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Zacks Small-Cap Research

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Interleukin Genetics (ILIU-OTC)

ILIU: PST Closer To Commercialization

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	03/28/2011
Current Price (03/29/13)	$0.50
Target Price	**$1.30**

OUTLOOK

Top-line data of the key UofM PST (periodontal disease) test study was announced on August 6th and looks very positive. This follows other encouraging news that Delta Dental injected $3MM in new financing into ILIU, a clear indication (in our opinion) of confidence in ILIU's PST test.

In 2013 ILIU signed initial agreement covering dental insurance reimbursement of PST. ILIU already preparing for the PST insurance-supported roll-out including hiring Chief Mktg Officer and increasing throughput of their lab. The next steps leading up to roll out of the high-potential PST test are publication of the full data and Renaissance Health/Delta Dental selling their plans covering the test to their customer base. We remain highly positive on ILIU and are maintaining our Outperform rating and $1.30 price target.

SUMMARY DATA

52-Week High	**$0.55**
52-Week Low	**$0.23**
One-Year Return (%)	**42.83**
Beta	**1.95**
Average Daily Volume (sh)	**18,353**
Shares Outstanding (mil)	**37**
Market Capitalization ($mil)	**$18**
Short Interest Ratio (days)	**3.49**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**1**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-30.6**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2013 Estimate	**N/A**
P/E using 2014 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**N/A**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in '000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	677 A	799 A	420 A	339 A	2,219 A
2013	455 E	508 E	565 E	575 E	2,103 E
2014					9,006 E
2015					21,519 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	-$0.04 A	-$0.03 A	-$0.03 A	-$0.03 A	-$0.14 A
2013	-$0.03 E	-$0.02 E	-$0.02 E	-$0.02 E	-$0.10 E
2014					-$0.03 E
2015					$0.00 E

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

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Q4 2012 RESULTS / INITIAL AGREEMENT W/ RENAISSANCE HEALTH

Q4 Results

Interleukin reported financial results for the fourth quarter ending December 31, 2012 on March 28th. Revenue again came in relatively soft and below our number, yet net income / EPS actually came in better than our estimate as a result of ILIU's ever stringent cost control measures which have significantly trimmed operating expenses. Management noted on the call that revenue may have been impacted by Amway launching a new weight management program which includes ILIU's weight management test within a bundled weight loss product, thereby potentially negatively affecting sales of the weight management test through their partner stores.

Revenue
Q4 revenue of $339k was down 41% yoy, down 19% sequentially and about 51% less than our $689k estimate. As noted, the relative softness in revenue was attributed to Amway's new bundled weight loss product. As we've noted in the past, we view ILIU's pipeline, particularly their PST and osteoarthritis tests, as the major catalysts for long-term revenue growth of the company and, as such, the relative weakness in revenue from the current suite of products is less meaningful from a mid-to-long term investment perspective.

GM / Operating Expenses / EPS
GM was 15% versus our 49% estimate. The difference, also directly attributable to the softness in revenue and the fixed-cost portion of COGS. Relative to operating expenses, management continues to do a great job of wringing out costs with operating expenses coming in well below where we estimated them the last three straight quarters. In Q4 operating expenses were $1.1 million, down 15% sequentially and significantly lower than our $1.6 million estimate. Net loss and EPS were $1.2 million and ($0.03), ahead of our $1.4 million (loss) and ($0.04) estimates despite the lower than estimated revenue.

Cash
During Q4 ILIU was able to extend the maturity of the $14.3 million (fully-tapped) Pyxis credit facility from November 30, 2012 to March 31, 2014. And as a reminder, in June 2012 ILIU raised $3 million (gross, $2.7 million net) in financing from the sale of convertible preferred stock to Delta Dental.

Cash used in operations in Q4 and for the full-year 2012 were $1.3 million and $4.5 million. We ballpark estimated cash burn of about $1 million/quarter in 2013, which should decrease upon commercialization of the PST test (early 2014?). ILIU exited 2012 with $1.2 million in cash and equivalents. Management expects to raise additional operating capital (equity or debt) in the very near term.

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 to get the PST test commercialized and supported by dental insurance reimbursement, 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 last year with Amway Europe, the test will be available in certain parts of Europe beginning in 2013. ILIU will receive 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 going forward, management made it clear on the call that they believe there is real potential opportunity to revive growth of the weight management test (and the other Inherent Health products) during 2013 and beyond.

> Osteoarthritis 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 submitted for publication. Following publication ILIU will seek to 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 (PST): As a reminder, positive top-line clinical trial data of their PST test was released in early August 2012 (see our Investor Note below). ILIU just recently penned the initial agreement with Renaissance Health Service Corp (RHSC) relative to reimbursement of the test. The dental plans covering the PST test will reimburse for one cleaning per year as standard or two cleanings if the PST test determines the patient is at high risk of periodontal disease. A manuscript has been submitted for publication in a peer-reviewed journal - a prerequisite for RHSC's affiliates (Delta Dental) to begin marketing dental plans that cover the PST test is that the article must be accepted by May 31, 2013. While there's essentially no insight into if or when the article may be accepted or published, clearly the hope is that it will happen in the near-term. The next steps involve Delta Dental putting together the marketing material and selling the plans for plan periods beginning Jan 2014 to their customer bases (which initially covers 8 states). If all goes well, the Delta Dental plans incorporating the PST test will be finalized and plan participants will be notified by mid-to-late next year for those policies that renew in early 2014. ILIU noted that they are already preparing for the roll-out which included hiring a Chief Marketing Officer in January to spearhead the launch and increased processing throughput of their lab to handle the anticipated increase in demand.

Initial Agreement With Renaissance Health

Interleukin penned an initial agreement with Renaissance Health Service Corp (RHSC) relative to reimbursement of the company's PST test. The publicly released portions of the agreement, filed in an 8K on 3/1/13, outlines in somewhat general terms the nature of the guaranteed pricing provisions that ILIU will provide for processing of the tests, which are dependent on RHSC hitting certain milestones relative to rolling out appropriate dental plans covering the test.

In particular, ILIU will process the PST tests at a fixed price (not disclosed) for RHSC's affiliates and in the event that ILIU offers the test to other parties for a lower price, this lower price will also be applicable to processing of RHSC affiliates' tests for the 3-year term (through 2/25/2016) of the agreement. Milestones that RHSC must meet for this pricing arrangement to remain in place are that 1) their affiliates must develop and offer dental plans that reimburses for the PST test and which a "significant portion" of the affiliate's customers are eligible for and 2) prior to a specified date (not disclosed), RHSC's affiliates must have sold policies for these dental plans for the year beginning 1/1/2014.

ILIU notes in the filing that since timing of the launch of these dental plans is highly uncertain, that they do not expect any significant revenues from this agreement until at least Q1 2014 and potentially substantially later. This is largely in-line with our prior and current expectations and reflected in our assumptions in our financial model for ILIU. And while the agreement probably provides somewhat substantial wiggle-room as far as timing of the launch of the dental plans (notwithstanding the milestones), we view consummation of this agreement as clear positive as it marks the most tangible step towards tying the PST test to dental insurance reimbursement. Given that the PST test is what we expect to be a major catalyst to ILIU's long-term revenue growth (assuming reimbursed by insurance), this is a meaningful event.

OUTLOOK / RECOMMENDATION

We think it's likely that ILIU's suite of currently commercialized products will experience only flat to moderately positive sales growth, which is unchanged from our recent previous assumptions and that the major future growth driver of the company lies with its PST test (and potentially other pipeline tests including their osteoarthritis test).

We continue to model only modest revenue growth until after substantial commercialization of the reimbursable PST test (we model to start in 2014). We look for revenue and EPS of $2.1 million / ($0.10) and $9.0 million / ($0.03) in 2013 and 2014, respectively. We are maintaining our $1.30 price target and Outperform rating.

Positive PST Study Top-Line Data (*per our 8/6/12 investor note*)

This morning (8/6/2012) Interleukin announced that the University of Michigan revealed top-line results of the eagerly awaited PST test study. The top-line data is positive, in favor of Interleukin's PST study showing efficacy on the primary endpoint, change in tooth loss based on patient risk category.

The study, officially titled *Periodontal Disease Prevention Study: A Retrospective Cohort Study to Assess the Effect of Genetics and Dental Preventive Care on Periodontal Disease* is funded by Renaissance Health Service/Delta Dental and conducted by the University of Michigan. It examined 16 years worth of data from over 5,000 patients taken from a large dental claims database. It is the pivotal study which is expected to show that certain risk factors, including a positive result on ILIU's PST genotyping test, can help predict periodontal disease and determine the optimal number of dental cleanings per year, which will provide support to reimburse for the PST from dental insurance providers.

Top-line data from the study showed exactly what Interleukin 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%, 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, patients were categorized as low risk of tooth loss if they were non-smokers, did not have diabetes and were PST test negative. High risk were smokers, diabetic and PST test positive. Of particular interest is that the top-line 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.

The full data set has since been submitted for publication by the UofM.

FINANCIAL MODEL

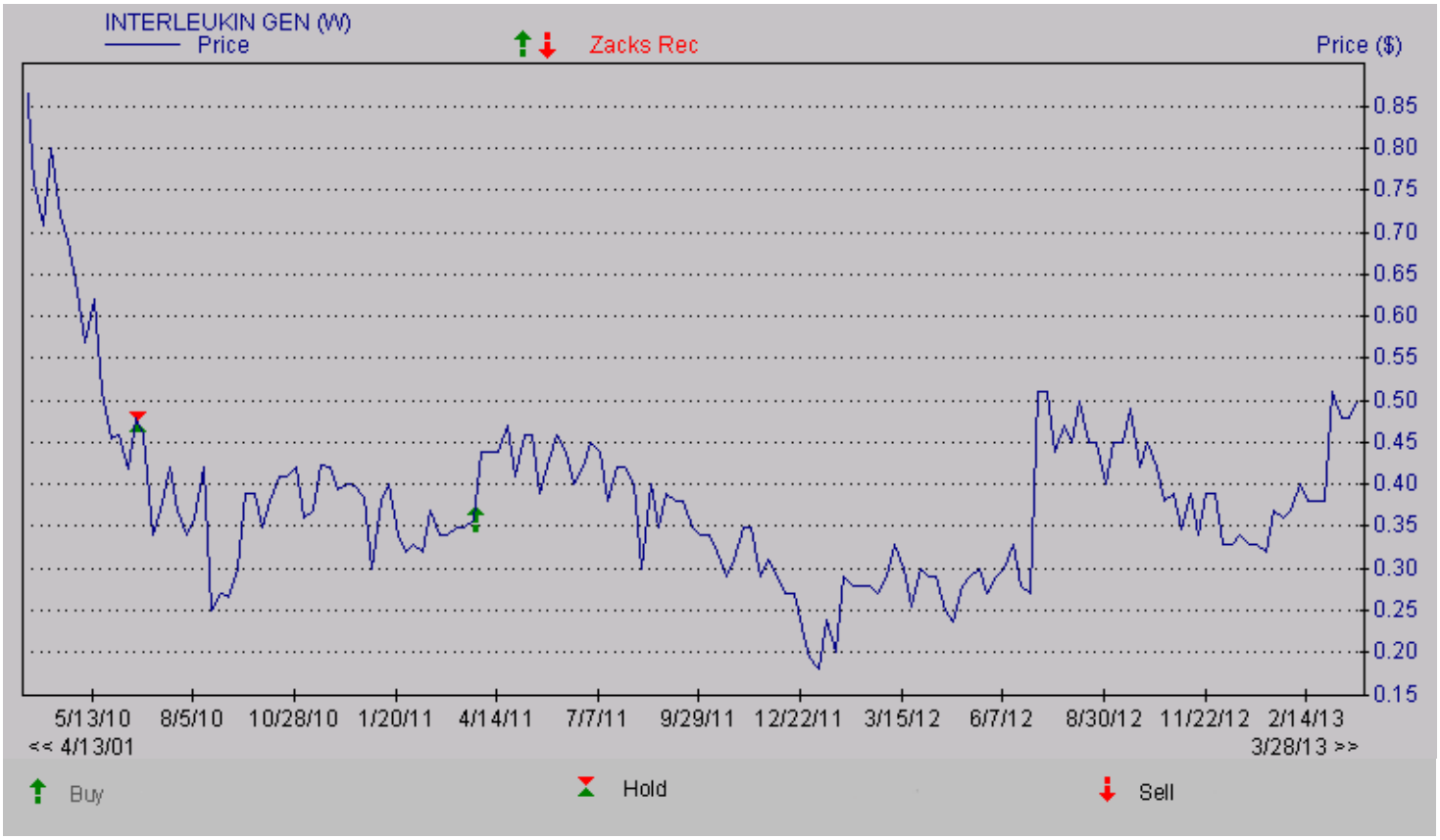
Interleukin Genetics, Inc.

	2012 A	Q1E	Q2E	Q3E	Q4E	2013 E	2014 E	2015 E	2016 E
Genetic testing	$2,154.7	$439.0	$490.0	$546.0	$554.0	$2,029.0	$8,744.0	$20,892.0	$28,137.0
YOY Growth	*-21.9%*	*-35.2%*	*-37.0%*	*42.6%*	*74.8%*	*-5.8%*	*331.0%*	*138.9%*	*34.7%*
Other	$64.6	$16.0	$18.0	$19.0	$21.0	$74.0	$262.3	$626.8	$844.1
Total Revenues	$2,219.4	$455.0	$508.0	$565.0	$575.0	$2,103.0	$9,006.3	$21,518.8	$28,981.1
YOY Growth	*-22.3%*	*-32.9%*	*-36.5%*	*34.5%*	*69.6%*	*-5.2%*	*328.3%*	*138.9%*	*34.7%*
Cost of Revenues	$1,328.5	$286.7	$309.9	$339.0	$339.3	$1,274.8	$4,323.0	$10,329.0	$13,910.9
Gross Income	$890.8	$168.4	$198.1	$226.0	$235.8	$828.2	$4,683.3	$11,189.8	$15,070.2
Gross Margin	*40.1%*	*37.0%*	*39.0%*	*40.0%*	*41.0%*	*53.0%*	*52.0%*	*52.0%*	*52.0%*
R&D	$1,311.9	$345.0	$345.0	$365.0	$370.0	$1,425.0	$1,850.0	$2,410.0	$3,070.0
% R&D	*59.1%*	*75.8%*	*67.9%*	*64.6%*	*64.3%*	*67.8%*	*20.5%*	*11.2%*	*10.6%*
R&D QTDP Grant	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
SG&A	$4,150.6	$855.0	$870.0	$905.0	$935.0	$3,565.0	$4,720.0	$8,284.7	$9,853.6
% SG&A	*187.0%*	*187.9%*	*171.3%*	*160.2%*	*162.6%*	*169.5%*	*52.4%*	*38.5%*	*34.0%*
Amortization	$115.5	$29.0	$29.0	$29.0	$29.0	$116.0	$155.0	$180.0	$200.0
Operating Income	($4,687.1)	($1,060.7)	($1,045.9)	($1,073.0)	($1,098.3)	($4,277.8)	($2,041.7)	$315.0	$1,946.6
Operating Margin	*-211.2%*	*-233.1%*	*-205.9%*	*-189.9%*	*-191.0%*	*-203.4%*	*-22.7%*	*1.5%*	*6.7%*
Total Other income	($441.4)	($100.0)	($100.0)	($100.0)	($100.0)	($400.0)	($400.0)	($300.0)	($100.0)
Pre-Tax Income	($5,128.6)	($1,160.7)	($1,145.9)	($1,173.0)	($1,198.3)	($4,677.8)	($2,441.7)	$15.0	$1,846.6
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	($5,120.2)	($1,160.7)	($1,145.9)	($1,173.0)	($1,198.3)	($4,677.8)	($2,441.7)	$15.0	$1,846.6
YOY Growth	*-1.2%*	*-18.0%*	*-6.8%*	*-8.8%*	*0.8%*	*-8.6%*	*-47.8%*	*-100.6%*	*12184.0%*
Net Margin	*-230.7%*	*-255.1%*	*-225.6%*	*-207.6%*	*-208.4%*	*-222.4%*	*-27.1%*	*0.1%*	*6.4%*
EPS (continuing ops)	($0.14)	($0.03)	($0.02)	($0.02)	($0.02)	($0.10)	($0.03)	$0.00	$0.02
YOY Growth	*-1.5%*					*-27.7%*	*-67.7%*	*-100.5%*	*10890.9%*
Diluted Shares O/S	36,755	36,702	47,000	47,000	55,000	46,426	75,000	85,000	95,000

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