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Zacks Small-Cap Research

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# Interleukin Genetics (ILIU-OTC)

***ILIU: Q4 Results. PST Test Update***

| | |
|---|---|
| **Current Recommendation** | **Outperform** |
| Prior Recommendation | N/A |
| Date of Last Change | 03/28/2011 |
| Current Price (03/30/12) | $0.30 |
| **Target Price** | **$1.30** |

## OUTLOOK

Enrollment of the key UofM PST (periodontal disease) test study just completed. Top-line data expected in April. If positive, this study data could lead to dental insurance reimbursement of the test, offering a potentially huge opportunity for ILIU. We have pushed back our timeline for substantial commercialization of the test until ~mid-2013.

An investment in ILIU is not without significant risk and our financial model assumes favorable outcomes of a number of current "unknowns" (including successfully addressing an impending debt maturity). We have moved our price target from $1.60 to $1.30, reflecting our updated PST test timelines. We are maintaining our Outperform rating.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$0.49** |
| **52-Week Low** | **$0.17** |
| **One-Year Return (%)** | **-2.78** |
| **Beta** | **1.82** |
| **Average Daily Volume (sh)** | **13,357** |
| **Shares Outstanding (mil)** | **37** |
| **Market Capitalization ($mil)** | **$11** |
| **Short Interest Ratio (days)** | **3.49** |
| **Institutional Ownership (%)** | **8** |
| **Insider Ownership (%)** | **6** |
| **Annual Cash Dividend** | **$0.00** |
| **Dividend Yield (%)** | **0.00** |
| **5-Yr. Historical Growth Rates** | |
| **Sales (%)** | **N/A** |
| **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** | **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) |
|---|---|---|---|---|---|
| 2011 | 719 A | 797 A | 765 A | 575 A | 2,857 A |
| 2012 | 798 E | 829 E | 898 E | 1,121 E | 3,646 E |
| 2013 | | | | | 7,917 E |
| 2014 | | | | | 23,113 E |

**Earnings per Share**

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2011 | -$0.03 A | -$0.04 A | -$0.03 A | -$0.04 A | -$0.14 A |
| 2012 | -$0.04 E | -$0.03 E | -$0.03 E | -$0.03 E | -$0.11 E |
| 2013 | | | | | -$0.05 E |
| 2014 | | | | | $0.04 E |

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

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## OPERATIONAL UPDATE / Q4 2011 RESULTS

Interleukin reported financial results for the fourth quarter ending December 31, 2011 on March 29th. While revenue came in significantly softer than our number, it was still up 13% y-o-y. In addition, Q4 has historically been relatively modest from a revenue standpoint. Despite the miss on the top line, net income and EPS were mostly in-line with our estimates as a result of the company's continued success with trimming expenses. For the full year, revenue grew 43% with net loss / EPS showing significant improvement.

The main operational points of interest relate to Interleukin's PST test - specifically the March 28th announcement that enrollment was completed for the University of Michigan PST study and a recently published study (from an unrelated meta-analysis) supporting the link between IL-1 genetic variations and the risk of periodontal disease (more on both studies below). Top-line data from the U of M study are expected in April. As the PST test is what we view as the biggest near-to-mid term opportunity for ILIU, we see these as meaningfully positive developments.

Relative to the weight management test, using data from a subset of patients from the initial *A to Z* study, Interleukin recently conducted an additional analysis using DNA from 291 of the original 311 individuals to determine if there was an association between certain genetic test patterns and weight loss response at 12 months based on which diet (Atkins, Zone, LEARN, or Ornish) the individual was assigned to in the *A to Z* study. Management noted on the Q4 call that the company conducted an analysis in March that indicated different genetic test patterns could determine weight loss response and this information could be used to modify some of the weight management test's initial diet assignments to achieve even greater weight loss. In March Interleukin began incorporating this information into its lab reporting system and updated diet recommendations for each genetic pattern, providing customers additional information to more effectively lose weight. This could potentially spark additional interest in the test - particularly from commercial customers such as weight loss clinics, many of which have wanted to see additional evidence supporting the benefits of the test before making a meaningful commitment to using it in their programs.

### Q4 RESULTS

**Revenue**
Q4 revenue of $575k was well below our $840k estimate but was up 13% from Q4 2011. We had modeled sequential growth from Q3 and acknowledge our estimate may have been aggressive given that Interleukin's Q4 is typically relative soft. 92% of total revenue came from genetic testing. Revenue fell 25% on a sequential basis. For the full year revenue was $2.9 million, up 43% from 2010.

**Gross Margin / Operating Expenses / EPS**
Gross margin, at 37.4%, was also relative soft in Q4 but came in at 46.5% for the full year 2011, compared to 18.9% in 2010. The improvement is a direct result of cost cutting and efficiencies in test processing, including lower material costs.

Operating expenses were slightly better than our estimates, coming in at $1.51 million compared to our $1.64 million forecast. For the full year operating expenses fell 13% ($6.94MM to $6.04MM), especially impressive given the 43% revenue growth over the same period. As we noted in the past, this is a testament to management's diligence in trimming costs where there's an opportunity to do so.

Q4 EPS was ($0.04) on net loss of $1.4 million, compared to our ($0.03) and $1.4 million (loss) estimates. For the full year 2011, EPS and net loss were ($0.14) and $5.2 million compared to ($0.18) and $6.5 million in 2010.

**Cash**
Interleukin exited the quarter with $1.73 million in cash and equivalents, compared to $1.01 million at 9/30/11. Cash used in operations was $1.29 million in Q4, up from $906k in Q3 ($1.17MM used in Q1, $1.13MM used in Q2). For the full year, cash used in operations was $4.5 million, down significantly from the $5.7 million used in 2010 - again, another result of cost and expense control.

The sequential increase in the cash balance was a result of a $2 million draw on the convertible credit facility with Pyxis in November. Interleukin still has $1.3 million of borrowing capacity under the Pyxis credit facility - which is available through June 30, 2012. This due date is fast approaching and Interleukin will need to either extend the

due date or refinance the debt. Management noted on the call that they continue to explore different avenues relative to financing. Total borrowed on the loan, currently stands at $13 million - which is convertible into Interleukin common stock at $5.68/share (i.e. - currently way out of the money).

## U of M PST Study Enrollment Completed

Completion of enrollment of the key University of Michigan PST study was announced on March 28th.

As a reminder, 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 is being 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 - the study is expected to confirm results of earlier studies. The prospective study examined 15 years worth of patient data taken from a large dental claims database and is comparing that to information from patients obtained from using the PST test. Total enrollment was expected to be about 4,000 individuals - final enrollment ended up being over 5,400 patients. The hypothesis for the study is to determine whether more than one dental cleaning per year is value-added for gene-negative (i.e. – low risk) patients and how many cleanings are optimal for gene-positive (i.e. – high risk) patients. Primary endpoint of the study is tooth loss at 10 and 15 years. The study, which commenced in late 2010, is the largest ever done to evaluate the application of genetic information for the prevention of periodontal disease.

Management had indicated previously that they expected enrollment to be wrapped up in early 2012 with data analysis expected to be available during the first quarter or second quarter of 2012. The most recent announcement that enrollment is completed is right on with management's timeline. Management further confirmed on the call that top-line data should be available in April. If the study results show what Interleukin believes it will (i.e. – that PST can predict periodontal disease based on genotyping), it could be a useful tool in determining optimal dental care for each individual patient – which includes the "correct" number of cleanings each year. This will hopefully support reimbursement for the PST test from dental insurance providers. Currently cost of the PST test (~ $150) is borne by the consumer as no insurers provide reimbursement for it. As such, gaining reimbursement will be key to driving demand for it.

Timelines for release of the full data set and (assuming positive results) submission for publication are substantially less clear, although it's possible this could be a current year event. Until then, there may be only limited demand for test. We had previously modeled a more meaningful revenue contribution from this PST in the current year (mostly back-weighted) - but based on what we now believe to be more realistic timelines, we have pushed back our estimate of substantial commercialization (i.e. - reimbursed through insurance) of the test by about 9 months (now ~ mid-2013).

## Meta-Analysis Supports Link Between IL-1 Gene Variation and Periodontal Disease

A meta-analysis of 13 studies showed a statistically significant association between the presence of variations of the interluekin-1 (IL-1) gene and the risk of periodontal disease. The IL-1 genetic variations used in the study are the same as those in Interleukin Genetics' PST test - which could node well for supporting use of ILIU's PST test. Results of the peer-reviewed study will be published in the Journal of Periodontology and were included in the online version of the publication in March.

## 2012 OUTLOOK / RECOMMENDATION

As noted, we have pushed back our estimated time to substantial commercialization of the PST test by about 9 months. As this test is the major catalyst to our modeled revenue growth, extending the date to widespread commercialization also has the effect of delaying our estimated ramp in Interleukin's revenue. Our current 2012 revenue estimate mostly reflects sales of the weight management test with significant contribution from PST not beginning until sometime in 2013. Indicative of these changes, our 2012 revenue estimate has moved from $6.9 million to $3.6 million currently. We now look for 2013 revenue of about $8 million. Our 2012 EPS estimate has moved from ($0.10) to ($0.11). The changes to our model also effect our price target, which has moved from $1.60/share to $1.30/share. We are maintaining our Outperform rating.

## FINANCIAL MODEL

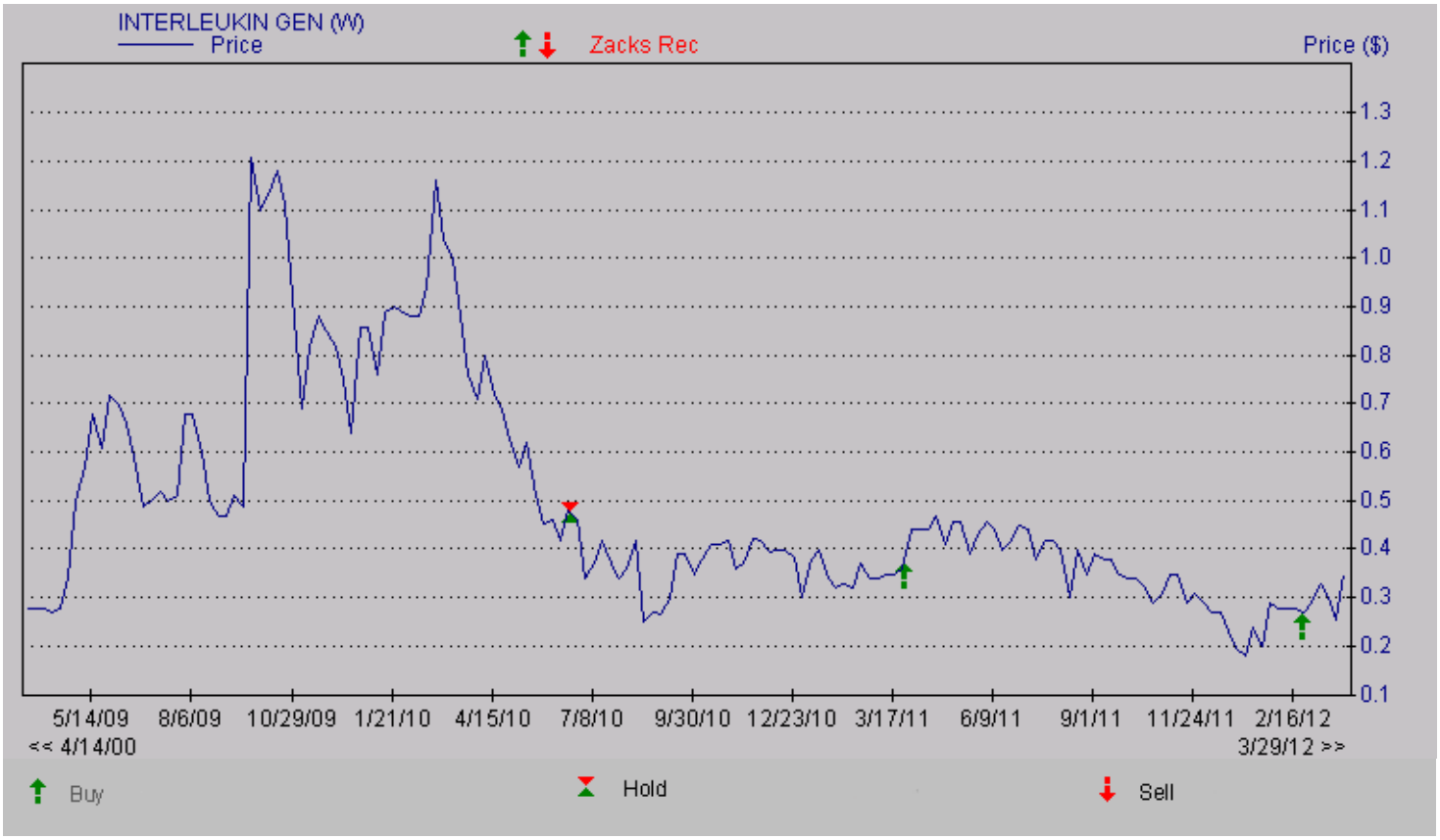
Interleukin Genetics, Inc.

| | 2011 A | Q1E | Q2E | Q3E | Q4E | 2012 E | 2013 E | 2014 E | 2015 E |
|---|---|---|---|---|---|---|---|---|---|
| Genetic testing | $2,757.4 | $775.0 | $805.0 | $872.0 | $1,088.0 | $3,540.0 | $7,686.0 | $22,440.0 | $41,558.0 |
| *YOY Growth* | *42.1%* | *7.7%* | *3.3%* | *19.3%* | *106.2%* | *28.4%* | *117.1%* | *192.0%* | *85.2%* |
| Other | $99.7 | $23.3 | $24.2 | $26.2 | $32.6 | $106.2 | $230.6 | $673.2 | $1,246.7 |
| Total Revenues | $2,857.1 | $798.3 | $829.2 | $898.2 | $1,120.6 | $3,646.2 | $7,916.6 | $23,113.2 | $42,804.7 |
| *YOY Growth* | *43.1%* | *10.9%* | *4.1%* | *17.3%* | *94.8%* | *27.6%* | *117.1%* | *192.0%* | *85.2%* |
| Cost of Revenues | $1,527.2 | $399.1 | $439.4 | $431.1 | $571.5 | $1,841.2 | $3,720.8 | $9,938.7 | $17,121.9 |
| Gross Income | $1,329.9 | $399.1 | $389.7 | $467.0 | $549.1 | $1,805.0 | $4,195.8 | $13,174.5 | $25,682.8 |
| *Gross Margin* | *46.5%* | *50.0%* | *47.0%* | *52.0%* | *49.0%* | *49.5%* | *53.0%* | *57.0%* | *60.0%* |
| R&D | $1,376.4 | $405.0 | $372.0 | $425.0 | $440.0 | $1,642.0 | $2,254.0 | $2,450.0 | $3,144.0 |
| *% R&D* | *48.2%* | *50.7%* | *44.9%* | *47.3%* | *39.3%* | *45.0%* | *28.5%* | *10.6%* | *7.3%* |
| R&D QTDP Grant | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| SG&A | $4,665.4 | $1,210.0 | $1,244.0 | $1,285.0 | $1,271.0 | $5,010.0 | $6,016.6 | $7,396.2 | $9,417.0 |
| *% SG&A* | *163.3%* | *151.6%* | *150.0%* | *143.1%* | *113.4%* | *137.4%* | *76.0%* | *32.0%* | *22.0%* |
| Amortization | $115.4 | $28.9 | $28.9 | $28.9 | $28.9 | $115.6 | $140.0 | $155.0 | $180.0 |
| Operating Income | ($4,827.3) | ($1,244.8) | ($1,255.2) | ($1,271.9) | ($1,190.8) | ($4,962.6) | ($4,214.8) | $3,173.3 | $12,941.8 |
| *Operating Margin* | *-169.0%* | *-155.9%* | *-151.4%* | *-141.6%* | *-106.3%* | *-136.1%* | *-53.2%* | *13.7%* | *30.2%* |
| Total Other income | ($356.2) | ($96.0) | ($96.0) | ($96.0) | ($96.0) | ($384.0) | ($110.0) | $0.0 | $50.0 |
| Pre-Tax Income | ($5,183.5) | ($1,340.8) | ($1,351.2) | ($1,367.9) | ($1,286.8) | ($5,346.6) | ($4,324.8) | $3,173.3 | $12,991.8 |
| 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 | ($5,183.5) | ($1,340.8) | ($1,351.2) | ($1,367.9) | ($1,286.8) | ($5,346.6) | ($4,324.8) | $3,173.3 | $12,991.8 |
| *YOY Growth* | *-19.9%* | *6.8%* | *-1.4%* | *20.6%* | *-9.5%* | *3.1%* | *-19.1%* | *-173.4%* | *309.4%* |
| *Net Margin* | *-181.4%* | *-168.0%* | *-163.0%* | *-152.3%* | *-114.8%* | *-146.6%* | *-54.6%* | *13.7%* | *30.4%* |
| EPS (continuing ops) | ($0.14) | ($0.04) | ($0.03) | ($0.03) | ($0.03) | ($0.11) | ($0.05) | $0.04 | $0.15 |
| *YOY Growth* | *-22.0%* | | | | | *-20.0%* | *-55.0%* | *-173.4%* | *309.4%* |
| Diluted Shares O/S | 36,661 | 36,750 | 50,750 | 50,800 | 50,800 | 47,275 | 85,000 | 85,000 | 85,000 |

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