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Zacks Small-Cap Research

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Transgenomic Inc. (TBIO-OTC)

TBIO: Miss In Q3. ScoliScore/C-GAAP Should Drive Clinical Lab Revs in 2013

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	01/12/2011
Current Price (11/08/2012)	$0.82
Target Price	**$2.50**

OUTLOOK

New product launches will help drive revenue in the clinical lab business. C-GAAP (Plavix response) test could be a winner for TBIO. ScoliScore looks like a needle-mover too. TBIO recently added headcount to support a bigger roll-out of both tests and expects this to really take hold starting in 2013.

Early indications also suggest TBIO's novel, ultra-sensitive ICE COLD PCR testing technology is garnering significant interest from pharma companies and medical institutions. Key to longer-term revenue growth will be to gain further traction in the pharmacogenomics segment, revenue from which has been somewhat disappointing but will hopefully p/u in 2013 with increased activity from key customers. We are maintaining our Outperform rating. Our per share price target is $2.50.

SUMMARY DATA

52-Week High	**$1.44**
52-Week Low	**$0.70**
One-Year Return (%)	**-31.20**
Beta	**1.78**
Average Daily Volume (sh)	**90,511**
Shares Outstanding (mil)	**72**
Market Capitalization ($mil)	**$62**
Short Interest Ratio (days)	**0.22**
Institutional Ownership (%)	**9**
Insider Ownership (%)	**2**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**5.4**
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	**Above Avg.,**
Type of Stock	**Small-Blend**
Industry	**Med Instruments**

ZACKS ESTIMATES

Revenue
(in '000 of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	7,480 A	7,667 A	8,253 A	8,571 A	31,971 A
2012	7,206 A	9,093 A	7,889 A	9,179 E	33,367 E
2013					40,069 E
2014					48,822 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.06 A	-$0.13 A	-$0.03 A	$0.00 A	-$0.22 A
2012	-$0.05 A	-$0.01 A	-$0.04 A	-$0.02 E	-$0.12 E
2013					-$0.07 E
2014					-$0.02 E

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

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WHAT'S NEW…..

Q3 2012 RESULTS

Transgenomic reported financial results for Q3 ending September 30, 2012 on November 8th. Revenue fell just over 4% yoy and was well below our estimate due to relatively disappointing numbers from the Pharmacogenomics and Instruments/Diagnostics segments. While Clinical Lab revenue was dead-on with our $4.5 million estimate, the 10% yoy growth in this segment was more than offset by a very poor showing in Pharmacogenomics ($220k, -60% yoy) and Instruments ($3.2 million, -12% yoy).

As a reminder, Pharmacogenomics activity can be highly variable q-to-q, largely dependent on customer directives and not in direct control of TBIO which makes forecasting this line difficult on a short-term basis. Nonetheless Pharmacogenomics revenue in aggregate has disappointed over the first nine months of the year - which we think relates at least in part to longer than anticipated timelines (and potentially delays) of TBIO's phase III clinical trial customer(s). TBIO is still awaiting the green-light from a pharma customer to commence processing for a phase III trial - our model had assumed this work would have already commenced - we are now pushing this assumption and the related revenue back to 2013.

Relative to the Instruments/Diagnostics business, management noted that while they sold more instruments in the quarter compared to the year earlier period, revenue was significantly softer as the majority were sold through Menarini, their European distributor (at a lower average price point relative to the year earlier period which were mostly non-distributor sales). Going forward we continue to expect bioconsumables to be the major revenue driver of the Diagnostics business, particularly with the launch of several cancer marker kits using ICE COLD PCR which should begin to show a meaningful contribution in 2013.

The quarter did have some important positive highlights, namely the ScoliScore acquisition and new collaborations with ICE COLD PCR (with NYU and Univ of Nebraska). Management also noted that C-GAAP, TBIO's Plavix response test, has seen strong physician interest and was a substantial contributor to the 10% growth in Clinical Lab revenues. ScoliScore, as we noted in our 8/9/12 Investor Note (see below), looks like a very solid addition to TBIO's Clinical Lab business and one which we think will make a meaningful top and bottom line impact as early as next year.

The collaboration with NYU's Langone Medical Center involves the use of ICE COLD PCR in the detection of mutations in the blood related to non-small cell lung cancer and response to existing a new therapies. Similar to the collaboration with the MD Anderson Cancer Center (Univ of Texas), the NYU study will focus on circulating tumor cells (CTCs) and use TBIO's CTC capture ScreenCell devices. The collaboration with the University of Nebraska Medical Center involves the use of ICE COLD PCR in the early detection of pancreatic cancer and is being funded by a $100k NIH grant awarded to TBIO which was announced in August. The project could result in a diagnostic test for early stage pancreatic cancer which is almost always fatal if not caught early.

Revenue
Q3 revenue was $7.9 million, down 4% y-o-y and $1.1 million (13%) less than our $9.0 million estimate. The difference came from a $555k variance ($220k A vs. $775k E) in Pharmacogenomics revenue and a $607k variance ($3.2 million A vs. $3.8 million E) in Instruments/Diagnostics with Clinical Lab revenue in-line with our $4.5 million estimate.

Gross Margin
Similar to Q1 and Q2, GM came in well softer than our estimate. Q3 GM was 48% compared to our 55% estimate. Lower than expected revenue from Pharmacogenomics continues to impact GM due to the fixed laboratory costs - while this segment should be highly leverageable with growing revenue, margins will be almost non-existent at the ~$250k and lower revenue level (this quarter was $220k). Management also noted that they've made some investments related to their Clinical Lab segment to improve efficiencies in anticipation of increased sales of C-GAAP and ScoliScore which slightly impacted margins in that business in Q3. We continue to look for GM to widen with growing revenues in Pharmacogenomics, an increase in contribution from the higher margin bionconsumables (as opposed to instruments) from the Diagnostics/Tools business and potentially (depending on reimbursement) very beefy margins from ScoliScore as well as C-GAAP.

Net Income / EPS
EPS and net income were ($0.04) and ($2.9) million compared to our ($0.02) and ($1.2) million estimates. The miss coming from both a softer top-line as well as SG&A materially higher ($5.6 million A vs. $5.2 million E). At least a portion of the relatively high SG&A was additions to the sales force for ScoliScore (as well as C-GAAP). TBIO also took a slightly higher bad debt charge in the quarter. SG&A expense was 71% of revenue in Q3 - we expect this to moderate significantly in Q4 and we continue to look for this to come down closer to 50% over the next several years as revenue grows.

Cash
Transgenomic exited Q3 with $8.8 million in cash and liquid investments, compared to $15.3 million at the end of Q2. The $6.5 million reduction in cash balance included $2.6 million used in operating activities and $3.9 million related to the ScoliScore acquisition.

The remaining $5.5 million of the PGx Health note is carried as a current liability. TBIO has noted in their 10-Q's over the past several quarters that "We have contacted PGx on numerous occasions to make arrangements for the prepayment to PGx in accordance with the terms of the Note, as well as to coordinate the timing of the prepayment. However, PGx has not responded to any of our outreach efforts. We made our initial payment of $1.2 million under the Note in June 2012, and intend to continue to comply with the original terms of the Note. "

OUR 2013 OUTLOOK
We've again made some slight tweaks to our model. We model 2013 revenue of $40.0 million, implying growth of 20% from 2012. We look for Laboratory Services and Instruments to generate revenue of $25.6 million (+27%) and $14.5 million (+10%), respectively. We think net income and EPS come in at ($5.3) million and ($0.07).

Laboratory Services
Our $25.6 million revenue estimate for Laboratory Services assumes meaningful contribution from new products in the clinical lab segment, including the C-GAAP Plavix response, atrial fibrillation, ScoliScore, and nuclear mitome tests. Very early indications are that there is real interest in TBIO's C-GAAP test. TBIO began adding headcount to promote C-GAAP earlier in 2012 and, with Medicare coverage now in place, expects the roll-out to gain even more momentum going into 2013. Management also has high expectations for ScoliScore. While reimbursement is currently somewhat spotty and payer specific, this could improve over time and with increased awareness. TBIO has already added headcount to help support their sales and marketing efforts of ScoliScore and thinks, depending on the level and prevalence of reimbursement, that they could break even on the $4.4 million purchase price in relatively short order. We model just over $2 million in ScoliScore revenue in 2013 - which, based on management's expectations could end up being highly conservative. In fact we estimate $2 million is about flat from the level of sales ScoliScore was generating prior to TBIO's acquisition - and we expect TBIO will be putting significantly more effort and resources behind sales/marketing of the test than did the predecessor. We will adjust our modeled sales of ScoliScore if and when it's reasonable to do so.

As noted, Pharmacogenomics revenue has been somewhat lackluster recently, but will hopefully rebound with the initiation of work on one or more phase III clinical trials which management has alluded to. Clearly there's real and growing interest in ICE COLD PCR which is further reinforced by the ongoing and recent collaborations with elite medical institutions. Management continues to indicate that there is substantial interest in their technology from some prominent names in pharma and they continue to score more and more clinical trials business. This remains the impetus to our expectations of significant growth in pharmacogenomics revenue over the longer term. And, as noted, due to its scalability, as this business grows TBIO's overall gross margins and profitability should accelerate at an even faster pace.

Instruments
We model the equipment portion of Transgenomic's instrument business to grow in the low single digits in 2013 largely as a result of the recent roll-out of WAVE MCE to Menarini. Meanwhile we look for the consumables portion of the diagnostic tools business to turn in double digit growth in 2013, benefitting from the launch of several new ICE COLD PCR cancer kits (K-RAS, BRAF, EGFR, PIK3CA).

RECOMMENDATION / VALUATION

We value TBIO using comp P/S ratio. Based on an average P/S comp of 4.7x, Transgenomic is valued at approximately to $2.50/share. The shares currently trade at $0.82, indicating significant upside. We are maintaining our Outperform rating.

ScoliScore Could Be A Needle-Mover For TBIO *(from our 8/9/12 Investor Note)*

Yesterday (8/28/2012) Transgenomic (TBIO) announced an agreement to acquire ScoliScore, a saliva-based genetic test to determine the likelihood that a mild curvature in the spine of adolescents will progress to one which eventually requires surgery.

In return for global rights to the ScoliScore Adolescent Idiopathic Scoliosis (AIS) Prognosis Test, TBIO will pay Axial Biotech $4.4 million in cash. The deal, which still needs to be ratified by Axial shareholders, is expected to close by October 1st (the deal was closed subsequent to this Investor Note).

Scoliosis is a side-to-side curvature of the spine (an "S" or "C" shape). Approximately 65% of scoliosis cases are characterized as idiopathic (unknown cause), with genetics identified as having a clear link to the disease. Mild (10 - 25 degree curve of the spine) AIS afflicts approximately 100k adolescents in the U.S. Although typically less 5% of cases result in the curvature of the spine progressing to the point where surgery is required, most patients will undergo strict monitoring which often includes regularly x-rays of the lumbar region. Lumbar x-rays expose patients to potentially unhealthy doses of radiation (studies have shown that radiation from lumbar x-rays is about 30 times that of chest x-rays), which can be particularly problematic in children.

The ScoliScore assay is indicated for use with Caucasians ages 9 to 13 with a mild curve of the spine. The test uses a saliva sample and looks at 53 specific DNA markers. Results of the test classify a patient as either low risk (1-50), intermediate risk (51-180), or high risk (181-200). On average, approximately 75% of mild AIS patients are classified as low risk. The test has shown a very high level of accuracy (negative predictive value of 99%) in predicting which low-risk patients will not progress to where surgical intervention will be required. While the label suggests using it as an adjunct to current clinical information including x-rays, the high accuracy indicates it may offer ~75% of the ~100k adolescents diagnosed with mild AIS every year the potential to forego (or at least reduce) the stringent, potentially unhealthy and costly monitoring associated with AIS.

Development of ScoliScore included validation on over 10,000 patient samples. It is the most rigorously studied genetic test for scoliosis and the only one on the market with high predictive value and accuracy.

The test was co-developed and is currently marketed by DePuy Spine (part of Johnson and Johnson) and Smith and Nephew (SNN), both of which specialize in orthopedic and spine devices, not genetic tests. JNJ and SNN are also relative behemoths compared to TBIO, with potentially less incentive to dedicate efforts to market the test (i.e. - tough to move the needle with these large companies).

We think ScoliScore could be a very solid fit for TBIO, offering meaningful top-line and margin expansion. The company will leverage their sales force (although they may add a handful of sales people) with the test processed at their existing lab facilities with existing personnel. While there is only spotty

(estimate ~30%) reimbursement, given the ability to leverage their infrastructure, we estimate the acquisition could be highly profitable for TBIO with just the existing already established base of physicians using the test. We also expect that TBIO will be aggressive in marketing the test, which could potentially significantly grow sales volumes of ScoliScore as well as potentially increasing the price point (which we estimate is already very high margin).

FINANCIAL MODEL

Transgenomic Inc.

	2011 A	Q1A	Q2A	Q3A	Q4E	2012 E	2013 E	2014 E	2015 E
Laboratory Services	$18,360.0	$4,001.0	$5,808.0	$4,718.0	$5,702.0	$20,229.0	$25,624.0	$33,459.9	$44,997.6
% of total revenue	57.4%	55.5%	63.9%	59.8%	62.1%	60.6%	63.9%	68.5%	73.2%
YOY Growth	*268.7%*	*6.5%*	*19.4%*	*1.7%*	*11.8%*	*10.2%*	*26.7%*	*30.6%*	*34.5%*
Instruments	$13,640.0	$3,205.0	$3,285.0	$3,171.0	$3,477.0	$13,138.0	$14,445.0	$15,362.0	$16,511.7
% of total revenue	42.7%	44.5%	36.1%	40.2%	37.9%	39.4%	36.1%	31.5%	26.8%
YOY Growth	*-9.5%*	*-13.9%*	*17.3%*	*-12.3%*	*-0.7%*	*-3.7%*	*9.9%*	*6.3%*	*7.5%*
Total Revenues	$31,971.0	$7,206.0	$9,093.0	$7,889.0	$9,179.0	$33,367.0	$40,069.0	$48,821.9	$61,509.3
YOY Growth	*59.5%*	*-3.7%*	*18.6%*	*-4.4%*	*7.1%*	*4.4%*	*20.1%*	*21.8%*	*26.0%*
Laboratory Services	$7,916.0	$2,353.0	$2,691.0	$2,371.0	$2,432.8	$9,847.8	$10,476.2	$12,384.7	$14,983.1
Lab Svcs margin	*56.9%*	*41.2%*	*53.7%*	*49.7%*	*57.3%*	*51.3%*	*59.1%*	*63.0%*	*66.7%*
Instruments	$6,255.4	$1,749.0	$1,840.0	$1,718.0	$1,947.1	$7,254.1	$7,352.5	$7,727.1	$8,189.8
Instruments margin	*54.1%*	*45.4%*	*44.0%*	*45.8%*	*44.0%*	*44.8%*	*49.1%*	*49.7%*	*50.4%*
Cost of Revenues	$13,532.0	$4,102.0	$4,531.0	$4,089.0	$4,379.9	$17,101.9	$17,828.7	$20,111.8	$23,172.9
Gross Income	$18,439.0	$3,104.0	$4,562.0	$3,800.0	$4,799.1	$16,265.1	$22,240.3	$28,710.1	$38,336.4
Gross Margin	*57.7%*	*43.1%*	*50.2%*	*48.2%*	*52.3%*	*48.7%*	*55.5%*	*58.8%*	*62.3%*
SG&A	$19,154.0	$4,994.0	$5,278.0	$5,559.0	$5,571.7	$21,402.7	$23,560.5	$26,656.8	$30,877.7
% SG&A	*59.9%*	*69.3%*	*58.0%*	*70.5%*	*60.7%*	*64.1%*	*58.8%*	*54.6%*	*50.2%*
R&D	$2,219.0	$549.0	$654.0	$668.0	$633.0	$2,504.0	$2,887.0	$3,166.0	$3,440.0
% R&D	*6.9%*	*7.6%*	*7.2%*	*8.5%*	*6.9%*	*7.5%*	*7.2%*	*6.5%*	*5.6%*
Restructuring charges	$41.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($2,975.0)	($2,439.0)	($1,370.0)	($2,427.0)	($1,405.6)	($7,641.6)	($4,207.3)	($1,112.6)	$4,018.7
Operating Margin	*-9.3%*	*-33.8%*	*-15.1%*	*-30.8%*	*-15.3%*	*-22.9%*	*-10.5%*	*-2.3%*	*6.5%*
Interest income, net	($954.0)	($273.0)	($231.0)	($207.0)	($185.0)	($896.0)	($400.0)	$0.0	$100.0
Expense on preferred stock	($6,066.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other income	$258.0	$20.0	$1,008.0	($6.0)	$0.0	$1,022.0	$0.0	$0.0	$0.0
Pre-Tax Income	($9,737.0)	($2,692.0)	($593.0)	($2,640.0)	($1,590.6)	($7,515.6)	($4,607.3)	($1,112.6)	$4,118.7
Taxes	$46.0	$4.0	($30.0)	$114.0	$34.8	$122.8	$0.0	$0.0	$0.0
Tax Rate	*-0.5%*	*-0.1%*	*5.1%*	*-4.3%*	*-2.2%*	*-1.6%*	*0.0%*	*0.0%*	*0.0%*
Preferred Dividends	($1,009.0)	($165.0)	($165.0)	($165.0)	($165.0)	($660.0)	($660.0)	($660.0)	($660.0)
Net Income	($10,792.0)	($2,861.0)	($728.0)	($2,919.0)	($1,790.4)	($8,298.4)	($5,267.3)	($1,772.6)	$3,458.7
YOY Growth	*-244.4%*	*-5.8%*	*-88.4%*	*88.9%*	*-3297.1%*	*-23.1%*	*-36.5%*	*-66.3%*	*-295.1%*
Net Margin	*-33.8%*	*-39.7%*	*-8.0%*	*-37.0%*	*-19.5%*	*-24.9%*	*-13.1%*	*-3.6%*	*5.6%*
EPS	($0.22)	($0.05)	($0.01)	($0.04)	($0.02)	($0.12)	($0.07)	($0.02)	$0.04
YOY Growth	*243.5%*	*-25.9%*	*-92.0%*	*30.1%*	*-2291.5%*	*-45.4%*	*-40.3%*	*-72.0%*	*-292.9%*
Diluted Shares O/S	49,361	62,684	71,646	71,646	72,250	69,556	74,000	89,000	90,000

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