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Zacks Small-Cap Research

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Interleukin Genetics (ILIU-OTC)

ILIU: PerioPredict Roll-Out Progressing

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	03/28/2011
Current Price (08/14/14)	$0.25
Target Price	**$1.00**

OUTLOOK

Key UofM PST (periodontal disease) test study results were overwhelmingly positive and published in June 2013. Dental plans are now covering cost of test. PerioPredict launched in early 2014 and indications are that feedback from dental providers and patients is positive. Game plan is to broaden commercial footprint and increase number of patients enrolled in plans covering the test. Company talking with other insurers and dental groups about adopting the test. ILIU has been very active in building awareness and in sales/mktg while conserving resources.

Another high potential pipeline test, for OA, also addresses increasing demand for personalized medicine and companion diagnostics. Game plan is to collaborate with a partner to bring the test to mrkt - discussions have already been initiated.

We remain highly positive on ILIU and are maintaining our Outperform rating.

SUMMARY DATA

52-Week High	**$0.44**
52-Week Low	**$0.20**
One-Year Return (%)	**-43.18**
Beta	**1.77**
Average Daily Volume (sh)	**10,533**
Shares Outstanding (mil)	**123**
Market Capitalization ($mil)	**$31**
Short Interest Ratio (days)	**3.49**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**27**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-5.5**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2014 Estimate	**N/A**
P/E using 2015 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in '000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	487 A	852 A	419 A	671 A	2,430 A
2014	488 A	529 A	575 E	827 E	2,419 E
2015					5,502 E
2016					11,805 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.03 A	-$0.02 A	-$0.02 A	-$0.02 A	-$0.08 A
2014	-$0.01 A	-$0.01 A	-$0.01 E	-$0.01 E	-$0.05 E
2015					-$0.03 E
2016					-$0.02 E

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

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Q2 2014: Results In-Line. Anecdotal Evidence Indicates More Progress w/ PerioPredict Roll-Out…

Interleukin reported financial results for the second quarter ending June 30, 2014. Results continue to come in largely in-line with our numbers with a slight beat in the quarter on both the top and bottom lines. The company also continues to do a good job with efficiently managing resources in the initial roll-out of PerioPredict.

And while management has not disclosed specifics in terms of the number of tests returned for processing or number of enrollees in plans covering the test, indications continue to be that early feedback is positive and volume of tests being processed is increasing (although still at a relatively low overall level). On the Q2 call management did provide a little more insight into utilization of PerioPredict - noting that dental offices with ten or more patients with insurance plans that cover the test are using PerioPredict "at a high rate." So while specifics relative to feedback from patients, payers and providers and quantitative metrics such number of enrollees, plans sold and plans up for renewal have yet to be disclosed, we continue to interpret the anecdotal information as very positive for the initial roll-out of PerioPredict.

With this being a novel product with a novel application, we continue to expect the roll-out to be measured as awareness-building may be drawn out and insurance plan renewals are in 6-month increments. Early indications are, however, that substantive progress is being made on both the education-side (to payers, patients, employers and dental practices) and on the enrollment end. The education message to payers and employers is that PerioPredict can lower costs as a result of fewer dental visits, while the patient is afforded better dental care. We think this message is already and will continue to resonate, although as noted, it may take some time.

Revenue
Q2 revenue of $529k was down 38% yoy and but about 13% above our $469k estimate. Included in the revenue number was $92k in "breakage" - related to an accounting change that ILIU began to recognize in Q4 2013 and allows for the recognition of years-earlier deferred revenue from test kits that have yet to be sent back to ILIU for processing (i.e. – given that it's unlikely these test kits will ever be returned for processing – which is when ILIU typically recognizes revenue - ILIU can go ahead and recognize this as revenue).

GM / Operating Expenses / EPS
Q2 GM was 32% compared to our 35% estimate. We continue to expect GM to widen as the PerioPredict test becomes a larger portion of overall revenue. Operating expenses were $1.7M, compared to our $1.8M estimate. The difference largely related to lower SG&A spend - some of which relates to lower sales commissions paid to Amway. Despite increased marketing activities related to the roll-out of PerioPredict, including attendance and presentations at industry conferences, management continues to have a focus on cost-containment and cash preservation - which is also indicative of the lower than modeled operating expenses.

Net loss and EPS were $1.6M and ($0.01), compared to our $1.6M and ($0.01) estimates

Cash
Cash used in operations in Q2 was $1.5M but excluding changes in working capital, cash used in operating activities was $1.4M. The balance sheet remains clean and free of debt and preferred stock. ILIU exited the quarter with $4.2M in cash and equivalents, down from $5.7M at Q1 quarter-end. An additional $5M (gross) could be raised in the near-term if investors in the May 2013 stock sale choose to exercise their option (initially expired 6/30/2014, subsequently extended to expiration on 12/31/14) to purchase their pro rata share of up to an additional $5M of shares.

Add'l Data Published in Journal of Periodontal Research
Additional positive data relative to the utility of PerioPredict was published in the online edition of the Journal of Periodontal Research in early April. The data relates to evidence that PerioPredict can stratify the risk of periodontal disease in multiple ethnicities. The study, titled *Association of interluekin-1 gene variations with moderate to severe chronic periodontitis in multiple ethnicities* included over 1,700 patients of different ethnicities including Caucasians, African Americans, Hispanics and Asians (Chinese). Results of the study indicated that PerioPredict has predictive utility between variations in the IL-1 gene and risk of moderate to severe periodontitis, regardless of ethnicity. In addition the study demonstrated that PerioPredict was able to identify a significant percentage of patients that were at increased risk of periodontitis yet would not have been classified as such had they not been tested with PerioPredict.

This study supplements the pivotal UofM study, results of which were published in June 2013 in the Journal of Dental Research. That study, which included data from over 5,000 patients, showed that the presence of the IL-1 gene is a risk factor for developing periodontitis and that the PerioPredict test has utility in determining the optimal number of dental cleanings a particular patient should have each year (based on the presence of IL-1). The UofM study was instrumental in gaining reimbursement of PerdioPredict from Renaissance Health and has facilitated the launch of the test. We expect the recent data from the ethnicity study to provide additional significant support for use of the test as it indicates that PerioPredict has utility across multiple ethnicities.

Operational Update

All eyes and ears continue to be on details of the roll-out of PerioPredict. While management has not provided specifics in terms of patient enrollment numbers in plans covering the cost of the test nor the number of tests shipped to-date, more qualitative comments on the last several earnings calls have us encouraged that the initial launch is meeting or exceeding expectations. Importantly, management has indicated that utilization of the test by dentists has been strong.



SOURCE: Interleukin Genetics

The test officially became covered by dental insurance when plans from Renaissance Health were introduced on January 1, marking a significant milestone for Interleukin. ILIU has structured the roll-out into multiple phases. Dentists with patients covered by these Right-Sized Dental policies in the initial roll-out began to receive letters in November 2013 informing them that certain of their patients are covered by these plans. This initial phase also included bringing on training staff to ensure dental practices know how to properly use the test. ILIU noted on the Q4 2013 call that in January they shipped PerioPredict test kits to approximately 600 dentists (mostly in Michigan) with patients covered by Right-Sized policies. The company noted on the Q2 2014 call that they are now engaged with 650 dental offices. ILIU has already begun receiving tests back for processing and has been reimbursed for the tests that they have received. Ane cdotal feedback from both patients and dental providers has been positive.

Follow-on phases of the roll-out encompass Renaissance (RHSC) enrolling patients in plans that come up for renewal in the mid-2014 and January 2015. It also involves expansion to insurance carriers besides Renaissance. As a reminder, in November ILIU and Renaissance amended the terms of their agreement. Included in the amendment was removal of a provision that ILIU would only offer the test exclusively to RHSC affiliates for one year following the date that RHSC affiliates first offered these plans.

On the recent conference calls management noted that they have been in active discussions with other insurance carriers in their quest to expand reimbursement of the test and have recently ramped up these efforts. ILIU has recently broadened their scope and is talking with benefits brokers and self-insured regional dental groups, along with insurance carriers about using PerioPredict. And while RHSC/Delta Dental is the largest dental insurance provider, with approximately 58 million covered lives, the dental insurance market is highly consolidated - with only six companies (including Delta) owning about 70%+ of all covered lives. This potentially affords ILIU a captive audience to market to, particularly as payers look for competitive differentiation. The potential for PerioPredict to lower costs for both payers and employers offers a compelling marketing message.

We expect an ongoing effort on the part of ILIU in terms of building awareness about the test and the benefits to patients, dentists and insurance carriers. As we have reported in the recent past, the company has been very

active on this front which we think likely benefitted the initial launch of the test. Key will be to maintain this momentum and broaden the message as ILIU looks to expand their commercialization footprint. While this, along with additional marketing, sales and training resources will almost certainly keep operating expenses somewhat elevated over the near term, the expectation is that these investment s will recouped in fairly short order with a steepening in the revenue growth rate.

Management has been very active on awareness-building activities related to PerioPredict. The company recently presented at several industry conferences including the Annual Meeting of the American Association of Dental Insurance Consultants, the American Academy of Periodontology and at the Personalized Medicine World Conference. RHSC is also active in promoting the utility and benefits of the test. Awareness also appears to be spreading beyond just the dental industry and to the broader companion diagnostics/personalized medicine market as well. In fact, PerioPredict was specifically referenced in a recent case report by the Personalized Medicine Coalition as an example of the importance and recent expansion of companion diagnostics.

As the majority of the ~600+ practices that ILIU has already shipped test kits reside in just Michigan, geographic expansion via new RHSC policies and through agreements with other insurance carriers/brokers/dental groups could potentially ramp the covered patient base fairly rapidly (although we continue to expect the roll-out to be a progression with the initial focus on awareness-building). In April ILIU received approval from the NYS Department of Health to offer and process PerioPredict - with this approval ILIU can now offer the test in all 50 states.

As we noted in our previous updates, while we now do not expect significant revenue related to processing of the PerioPredict test during 2014, the fact that policies covering the test are in place and the roll-out is now underway (and seemingly successful) are important milestones and indicative that meaningful progress has been made over the last several months. We continue to expect a much more meaningful contribution from the test in 2015.

Product Update

We think management remains intently focused not only near-term commercialization of their late-stage pipeline but also on reviving the recent lagging sales of their weight management test. While the main and most important focus right now is with the ongoing roll-out of the PerioPredict test, the osteoarthritis test which could have enormous potential, particularly (at least initially) as a companion diagnostic in drug development clinical trials, could be next in-line as a revenue driver for ILIU.

> Weight Management Test: per the agreement signed in 2012 with Amway Europe, the test became available in certain parts of Europe. ILIU receives a royalty for each test sold. Relative to the Amway (U.S.) bundled weight loss product, while it's currently unknown how this may affect sales over the long term, management remains focused on reviving growth of the weight management test (and the other Inherent Health products).

> Osteoarthritis (OA) Test: the game plan continues to be to collaborate with a partner to bring the test to market. A paper with findings of the company's (in collaboration with Univ of North Carolina) 1,154-patient study validating the test as a predictor of progression of knee osteoarthritis was published in the online version of Osteoarthritis and Cartilage. The study found that a specific gene pattern was indicative of increased risk of progression of knee osteoarthritis to a severe state. This was particularly true for individuals with high body mass index. While ILIU continues to be intently focused on commercialization of PerioPredict, their current game plan with the OA test includes looking for a commercialization partner. The test could have enormous potential value as a companion diagnostic in enrollment selection of clinical studies for the development of drugs to treat osteoarthritis, currently a huge unmet need.

> Periodontal Disease Test (PerioPredict or PST): As a reminder, positive top-line clinical trial data of their PST test was released in early August 2012. In February 2013 ILIU penned the initial agreement with Renaissance Health Service Corp (RHSC) relative to reimbursement of the test (this agreement was slightly modified in November). The dental plans covering the PST test, which are called "Right-Sized Dental" were introduced in January 2014 and have already began reimbursing for the test.

ILIU is approaching the roll-out in several phases. Dentists with patients covered by these Right-Sized Dental policies in the initial roll-out began to receive letters in November 2013 informing them that certain of their patients are covered by these plans. This initial phase also included bringing on training staff to ensure dental practices know how to properly use the test. ILIU noted on the Q4 call that in January they shipped PerioPredict test kits to approximately 600 dentists (mostly in Michigan) with patients covered by Right-Sized policies. The company noted on the Q2 2014 call that they are now engaged with 650 dental offices. ILIU has already begun receiving tests back for processing and has been reimbursed for the tests that they have received.

Follow-on phases of the roll-out encompass Renaissance (RHSC) enrolling patients in plans that come up for renewal inmid-2014 and January 2015. It also involves expansion to insurance carriers and other potential partners besides Renaissance. As a reminder, in November ILIU and Renaissance amended the terms of their agreement. Included in the amendment was removal of a provision that ILIU would only offer the test exclusively to RHSC affiliates for one year following the date that RHSC affiliates first offered these plans.

On the recent conference calls management noted that they have been in active discussions with other insurance carriers in their quest to expand reimbursement of the test and have recently ramped up these efforts. ILIU has recently broadened their scope and is talking with benefits brokers and self-insured regional dental groups, along with insurance carriers about using PerioPredict. And while RHSC/Delta Dental is the largest dental insurance provider, with approximately 58 million covered lives, the dental insurance market is highly consolidated - with only six companies (including Delta) owning about 70%+ of all covered lives. This potentially affords ILIU a captive audience to market to, particularly as payers look for competitive differentiation. The potential for PerioPredict to lower costs for both payers and employers offers a compelling marketing message.

The company had previously began preparing for the roll-out which included increasing processing throughput of their lab to handle the anticipated increase in demand.

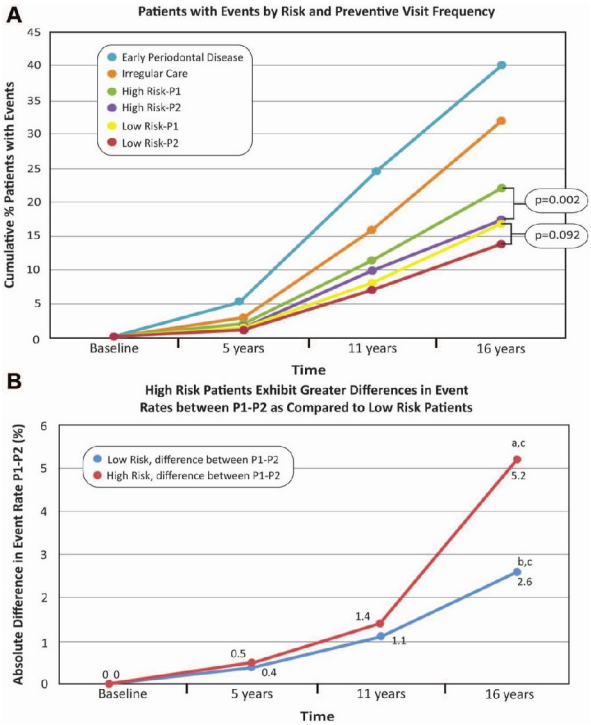
Interleukin has also had a dedicated focus on building awareness about PerioPredict which almost certainly benefitted the early success of the launch. The company recently hired a Chief Marketing Officer to spearhead the introduction of the test and to generate early awareness. These efforts have included a guest editorial by ILIU published in August 2013 in the Journal of the American Dental Association, which reaches over 200k dentists, titled *Personalized Medicine Enters Dentistry: What Might This Mean For Clinical Practice.* The company has also been and will continue to be very active in attending and presenting at key dental industry conferences and events to help their awareness building efforts. This includes recent presentations at the Annual Meeting of the American Association of Dental Insurance Consultants, the American Academy of Periodontology and at the Personalized Medicine World Conference.

University of Michigan PST Study (a refresher)
In August 2010 Interleukin announced an agreement with the University of Michigan for a large study to test whether certain risk factors, including genetic variations, can help guide better medical intervention of periodontal disease and improve patient outcomes. Funding for the study was provided by Renaissance Health Service, parent company of a large and diverse set of insurance companies focused on dental health. A new version of Interleukin's PST test was used in the study for identification of predictive risk factors of periodontal disease to confirm results of earlier studies. The prospective study examined 16 years worth of data from over 5,000 patients taken from a large dental claims database. The hypothesis for the study was to determine whether more than one dental cleaning per year is value-added for low risk patients and how many cleanings are optimal for high risk patients. Primary endpoint of the study was tooth loss at 10 and 15 years. The study was the largest ever done to evaluate the application of genetic information for the prevention of periodontal disease.

The study commenced in late 2010 and top-line data was released in August 2012. The data showed exactly what Interleukin had hoped, that high risk patients are likely to benefit from more than one cleaning per year while low risk patients are not. Specifically the data showed that there was no significant difference between two dental cleanings and one dental cleaning in reducing the number of tooth extractions in the low-risk patient population (13.8% vs. 16.4%, 95% CI, p=0.092). By contrast there was a significant difference between two dental cleanings and one dental cleaning in reducing the number of tooth extractions in the high-risk patient population (16.9% vs. 22.1%, p=0.002).

Per the trial protocol, high risk were categorized as having one or more of the following risk factors; smokers, diabetic or interlukin-1 genotype (ie - PST test positive). Low-risk was categorized has having none of these risk factors. Of particular interest is that the data also shows a highly significant ($p<0.001$) correlation between the number of positive risk factors and extractions - implying that all risk factors (i.e. - including PST) are indicative of risk of tooth loss.

In early June 2013 the study, titled, *Patient Stratification for Preventive Dental Care,* was published in the online version of the Journal of Dental Research.



PST Test market:. Approximately 200 million Americans go to their dentist every year, representing about 400 million total visits with 75% related to regular exams and cleanings. Based on the large market size, the prevalence and potential seriousness of periodontal disease, support from clinical studies that the PST test works, vast distribution (via Renaissance) and support from significant use in clinical practice we think that the test may offer a multi-million dollar opportunity for Interleukin. Using rough estimates the periodontal disease market could be worth as much as $8 billion to Interleukin (assumes 200MM tests at $40 net (our estimate) to Interleukin per test). ILIU has noted that since the initial roll-out that total reimbursement per test is in the range of $125-$200. Capturing just 10% of this (which might be very conservative) equates to an $800 million potential market. Renaissance Health alone, through its family of companies including Delta Dental, touches as many as 58 million covered lives, which is a great start.

The amended agreement with RHSC, which became effective November 2013, allows ILIU to also immediately shop the test to other insurance carriers, which instantly expanded the potential geographic commercial footprint for PerioPredict.

We note that ILIU already had a similar PST test commercialized but that the cost of the test (~ $150) is borne by the consumer, which limits its use. Reimbursement from dental insurers could be a huge catalyst to driving demand and adoption for the test - as such, this agreement with RHSC (as well as potential similar agreements with other carriers) could be the beginning of a new inflection point for ILIU. Periodontal disease is preventable and treatable and if diagnosed earlier, the better likelihood of improved outcomes. The test has already been used over 10,000 times in clinical practice. Interleukin notes in their literature that its PST test is one of the top ten genetic tests in terms of volume and one of the first of a new generation of predictive genetic tests for common diseases in medicine.

OUTLOOK / RECOMMENDATION

We continue to believe that the major near and mid-term growth driver of the company lies with PerioPredict. We think their legacy product suite will experience only flat to moderately positive sales growth, which is unchanged from our recent previous assumptions. We have yet to model any contribution from other pipeline products including the OA test, which could provide some upside to our longer-dated estimates.

While we expect to see some revenue contribution from processing of PerioPredict in 2014, we continue to model only modest revenue growth throughout the remainder of the current year. We expect a greater rate of revenue growth to materialize in 2015 as ILIU begins to realize benefits of increased patient enrollments from mid and year-end plan renewals.

We look for revenue and EPS of $2.4 million / ($0.05) and $5.5 million / ($0.03) in 2014 and 2015, respectively. We are maintaining our Outperform rating. Our price target is $1.00.

FINANCIAL MODEL

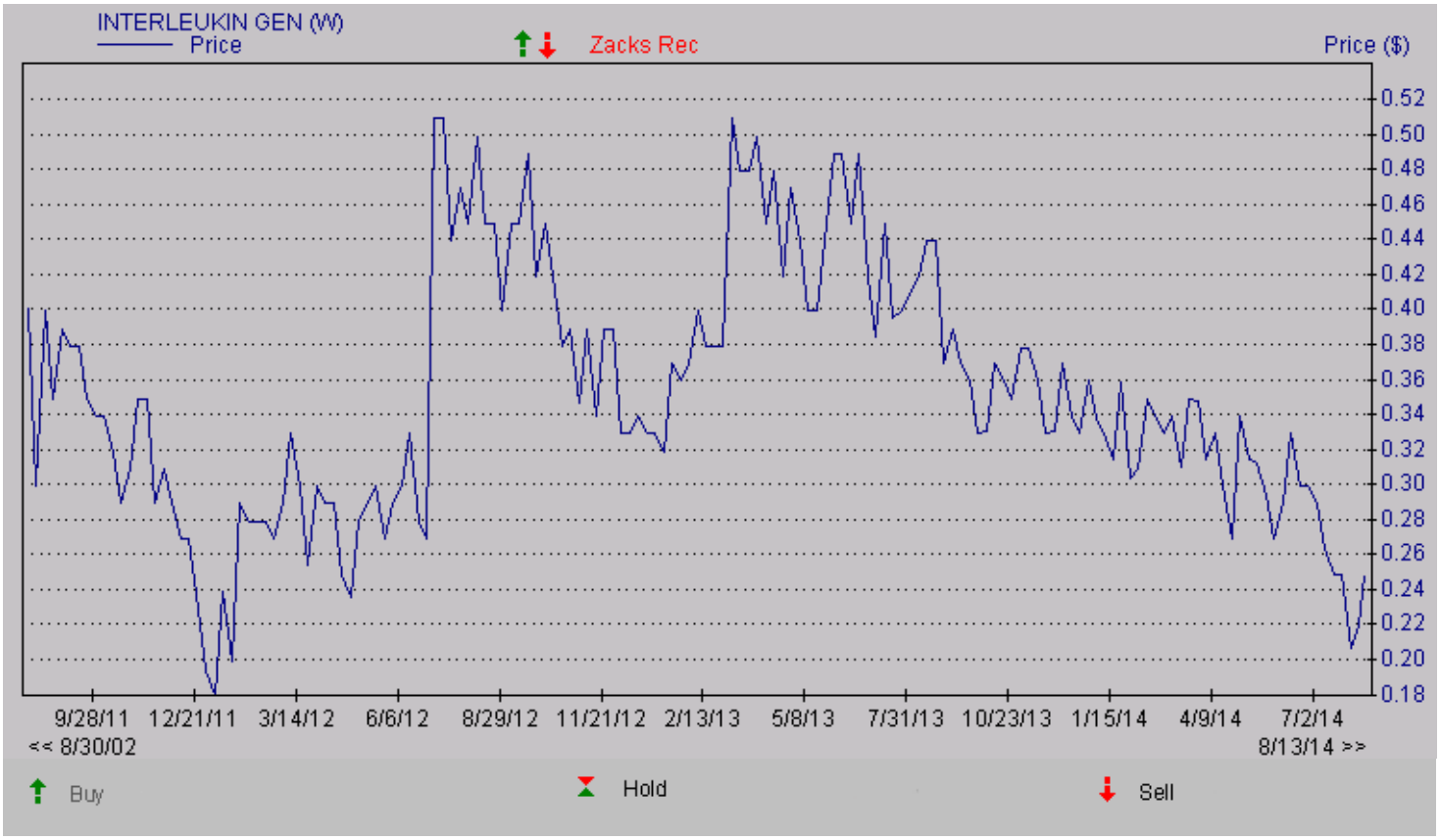
Interleukin Genetics, Inc.

	2013 A	Q1A	Q2A	Q3E	Q4E	2014 E	2015 E	2016 E	2017 E
Genetic testing	$2,168.7	$420.3	$483.2	$535.0	$766.0	$2,204.5	$5,342.0	$11,461.0	$14,908.0
YOY Growth	*0.7%*	*-13.0%*	*-43.1%*	*30.0%*	*80.5%*	*1.7%*	*142.3%*	*114.5%*	*30.1%*
Other	$260.9	$67.2	$45.4	$40.1	$61.3	$214.0	$160.3	$343.8	$447.2
Total Revenues	$2,429.6	$487.6	$528.6	$575.1	$827.3	$2,418.6	$5,502.3	$11,804.8	$15,355.2
YOY Growth	*9.5%*	*0.0%*	*-38.0%*	*37.2%*	*23.3%*	*-0.5%*	*127.5%*	*114.5%*	*30.1%*
Cost of Revenues	$1,632.5	$394.8	$361.7	$391.1	$546.0	$1,693.6	$3,411.4	$6,787.8	$8,445.4
Gross Income	$797.1	$92.8	$166.8	$184.0	$281.3	$725.0	$2,090.9	$5,017.1	$6,909.9
Gross Margin	*32.8%*	*19.0%*	*31.6%*	*32.0%*	*34.0%*	*30.0%*	*38.0%*	*42.5%*	*45.0%*
R&D	$721.6	$209.2	$215.5	$201.0	$198.0	$823.7	$884.0	$1,148.0	$1,347.0
% R&D	*29.7%*	*42.9%*	*40.8%*	*34.9%*	*23.9%*	*34.1%*	*16.1%*	*9.7%*	*8.8%*
R&D QTDP Grant	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
SG&A	$6,564.8	$1,526.6	$1,506.1	$1,562.0	$1,588.0	$6,182.7	$6,402.0	$6,856.0	$7,232.3
% SG&A	*270.2%*	*313.1%*	*284.9%*	*271.6%*	*192.0%*	*255.6%*	*116.4%*	*58.1%*	*47.1%*
Amortization	$109.3	$23.5	$23.5	$23.5	$23.5	$94.1	$140.0	$165.0	$165.0
Operating Income	($6,598.5)	($1,666.5)	($1,578.3)	($1,602.5)	($1,528.2)	($6,375.4)	($5,335.1)	($3,151.9)	($1,834.5)
Operating Margin	*-271.6%*	*-341.8%*	*-298.6%*	*-278.6%*	*-184.7%*	*-263.6%*	*-97.0%*	*-26.7%*	*-11.9%*
Total Other income	($459.4)	$2.0	$1.6	$1.0	$1.0	$5.6	$0.0	$0.0	$0.0
Pre-Tax Income	($7,057.9)	($1,664.5)	($1,576.6)	($1,601.5)	($1,527.2)	($6,369.9)	($5,335.1)	($3,151.9)	($1,834.5)
Taxes	$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%*
Net Income	($7,057.9)	($1,664.5)	($1,576.6)	($1,601.5)	($1,527.2)	($6,369.9)	($5,335.1)	($3,151.9)	($1,834.5)
YOY Growth	*37.8%*	*38.5%*	*-11.2%*	*-26.4%*	*-20.1%*	*-9.7%*	*-16.2%*	*-40.9%*	*-41.8%*
Net Margin	*-290.5%*	*-341.4%*	*-298.3%*	*-278.5%*	*-184.6%*	*-263.4%*	*-97.0%*	*-26.7%*	*-11.9%*
EPS (continuing ops)	($0.08)	($0.01)	($0.01)	($0.01)	($0.01)	($0.05)	($0.03)	($0.02)	($0.01)
YOY Growth	*-44.0%*					*-35.8%*	*-31.3%*	*-42.8%*	*-43.6%*
Diluted Shares O/S	90,450	122,482	122,516	122,555	141,100	127,163	155,000	160,000	165,000

Brian Marckx, CFA

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Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters.
Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 17.0%, Hold/Neutral- 76.3%, Sell/Underperform – 5.7%. Data is as of midnight on the business day immediately prior to this publication.