November 18, 2013

Zacks Small-Cap Research

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Interleukin Genetics (ILIU-OTC)

ILIU: Initial Roll-Out of PST Test

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	03/28/2011
Current Price (11/18/13)	$0.36
Target Price	**$1.10**

OUTLOOK

Key UofM PST (periodontal disease) test study results were overwhelmingly positive and published in June. RHSC will now sell dental policies covering the test. $12MM capital raise in May provides cash runway for launch of the test. ILIU already preparing for the PST insurance-supported roll-out including hiring Chief Mktg Officer, increasing throughput of their lab, notifying and educating dental practices, and focused awareness-building efforts.

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. Our price target has moved to $1.10.

SUMMARY DATA

52-Week High	**$0.55**
52-Week Low	**$0.23**
One-Year Return (%)	**5.91**
Beta	**1.87**
Average Daily Volume (sh)	**20,976**
Shares Outstanding (mil)	**122**
Market Capitalization ($mil)	**$44**
Short Interest Ratio (days)	**3.49**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**1**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-18.5**
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	**Small-Growth**
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	487 A	852 A	419 A	535 E	2,294 E
2014					3,811 E
2015					9,461 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 A	-$0.02 A	-$0.02 A	-$0.01 E	-$0.07 E
2014					-$0.03 E
2015					-$0.02 E

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

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Q3 2013 RESULTS

Q3 2013: On Front End of PST Roll-Out

Interleukin reported financial results for the third quarter ending September 30, 2013 on November 14th. Revenue was moderately lower than our estimate but operating income was significantly lower as ILIU ramped up spend on marketing activities related to the PST test.

Revenue
Q3 revenue of $419k was flat from Q3 2012, down 51% sequentially and about 17% less than our $505k estimate. The majority of revenue continues to be generated from sales of the Weight Management test. Since Amway began bundling the test as part of its promotional product bundle, sales of the test have been less regular q-to-q. And while we think there's potential for future growth of the test, we view the PST and osteoarthritis tests as the major catalysts for long-term revenue growth of the company.

GM / Operating Expenses / EPS
GM was 13% versus our 40% estimate. The significant contraction in GM is due to lower average price per test processed as a result of substantial amount (~43%) of sales of the Weight Management test made through the promotional bundle. Operating expenses were $2.2 million, significantly higher than our $1.6 million estimate as a result of the aforementioned PST test marketing expenditures. Net loss and EPS were $2.2 million and ($0.02), compared to our $1.4 million and ($0.01) estimates.

Cash
Cash used in operations in Q3 was $1.8 million, excluding changes in working capital cash used in operations was about $2.1 million. ILIU exited Q3 with $8.7 million in cash and equivalents, representing about 4 - 5 quarters worth of cash at the current burn rate, which should get them well into the initial roll-out of the PST.

As a reminder, in May Interleukin raised $12 million (gross) through the sale of 43.7 million shares of common stock. This relieved the impending liquidity crunch and cleaned up the balance sheet and capital structure, eliminating all the preferred stock and debt.

Operational Update
The most noteworthy recent update is the initial roll-out of dental plans covering the PST test has now started. ILIU expects this to be a measured launch, initially encompassing smaller employer groups on the front end, and then targeting a broader set of employers towards the back half of 2014 and into 2015. Dentists with patients covered by these Right-Sized Dental policies in the initial roll-out will receive letters in November informing them that certain of their patients are covered by these plans. These dentists will receive additional information about the policies and PST test and in early January will receive collection kits for collecting patient samples. While we now do not expect significant revenue related to processing of the PST test during 2014, the fact that policies covering the test have been created and the roll-out is now underway are important milestones and indicative that meaningful progress has been made over the last few months. We continue to expect a much more meaningful contribution from the PST test in 2015.

The other noteworthy update relates to certain changes to the agreement with RHSC which are outlined in an 8K filed by ILIU on November 7th. As a reminder, in February 2013 ILIU and RHSC entered an agreement relative to reimbursement of the PST test. Under that agreement, 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 2/25/2013) 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. Furthermore, ILIU agreed that for one year following the date that RHSC affiliates first offered these plans, ILIU would offer the test exclusively to RHSC affiliates and to no other parties.

The changes in the revised agreement (for RHSC affiliates to receive the preferred pricing) relate to 1) seemingly increasing the flexibility of timing (i.e. - there is no longer a "specified timeframe") of when plans must be made available that cover a significant portion of RHSC affiliates' clients, 2) removal of "a specified date" related to when RHSC affiliates had to have sold policies for these reimbursed dental plans for the year beginning 1/1/2014 (instead

RHSC affiliates are now obligated to "use best efforts to maximize the number of customers that offer" this dental plan), and 3) removal of the 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.

The amended agreement allows ILIU to immediately shop the test to additional dental plans but we also feel it provides additional time and flexibility to RHSC in terms of selling the plans. However, as we indicated when the initial plan was announced, that agreement already afforded somewhat substantial wiggle-room as far as timing of the launch of the dental plans (notwithstanding the milestones). So we would not characterize the softening provided to RHSC in the amended agreement as overly material. On the Q3 call management also made an interesting point, that being that under the initial agreement which gave RHSC exclusivity during the first year, dental practices that had some patients covered by these policies could not request a PST for other patients not covered by these policies even if the patient were to pay out of pocket. With the amended agreement, which provides for much broader availability to patients and insurers, this is now possible.

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 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 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. 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" 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. With the UofM PST study published in the Journal of Dental Research in June 2013, that prerequisite has been met and RHSC's affiliates (Delta Dental) will market dental plans that cover the PST test to their customers. 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 this year for those policies that renew in early 2014. ILIU noted on the Q3 call that this is now happening. The expectation is that the early roll-out will encompass smaller employer groups but then progress to larger employers going into late 2014 and 2015. Case studies garnered from the initial launch will be used to help promote these plans and the PST to larger groups.

ILIU noted that they are already preparing for the roll-out which included increasing processing throughput of their lab to handle the anticipated increase in demand. ILIU is also actively engaging dental practices in order to facilitate education about the test and making sure they have test kits available in the early phase of the launch of these plans. Dentists with patients covered by Right-Sized policies in the initial roll-out will receive letters in November informing them that certain of their patients are covered by these plans. These dentists will receive additional information about the policies and PST test and in early January will receive collection kits for collecting patient samples.

Management recently noted that since the study publication that they have already received positive feedback from key opinion leaders on the PST test. Interleukin is also focused on building awareness about the PST test which should complement's RHSC's marketing efforts and facilitate the chances for a strong launch. The company recently hired a Chief Marketing Officer to spearhead the introduction and launch of PST and to generate early awareness. Interleukin is already making headway with awareness building in an effort to introduce the PST test to dental professionals across the country. In early August the company published a guest editorial 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 also 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 the annual meetings of the American Academy of Periodontology, the American College of Prosthodontists, American Dental Association workshops and a presentation at the National Institutes of Health which is expected to have several hundred dentists in attendance.

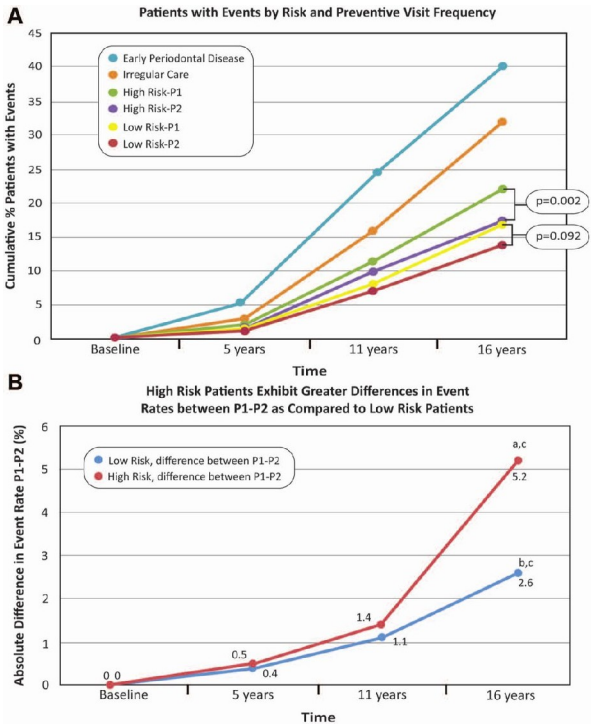
University of Michigan PST Study

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). 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 54 million covered lives, which is a great start.

We note that ILIU already has 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 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 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 $2.3 million / ($0.07) and $3.8 million / ($0.03) in 2013 and 2014, respectively. We are maintaining our Outperform rating. Our price target has moved to $1.10.

FINANCIAL MODEL

Interleukin Genetics, Inc.

	2012 A	Q1A	Q2A	Q3A	Q4E	2013 E	2014 E	2015 E	2016 E
Genetic testing	$2,154.7	$483.4	$849.4	$411.6	$514.0	$2,258.3	$3,700.0	$9,185.0	$18,000.0
YOY Growth	*-21.9%*	*-28.6%*	*9.2%*	*7.5%*	*62.1%*	*4.8%*	*63.8%*	*148.2%*	*96.0%*
Other	$64.6	$4.0	$2.7	$7.5	$21.0	$35.2	$111.0	$275.6	$540.0
Total Revenues	$2,219.4	$487.4	$852.1	$419.0	$535.0	$2,293.6	$3,811.0	$9,460.6	$18,540.0
YOY Growth	*-22.3%*	*-28.1%*	*6.6%*	*-0.2%*	*57.8%*	*3.3%*	*66.2%*	*148.2%*	*96.0%*
Cost of Revenues	$1,328.5	$383.6	$496.4	$362.8	$315.7	$1,558.4	$2,096.1	$5,203.3	$10,197.0
Gross Income	$890.8	$103.8	$355.7	$56.3	$219.4	$735.2	$1,715.0	$4,257.2	$8,343.0
Gross Margin	*40.1%*	*21.3%*	*41.7%*	*13.4%*	*41.0%*	*32.1%*	*45.0%*	*45.0%*	*45.0%*
R&D	$1,311.9	$160.4	$187.8	$161.4	$225.0	$734.5	$855.0	$1,250.0	$1,525.0
% R&D	*59.1%*	*32.9%*	*22.0%*	*38.5%*	*42.1%*	*32.0%*	*22.4%*	*13.2%*	*8.2%*
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	$1,002.2	$1,573.4	$2,035.2	$1,425.0	$6,035.7	$5,470.0	$5,203.3	$7,786.8
% SG&A	*187.0%*	*205.6%*	*184.6%*	*485.7%*	*266.4%*	*263.2%*	*143.5%*	*55.0%*	*42.0%*
Amortization	$115.5	$28.9	$25.8	$27.3	$29.0	$111.0	$155.0	$180.0	$200.0
Operating Income	($4,687.1)	($1,087.6)	($1,431.2)	($2,167.6)	($1,459.7)	($6,146.0)	($4,765.1)	($2,376.1)	($1,168.8)
Operating Margin	*-211.2%*	*-223.1%*	*-168.0%*	*-517.3%*	*-272.8%*	*-268.0%*	*-125.0%*	*-25.1%*	*-6.3%*
Total Other income	($441.4)	($114.0)	($345.1)	($8.5)	$0.0	($467.6)	$0.0	$0.0	$0.0
Pre-Tax Income	($5,128.6)	($1,201.6)	($1,776.3)	($2,176.1)	($1,459.7)	($6,613.6)	($4,765.1)	($2,376.1)	($1,168.8)
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)	($1,201.6)	($1,776.3)	($2,176.1)	($1,459.7)	($6,613.6)	($4,765.1)	($2,376.1)	($1,168.8)
YOY Growth	*-1.2%*	*-15.1%*	*44.4%*	*69.2%*	*22.7%*	*29.2%*	*-28.0%*	*-50.1%*	*-50.8%*
Net Margin	*-230.7%*	*-246.5%*	*-208.5%*	*-519.3%*	*-272.8%*	*-288.4%*	*-125.0%*	*-25.1%*	*-6.3%*
EPS (continuing ops)	($0.14)	($0.03)	($0.02)	($0.02)	($0.01)	($0.07)	($0.03)	($0.02)	($0.01)
YOY Growth	*-1.5%*					*-47.4%*	*-53.5%*	*-55.0%*	*-52.3%*
Diluted Shares O/S	36,755	36,776	79,006	122,277	123,000	90,265	140,000	155,000	160,000

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