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Zacks Small-Cap Research

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Interleukin Genetics (ILIU-OTC)

ILIU: PerioPredict Adoption Still Slow But Making Progress

Current Recommendation	**Buy**
Prior Recommendation	Hold
Date of Last Change	03/28/2011
Current Price (03/21/16)	$0.08
Target Price	**$0.25**

OUTLOOK

Key UofM PST (periodontal disease) test study results were overwhelmingly positive and published in June 2013. PerioPredict launched in early 2014. Revenue has been immaterial but indications are that feedback from insurers, employer groups and patients is positive. Brought on new CEO, benefits consulting firm and revised strategy in early 2015 in order to help speed adoption of PerioPredict. Gameplan is to leverage evidence showing better dental care = lower medical costs. Company implementing 2-phased approach: target large self-insured employers for implementation into wellness programs and insurance carriers for coverage under new or modified plans. Adding personnel to facilitate strategy. Just brought on top-notch clinical advisory board to help with PerioPredict awareness-building, generation of additional clinical evidence and with overall PerioPredict strategy. First employer client signed with Metagenics. Adoption slow but making progress.

SUMMARY DATA

52-Week High	**$0.17**
52-Week Low	**$0.04**
One-Year Return (%)	**-46.06**
Beta	**0.73**
Average Daily Volume (sh)	**25,013**
Shares Outstanding (mil)	**173**
Market Capitalization ($mil)	**$15**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**44**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-11.9**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 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)
2015	403 A	376 A	296 A	366 A	1,441 A
2016	268 E	252 E	247 E	360 E	1,127 E
2017					5,203 E
2018					7,164 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.01 A	-$0.01 A	-$0.01 A	-$0.01 A	-$0.05 A
2016	-$0.01 E	-$0.01 E	-$0.01 E	-$0.01 E	-$0.04 E
2017					-$0.03 E
2018					-$0.02 E

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

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Q4 2015: PerioPredict Adoption Still Slow, But Making Progress. Top-Notch Clinical Advisory Board Brought On

Interleukin reported financial results for the fourth quarter ending December 31st. The majority of revenue continues to come from the Weight Management test although genetic testing revenue continues to slide, including a 6% contraction from Q3 of this year. For the full year genetic testing revenue fell 30%, from $1.6M in 2014 to $1.2M in 2015. We continue to expect little to no growth in revenue of the Weight Management test from the Amway channel, where sales began to soften shortly following Amway's decision to include the Weight Management test as a promotional bundle, which took effect in early 2013.

We also do not expect any material increase in total sales until there is traction from new products, with PerioPredict being the candidate that likely holds the most promise to significantly jump-start the growth curve. And while management has made substantive progress in laying the groundwork for eventually monetizing this product via their two-pronged (large employers and insurers) strategy, adoption of the test in benefit and insurance plans is clearly a process that will take more time. To facilitate both awareness and adoption of PerioPredict, last week ILIU announced the appointment of a clinical advisory board made up leading experts in the field of chronic inflammatory diseases. A particular focus for the advisory board will be generation and publication of additional clinical data supporting the use of PerdioPredict, including the benefit to lower health care costs and improved patient outcomes.

ILIU also has other irons in the fire besides PerioPredict including potential companion diagnostics for cardiovascular disease (CVD) and osteoarthritis. Management noted on the call that they are aware of 28 drug candidates that are in development by various companies that incorporate an interleukin-1 blocking mechanism and which potentially could be a fit for ILIU's technology – either as an aid for clinical trial enrollment or as an eventual companion diagnostic for a commercialized drug. We continue to believe that there is substantive potential in this space and one we think may offer ancillary opportunities for ILIU – stay tuned.

PerioPredict:

As a reminder, Mark Carbeau, who was appointed CEO in April 2015, recently laid out a somewhat revised / enhanced strategy for the initial commercialization of PerioPredict aimed at increasing early adoption. Employee Benefit Consulting Group (EBCG), which works with employers and insurers to help align benefit packages with the needs of employer groups and their employees, was brought on to help with implementation.

The strategy is dual-pronged – focusing on large employers, which is expected to provide the initial revenue, and insurance companies, which are expected to require a longer sales cycle but also offer more scalability and upside.

A major focus of the new strategy to help drive adoption of PerioPredict is to leverage evidence that shows that proper dental care can reduce medical expenses and communicate this message to stakeholders (employers, employer groups, insurance carriers, individuals). As support for pursuing this strategy ILIU cites a major study led by Dr. Marjorie Jeffcoat, Professor of Periodontology at the University of Pennsylvania School of Dentistry which evaluated the connection between periodontal disease treatment and medical costs.

The study looked at five years' worth of medical and dental records data from almost 339k patients. It compared the medical treatment and related costs of individuals that completed treatment and maintenance of gum disease with those that did not. Subsets included a.) diagnosis of at least one specified medical condition and b.) evidence of periodontal disease. Chronic conditions included cerebral vascular disease (stroke), coronary artery disease and type-2 diabetes. Results, which were published in 2014 in the American Journal of Preventive Medicine in an article titled *Impact of Periodontal Therapy on General Health* and presented by Dr. Jeffcoat at the American Association of Dental Research meeting in Charlotte that same year, showed that for individuals that completed treatment and maintenance of gum disease as compared to those that didn't had;

- annual medical cost savings of
    - almost $5,700 for those with stroke (41% reduction)
    - almost $1,100 for those with coronary artery disease (11% reduction)
    - over $2,800 for those with diabetes (40% reduction)
    - over $2,400 for women who were pregnant (74% reduction)

- annual hospital reductions of
    - 21% for those with stroke

- 29% for those with heart disease
- 39% for those with diabetes

All differences were statistically significant at p<0.05. The study also looked at those with rheumatoid arthritis although this population did not show a statistically significant reduction in medical costs.

Table 3 Chronic medical conditions: comparison of costs and hospitalizations

	Chronic systemic disease							
	Type 2 diabetes		**Cerebral vascular disease**		**Coronary artery disease**		**Rheumatoid arthritis**	
Periodontal treatment								
Total number of qualifying subjects in Year 0 (2005)	91,242		13,007		8,458		81,439	
ICD-9 codes for inclusion in cohort	250–25099, 3572–35729, 3620–36209, 36641, 6480		433, 434		411, 413, 414, 4292		7140, 7141, 7142, 71481	
Periodontal treatment received	Untreated	Treated	Untreated	Treated	Untreated	Treated	Untreated	Treated
Number in cohort	90,329	913	12,868	139	8,368	90	80,903	536
Percentage periodontally treated	1.0%		1.1%		1.1%		0.7%	
OUTCOMES								
Total medical costs								
Total medical costs per subject per year (mean 2006–2009)	$7,056	$4,216	$13,895	$8,214	$10,222	$9,133	$9,218	$8,637
Annual reduction with treatment	$2,840 (40.2%)		$5,681 (40.9%)		$1,090 (10.7%)		$581 (6.3%)	
Significance, Wilks's lambda	***p*<0.04**		***p*<0.04**		***p*<0.04**		NS	
Hospital admission								
Inpatient admissions per 1,000 subjects per year (mean 2006–2009)	66.6	40.4	444.4	350.0	65.2	46.6	142.7	136.3
Annual reduction with treatment	26.3	(39.4%)	94.4	(21.2%)	18.7	(28.6%)	6.4	(4.5%)
Significance, Wilks's lambda	***p*<0.05**		***p*<0.002**		***p*<0.01**		NS	

SOURCE: Jeffcoat, et al. AJPM. August 2014, Vol. 47, Issue2 Pgs 166-174

So to leverage this type of evidence that proper dental care can reduce medical expenses ILIU and EBCG are targeting both large employers who self-insure and insurance carriers. The initial focus, and likely the lower hanging fruit, is to encourage PerioPredict testing of individuals with chronic conditions such as CVD and type-2 diabetes as this is where the evidence shows more informed dental care can reduce medical costs.

ILIU and EBCG are dedicating most of their initial focus on employers as they believe the sales and adoption cycle may be quicker, given that there are less structural hurdles to overcome (as compared to insurance carriers which requires a modification to plans and have more red tape in general).

On the large-employer side, the value proposition is that PerioPredict can fit into wellness programs (similar to smoking cessation) – essentially that if employers sponsor (or perhaps co-sponsor with employees bearing some of the cost) PerioPredict testing that this cost will be more than recouped in lower medical costs and less

employee downtime and missed worked days. The employer then may coordinate with their dental carrier to modify coverage, if appropriate. This is still expected to follow a "phased-in" approach whereby, for instance, wellness plans incorporating PerioPredict might initially target high-risk groups (such as those identified in the Jeffcoat study) and over time expand to a greater portion of the employee population.

In February of this year ILIU scored their first employer contract with Metagenics which will use PerioPredict in their employee benefit plans to help determine which individuals are most susceptible to developing periodontitis. This will not only provide additional guidance for most appropriate dental care but also, per ILIU's press release, act "as an access point to reduce their systemic inflammatory burden". Interleukin will provide the PerioPredict genetic testing as well as dental support to their dental providers. We think Metagenics should not only provide a good test-case for incorporating PerioPredict into a company's benefit plan, but as the duo already have a long-standing relationship, this also has the potential to provide valuable feedback to Interleukin relative to how best to implement their test as well as "what-works and "what-doesn't" type of feedback.

On the insurance carrier side, ILIU and EBCG have had and continue to have discussions with various carriers in incorporating coverage of PerioPredict in their plans. As noted the insurance-carrier sales cycle is anticipated to be longer – management noted that carriers want to see data-driven pilot and demonstration programs to assess the potential benefits. This, along with various decision-making layers at these large carriers as well as requisite time for new plan design, implementation and the fact that enrollment in new plans is typically a first-of-the-year event, means the insurance carrier channel is likely to be a more drawn out process.

On the Q4 2015 call management noted that the early focus, which may be the low-hanging fruit on the insurance carrier side, will be with those pursing "DMI" plans. These dental-medical integration plans provide employers with both dental and medical benefits. As it seems that integration of PerioPredict into employer benefit plans may be somewhat less than seamless – with one hurdle being how to coordinate between the different medical and dental benefits – these DMI plans may overcome some of these challenges. Of course these plans must first incorporate PerioPredict coverage in the plans first – pilot studies are expected to help facilitate that process.

Particularly positive, we believe is that while integration in both employer benefit plans and within insurance policies seems to be somewhat of a work-in-process with some wrinkles still need to be ironed out, that the potential benefits of PerioPredict do seem to be resonating. Management indicated as much on prior calls as well as the Q4 conference call. This, in our view, is a critically important first step – next is implementation. To aid on both the awareness/utility message and to help on the implementation side, ILIU brought on the advisory board and also expects to bring on additional sales personnel as well as potential increasing their benefits consulting capabilities.

Revenue

Q4 revenue of $366k was up 24% sequentially, up 14% yoy and about 18% better than our $310k estimate. Included in the revenue is $51k 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

Q4 gross margin was negative 17%, down from 1% in the comparable year-earlier period and negative 9% in Q3 of this year. GM has contracted significantly with the recent slide in revenue due to less revenue to cover fixed manufacturing costs. Based on historical numbers as well as the most recent period, it appears ~$300k in revenue is the approximate level of break-even gross profit. OpEx was $1.6M, flat from Q3 2014 but down from $1.8M in Q3 2015 and better than our $1.9M estimate. The yoy increase is mostly related to bringing on the new CEO (and Dr. Kornman continuing to serve as Chief Scientific Officer). We expect OpEx to remain at higher levels than in the recent past with additions to the sales and support staff.

Net loss and EPS were $1.9M and ($0.01), which compares to $1.6M / ($0.01) in Q4 2014, $2.0M / ($0.01) in Q3 2015 and our estimate of $2.1M / ($0.01) – with the slight beat to our net loss number mostly coming from lower than anticipated operating expenses.

Cash

Cash used in operating activities was $1.5M in Q4 and $6.7 for the full year 2015. Ex-changes in working capital cash used was $6.5M in 2015. ILIU expects the current cash balance, which was $4.7M at 2015 year-end, to fund the company into the second half of 2016.

OUTLOOK / RECOMMENDATION

We continue to believe that the major near and mid-term growth driver of the company lies with PerioPredict. We think the Weight Management test (the prior major growth driver and current most significant revenue contributor) will experience continued contraction. 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.

We expect a greater rate of revenue growth to materialize in 2017 as ILIU begins to realize benefits of increased patient enrollments in insurance plans and from employer wellness programs related to PerioPredict. We also could see some incremental revenue from companion-diagnostic type of relationships or similar agreements that could happen in the future although we have yet to include these in our forecasts – this will be updated if and when we feel it is appropriate.

We have made some adjustments to our revenue estimates – pushing out anticipated initial revenue of PerioPredict by approximately 9 months as a result of extension of the anticipated runway for more substantial commercialization of the test. The delay reflects the longer than initially anticipated adoption process by large employer groups and insurance carriers. We look for revenue and EPS of $1.1 million / ($0.04) and $2.3 million / ($0.03) in 2016 and 2017, respectively. We are maintaining our Buy recommendation. Our per-share price target has moved from $0.30 to $0.25 as a result of the aforementioned updates to our model.

FINANCIAL MODEL

Interleukin Genetics, Inc.

	2015 A	Q1E	Q2E	Q3E	Q4E	2016 E	2017 E	2018 E	2019 E
Genetic testing	$1,156.0	$218.0	$202.0	$197.0	$310.0	$927.0	$2,192.0	$5,051.0	$6,955.0
YOY Growth	*-29.6%*	*-37.3%*	*-37.8%*	*-20.8%*	*32.3%*	*-19.8%*	*136.5%*	*130.4%*	*37.7%*
Other	$284.9	$50.0	$50.0	$50.0	$50.0	$200.0	$65.8	$151.5	$208.7
Total Revenues	$1,440.9	$268.0	$252.0	$247.0	$360.0	$1,127.0	$2,257.8	$5,202.5	$7,163.7
YOY Growth	*-20.4%*	*-33.5%*	*-33.0%*	*-16.6%*	*-1.5%*	*-21.8%*	*100.3%*	*130.4%*	*37.7%*
Cost of Revenues	$1,414.1	$262.6	$247.0	$242.1	$352.8	$1,104.5	$1,548.8	$3,163.1	$3,983.0
Gross Income	$26.8	$5.4	$5.0	$4.9	$7.2	$22.5	$708.9	$2,039.4	$3,180.7
Gross Margin	*1.9%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*31.4%*	*39.2%*	*44.4%*
R&D	$1,299.5	$344.0	$351.0	$382.0	$411.0	$1,488.0	$1,441.0	$1,361.0	$1,487.0
% R&D	*90.2%*	*128.4%*	*139.3%*	*154.7%*	*114.2%*	*132.0%*	*63.8%*	*26.2%*	*20.8%*
SG&A	$5,878.9	$1,288.0	$1,351.0	$1,444.0	$1,515.0	$5,598.0	$5,892.8	$6,295.1	$6,518.9
% SG&A	*408.0%*	*480.6%*	*536.1%*	*584.6%*	*420.8%*	*496.7%*	*261.0%*	*121.0%*	*91.0%*
Amortization	$136.9	$19.4	$19.4	$19.4	$19.4	$77.7	$80.0	$90.0	$100.0
Operating Income	($7,288.6)	($1,646.1)	($1,716.4)	($1,840.5)	($1,938.2)	($7,141.1)	($6,704.8)	($5,706.7)	($4,925.3)
Operating Margin	*-505.8%*	*-614.2%*	*-681.1%*	*-745.1%*	*-538.4%*	*-633.6%*	*-297.0%*	*-109.7%*	*-68.8%*
Total Other income	($609.4)	($154.0)	($154.0)	($139.0)	($125.0)	($572.0)	($386.0)	($225.0)	($400.0)
Pre-Tax Income	($7,898.0)	($1,800.1)	($1,870.4)	($1,979.5)	($2,063.2)	($7,713.1)	($7,090.8)	($5,931.7)	($5,325.3)
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	($7,898.0)	($1,800.1)	($1,870.4)	($1,979.5)	($2,063.2)	($7,713.1)	($7,090.8)	($5,931.7)	($5,325.3)
YOY Growth	*24.7%*	*-2.3%*	*-13.7%*	*-2.3%*	*10.8%*	*-2.3%*	*-8.1%*	*-16.3%*	*-10.2%*
Net Margin	*-548.1%*	*-671.7%*	*-742.2%*	*-801.4%*	*-573.1%*	*-684.4%*	*-314.1%*	*-114.0%*	*-74.3%*
EPS (continuing ops)	($0.05)	($0.01)	($0.01)	($0.01)	($0.01)	($0.04)	($0.03)	($0.02)	($0.02)
YOY Growth	*-10.7%*					*-15.2%*	*-29.7%*	*-27.5%*	*-17.1%*
Diluted Shares O/S	172,813	172,887	172,900	215,000	235,000	198,947	260,000	300,000	325,000

Brian Marckx, CFA

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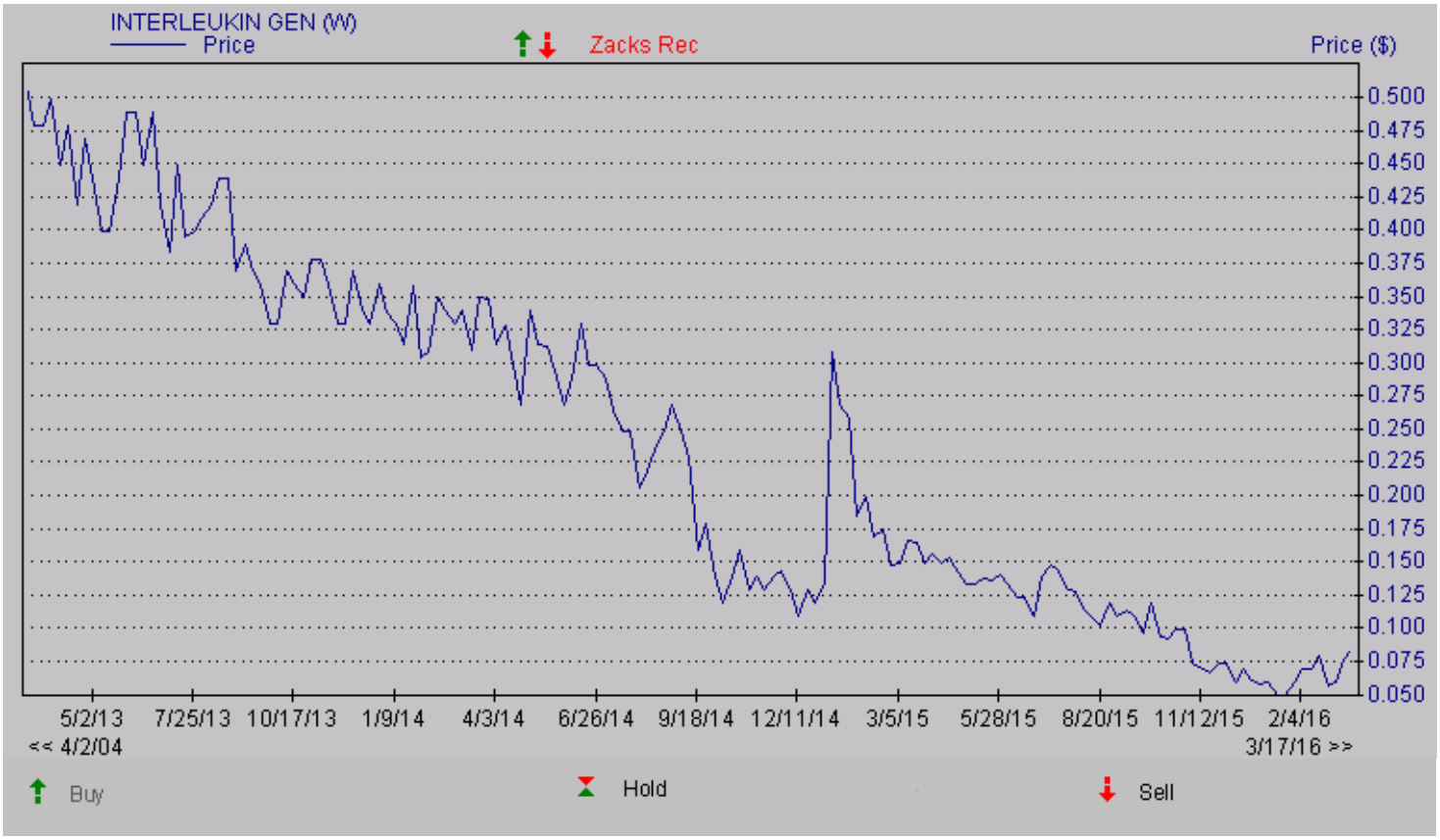

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