	*59.0%*	*47.0%*	*54.3%*	*54.0%*	*54.0%*	*54.0%*
Instruments	$6,743.0	$1,356.0	$1,489.0	$1,386.2	$1,678.2	$5,909.4	$5,770.7	$5,671.3	$5,778.3
Instruments margin	*55.3%*	*63.6%*	*54.8%*	*58.5%*	*50.9%*	*57.1%*	*54.8%*	*54.5%*	*54.2%*
Cost of Revenues	$10,284.0	$3,326.0	$3,891.6	$3,728.4	$4,233.0	$15,179.0	$16,806.3	$19,126.1	$21,998.8
Gross Income	$9,764.0	$4,154.0	$5,055.4	$5,165.6	$5,032.0	$19,407.0	$21,937.7	$27,192.9	$33,417.2
Gross Margin	*48.7%*	*55.5%*	*56.5%*	*58.1%*	*54.3%*	*56.1%*	*56.6%*	*58.7%*	*60.3%*

HISTORICAL ZACKS RECOMMENDATIONS



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