March 21, 2014

Zacks Small-Cap Research

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# Interleukin Genetics (ILIU-OTC)

## ILIU: Strong Launch of PerioPredict

| | |
|---|---|
| **Current Recommendation** | **Outperform** |
| Prior Recommendation | N/A |
| Date of Last Change | 03/28/2011 |
| Current Price (03/20/14) | $0.35 |
| **Target Price** | **$1.10** |

## 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 it is meeting or exceeding expectations. Game plan is to broaden commercial footprint and increase number of patients enrolled in plans covering the test. ILIU has been very active in building awareness and in sales/mktg while conserving resources. $12MM capital raise in May 2013 provides cash cushion to get through initial phase of the roll-out.

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** | **$0.25** |
| **One-Year Return (%)** | **-20.00** |
| **Beta** | **2.35** |
| **Average Daily Volume (sh)** | **16,394** |
| **Shares Outstanding (mil)** | **122** |
| **Market Capitalization ($mil)** | **$43** |
| **Short Interest Ratio (days)** | **3.49** |
| **Institutional Ownership (%)** | **7** |
| **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) |
|---|---|---|---|---|---|
| 2013 | 487 A | 852 A | 419 A | 671 A | 2,430 A |
| 2014 | 544 E | 664 E | 904 E | 1736 E | 3,848 E |
| 2015 | | | | | 9,461 E |
| 2016 | | | | | 18,540 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 E | -$0.01 E | -$0.01 E | -$0.01 E | -$0.05 E |
| 2015 | | | | | -$0.03 E |
| 2016 | | | | | -$0.01 E |

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

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## Q3 2013 RESULTS

**Q4 2013:** SG&A Jumps In Support of PST Launch. 600 Dental Practices Already Rec'd PST Test…

Interleukin reported financial results for the fourth quarter and year ending December 31, 2013. While revenue was ahead of our number, a jump in SG&A expense related to supporting the roll-out of the PST test resulted in a larger than estimated net loss. More significant as far as the bigger picture, however, is that management indicated meaningful progress on several fronts with the just-launched PST test ("PerioPredict").

**Revenue**
Q4 revenue of $671k was up 98% from the same period in 2012 and was 25% better than our $535k estimate but benefitted by about $213k from an accounting change. The accounting change ("breakage" using the remote method) allows ILIU to recognize 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).

For the full-year, revenue was $2.4M, up about 10% from 2012. Deferred revenue at the end of 2013 was $3.8M, up significantly from $1.6M at the end of 2012 and potentially indicative of a much stronger revenue year for 2014 (the majority of deferred revenue is recognized as revenue over the following two years).

**GM / Operating Expenses / EPS**
Q4 GM was 42%, slightly better than our 41% estimate. We continue to expect this to widen as the PerioPredict test becomes a larger portion of overall revenue. Operating expenses were $2.2M, compared to our $1.7M estimate. The difference largely related to an earlier than expected ramp in marketing activities associated with the roll-out of PerioPredict. We model relatively elevated SG&A expense throughout 2014, again reflecting additional sales and marketing expenditures for PerioPredict as ILIU expands the commercialization footprint. Net loss and EPS were $1.9M and ($0.02), compared to our $1.5M and ($0.01) estimates. For the full-year, net loss and EPS were $7.1M and ($0.08), compared to $5.1M and ($0.14) in 2012 with the yoy improvement in EPS related a significant increase in the share count from the May 2013 equity issuance.

**Cash**
Cash used in operations in Q4 and for the full-year 2013 were $651k and $4.0M with Q4 benefitting from a $2.0M increase in deferred revenue. ILIU exited 2013 with $7.5M in cash and equivalents, up from $1.2M at the end of 2012. Cash balance was bolstered in 2013 from the May sale of $12M (gross) of common shares. The balance sheet remains debt and preferred stock-free. Management noted that they expect the current cash balance to sustain operations until early 2015. If investors in the May 2013 stock sale choose to exercise their option (expires 6/30/14) to purchase their pro rata share of up to an additional $5M of shares, management believes they will not need additional funds until at least Q4 2015.

**Operational Update**
All eyes and ears continue to be on details of the roll-out of PerioPredict. While management did not provide 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 call have us encouraged that the initial launch is meeting or exceeding expectations.

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 call that in January they shipped PerioPredict test kits to approximately 600 dentists (mostly in Michigan) with patients covered by Right-Sized policies. 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 in 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 Q4 call management noted that they have been in active discussions with other insurance carriers in their quest to expand reimbursement of the test.

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.

As the majority of the ~600 practices that ILIU has already shipped test kits to reside in just Michigan, geographic expansion via new RHSC policies and through agreements with other insurance carriers could potentially ramp the covered patient base fairly rapidly.

As we noted in our previous update, 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. 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 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 Q4 call management noted that they have been in active discussions with other insurance carriers in their quest to expand reimbursement of the test.

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.

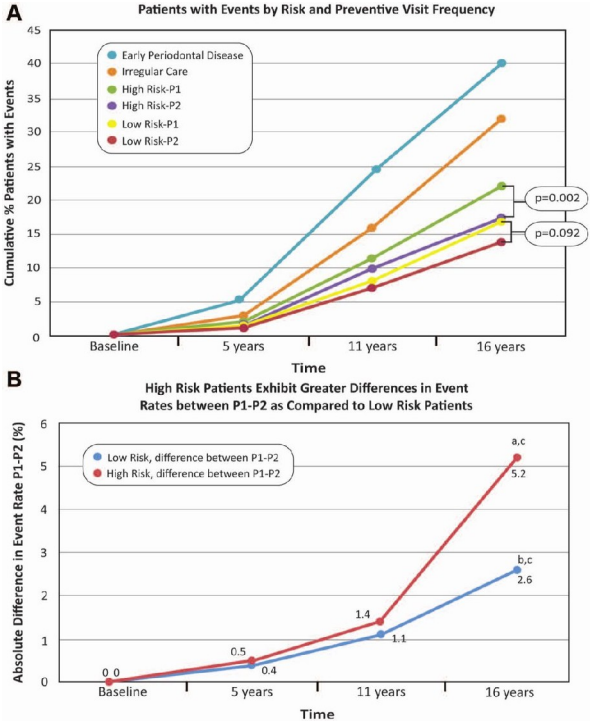
Interleukin has also had a dedicated focus on building awareness about PerioPredict which almost certainly benefitted the early success of the launch. The company recently hired a Chief Marketing Officer to spearhead the introduction of the test and to generate early awareness. These efforts have included 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 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. Most recently, In January 2014 Dr. Ken Kornman presented at the Personalized Medicine World Conference in California.

**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 54 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 beginning in Q1 of this year, we continue to model only modest revenue growth throughout most of 2014. We expect a greater rate of revenue growth to materialize towards the end of 2014 into early 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 $3.8 million / ($0.05) and $9.5 million / ($0.03) in 2014 and 2015, respectively. We are maintaining our Outperform rating and $1.10 price target.

## FINANCIAL MODEL

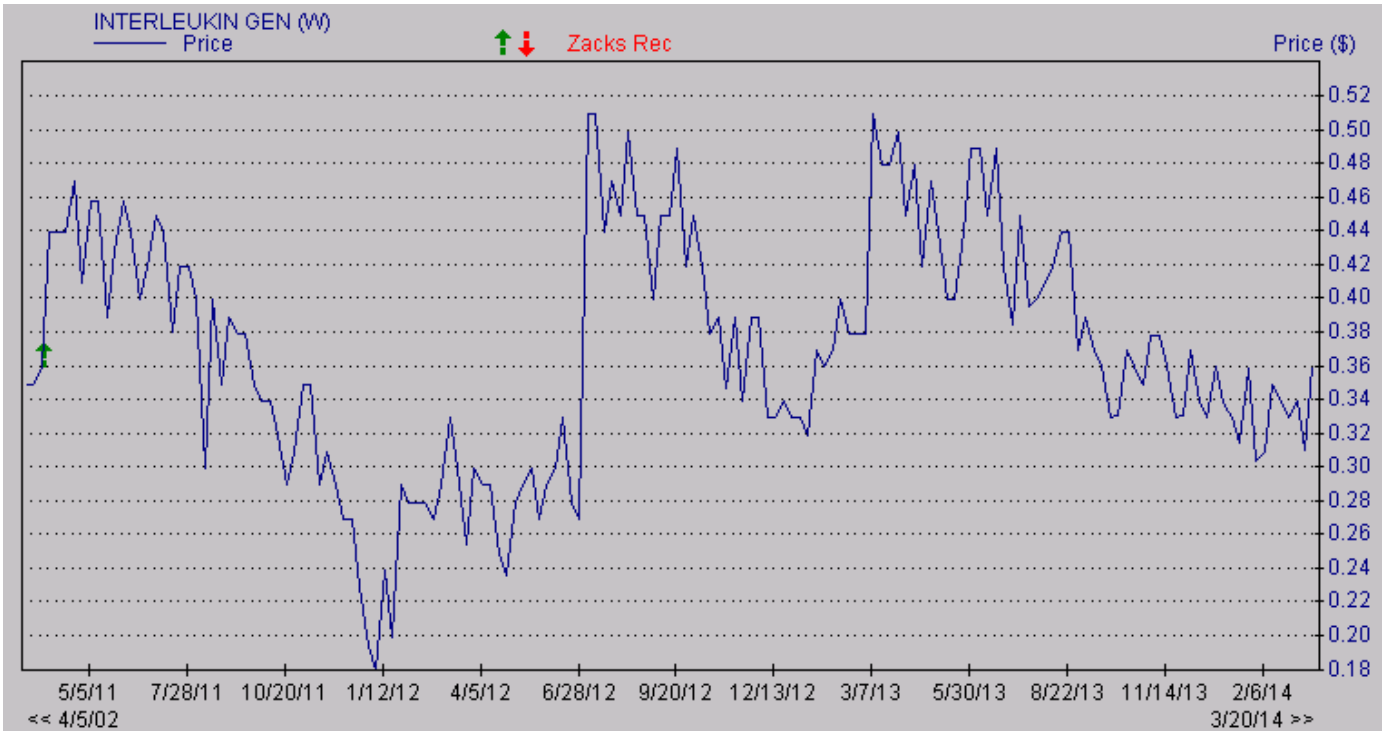
Interleukin Genetics, Inc.

| | 2013 A | Q1E | Q2E | Q3E | Q4E | 2014 E | 2015 E | 2016 E | 2017 E |
|---|---|---|---|---|---|---|---|---|---|
| Genetic testing | $2,168.7 | $528.0 | $645.0 | $878.0 | $1,685.0 | $3,736.0 | $9,185.0 | $18,000.0 | $22,855.0 |
| *YOY Growth* | *0.7%* | *9.2%* | *-24.1%* | *113.3%* | *297.0%* | *72.3%* | *145.9%* | *96.0%* | *27.0%* |
| Other | $260.9 | $15.8 | $19.4 | $26.3 | $50.6 | $112.1 | $275.6 | $540.0 | $685.7 |
| Total Revenues | $2,429.6 | $543.8 | $664.4 | $904.3 | $1,735.6 | $3,848.1 | $9,460.6 | $18,540.0 | $23,540.7 |
| *YOY Growth* | *9.5%* | *11.6%* | *-22.0%* | *115.8%* | *158.6%* | *58.4%* | *145.9%* | *96.0%* | *27.0%* |
| Cost of Revenues | $1,632.5 | $369.8 | $431.8 | $560.7 | $1,006.6 | $2,368.9 | $5,203.3 | $10,197.0 | $12,947.4 |
| Gross Income | $797.1 | $174.0 | $232.5 | $343.6 | $728.9 | $1,479.1 | $4,257.2 | $8,343.0 | $10,593.3 |
| *Gross Margin* | *32.8%* | *32.0%* | *35.0%* | *38.0%* | *42.0%* | *45.0%* | *45.0%* | *45.0%* | *45.0%* |
| R&D | $721.6 | $170.0 | $170.0 | $170.0 | $170.0 | $680.0 | $918.0 | $1,246.0 | $1,420.0 |
| *% R&D* | *29.7%* | *31.3%* | *25.6%* | *18.8%* | *9.8%* | *17.7%* | *9.7%* | *6.7%* | *6.0%* |
| 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 | $1,821.0 | $1,678.0 | $1,718.0 | $1,812.0 | $7,029.0 | $7,650.0 | $8,244.0 | $9,180.9 |
| *% SG&A* | *270.2%* | *334.8%* | *252.6%* | *190.0%* | *104.4%* | *182.7%* | *80.9%* | *44.5%* | *39.0%* |
| Amortization | $109.3 | $28.0 | $28.0 | $28.0 | $28.0 | $112.0 | $180.0 | $200.0 | $200.0 |
| Operating Income | ($6,598.5) | ($1,845.0) | ($1,643.5) | ($1,572.4) | ($1,281.1) | ($6,341.9) | ($4,490.8) | ($1,347.0) | ($207.6) |
| *Operating Margin* | *-271.6%* | *-339.2%* | *-247.4%* | *-173.9%* | *-73.8%* | *-164.8%* | *-47.5%* | *-7.3%* | *-0.9%* |
| Total Other income | ($459.4) | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| Pre-Tax Income | ($7,057.9) | ($1,845.0) | ($1,643.5) | ($1,572.4) | ($1,281.1) | ($6,341.9) | ($4,490.8) | ($1,347.0) | ($207.6) |
| 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 | ($7,057.9) | ($1,845.0) | ($1,643.5) | ($1,572.4) | ($1,281.1) | ($6,341.9) | ($4,490.8) | ($1,347.0) | ($207.6) |
| *YOY Growth* | *37.8%* | *53.5%* | *-7.5%* | *-27.7%* | *-33.0%* | *-10.1%* | *-29.2%* | *-70.0%* | *-84.6%* |
| *Net Margin* | *-290.5%* | *-339.2%* | *-247.4%* | *-173.9%* | *-73.8%* | *-164.8%* | *-47.5%* | *-7.3%* | *-0.9%* |
| EPS (continuing ops) | ($0.08) | ($0.01) | ($0.01) | ($0.01) | ($0.01) | ($0.05) | ($0.03) | ($0.01) | ($0.00) |
| *YOY Growth* | *-44.0%* | | | | | *-39.7%* | *-38.5%* | *-70.9%* | *-85.1%* |
| Diluted Shares O/S | 90,450 | 124,000 | 124,500 | 145,000 | 145,200 | 134,675 | 155,000 | 160,000 | 165,000 |

*Brian Marckx, CFA*

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## HISTORICAL ZACKS RECOMMENDATIONS




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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- 17.8%, Hold/Neutral- 74.3%, Sell/Underperform – 7.3%. Data is as of midnight on the business day immediately prior to this publication.