

LED Medical Diagnostics (V.LMD)

V.LMD: Revenue +240% in 2014, +90% in 2015?!

Current Recommendation	Outperform
Prior Recommendation	N/A
Date of Last Change	01/20/2014
Current Price (01/21/2015)	\$0.27
Target Price	\$2.25

OUTLOOK

LED Medical's VELscope is the world's leading device used for oral cancer screening with 13k units sold and 25 million scans done since the 2006 launch. Demand is fueled by a quantity of clinical data and recommendations from influential sources supporting use of the device as well as increased awareness of the dangers of oral cancer. Despite their leading position, the market remains barely penetrated, offering significant upside opportunity.

LED recently revamped its sales strategy to one with multiple distributors and complemented by a direct sales force. This is expected to further expand their footprint, drive utilization and increase profitability. LED is also now highly focused on bringing new products to market, specifically in the dental imaging market. These products have already begun to make a major contribution to revenue and are expected to be a significant driver of growth for the foreseeable future.

SUMMARY DATA

52-Week High	\$0.57
52-Week Low	\$0.19
One-Year Return (%)	-37
Beta	N/A
Average Daily Volume (sh)	114,189

Shares Outstanding (mil)	89
Market Capitalization (\$mil)	24
Short Interest Ratio (days)	N/A
Institutional Ownership (%)	N/A
Insider Ownership (%)	N/A

Annual Cash Dividend	N/A
Dividend Yield (%)	N/A

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 2014 Estimate	N/A
P/E using 2015 Estimate	N/A

Zacks Rank	N/A
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Risk Level	N/A
Type of Stock Industry	Large-Growth Med/Dental-Supp

ZACKS ESTIMATES

Revenue (in '000)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	\$310 A	\$1083 A	\$911 A	\$216 A	\$2519 A
2014	\$1055 A	\$1590 A	\$1629 A	\$4207 E	\$8481 E
2015					\$15045 E
2016					\$26499 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-\$0.03 A	-\$0.05 A	-\$0.03 A	-\$0.02 A	-\$0.13 A
2014	-\$0.04 A	\$0.00 A	-\$0.03 A	-\$0.02 E	-\$0.09 E
2015					-\$0.03 E
2016					-\$0.00 E

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

2014 Revenue Preannouncement: \$9.7M In Orders, In-Line w/ Expectations, Should Recognize \$8.5M in 2014

This morning (1/21/2015) LED Medical issued preliminary sales for the full year 2014 of \$9.7 million, \$8.5 million of which is expected to be recognized as revenue in fiscal 2014. The \$9.7 million of orders is at about the midway of the previous issued guidance of \$9.0 million - \$11.0 million. The significant order flow towards the end of the year created a backlog which means ~\$1.2 million of the orders will be recognized as revenue in early 2015.

The implied ~\$4.2 million in revenue for Q4 compares to our estimate (prior to the preannouncement) of \$5.0 million. LED also provided preliminary 2015 revenue guidance of \$15 million to \$16 million – compared to our estimate (prior to the preannouncement of \$14.2 million). We have now reduced our Q4 2014 estimate by \$800k (to \$4.2 million) and pushed this \$800k to early 2015 – resulting in our 2015 revenue estimate increasing to \$15 million.

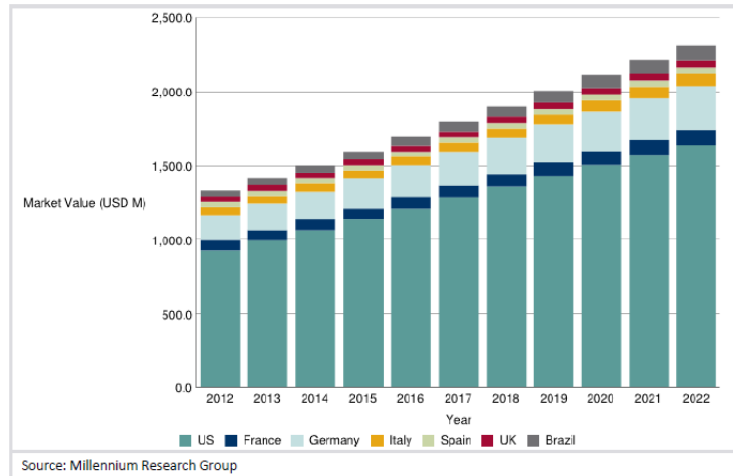
Importantly, LED notes in this morning's press release that much of ~\$6.0 million revenue growth (+240%) from 2013 to 2014 was driven by a significant increase in contribution from VELscope products – indicating that the full initial potential from the company's dental imaging product line may yet to have been realized. We think the revival in the VELscope line, combined with a much more significant contribution from the dental imaging business bodes well for additional significant revenue growth and improved earnings in 2015 and beyond. In addition, incremental contribution is expected to materialize from the continued build-out of the sales/distribution infrastructure and additions to the imaging product portfolio.

As we have recently noted, revenue growth is being driven by the recent expanded distribution of VELscope as well as the newly established digital imaging product line. LED further beefed-up their sales capabilities with the recently signed distribution agreement with DenMat Holdings for VELscope ex-U.S. They also increased their geographic reach for RAYSCAN Alpha-Expert and RIOSensor intraoral sensor, which had previously only included the U.S. market until the announcement in December that LED signed an exclusive distribution agreement with Ray Co. for Canada. While we believe these agreements likely only provided modest contribution in Q4, we think much more substantial revenue will be provided from these territories beginning in early 2015.

LED Returns to Growth Via Exploiting Changes in Dental Imaging Market, Reviving VELscope

As we have highlighted in our ongoing coverage of LED, the company's recent shift strategy aimed at reviving revenue and earnings growth includes a beefing up of their product portfolio. New additions to LED's leadership including CEO Dr. David Gane, Lamar Roberts (President of the newly formed LED Dental division) and Al Fiore (company advisor) came from high level positions with major dental imaging and dental technology companies.

Along with regaining growth of the company's proprietary VELscope oral cancer screening device, one of the first orders of business of the new leadership was to diversify their revenue base via high-potential new product offerings. Gane and his team, relying on their expertise, experience and first-hand knowledge of market dynamics of the dental industry see certain changes within the dental imaging space as offering opportunities that hold potential for outsized growth. Market research supports their view of a changing landscape in dental imaging, specifically an ongoing shift to greater demand for digital imaging. The U.S., LED's major focus, is also where the bulk the opportunity lies as it is the largest dental imaging market and is expected to grow from \$991M in 2012 to \$1.6B in 2022 (per Millennium Research Group).



During 2014 the company formed a new operating subsidiary, LED Imaging, which is charged with exploiting these changes, specifically growth of dental digital imaging. These growth opportunities include the rapid adoption of 3D imaging, the ongoing switch from film to digital imaging methods and the increasing use of advanced software for design and manufacturing of dental restorations.

CBCT Fastest Growing Dental Imaging Modality, LED Riding the Wave...

Cone beam computed tomography, or CBCT, are extraoral (i.e. - outside the mouth) scanners which rotate around the head during an exam, providing a 360° view and with 3D images. Extraoral imaging is used to examine both the teeth and bones of the face and jaw, largely for the purposes of implantology (i.e. - assessment and planning of dental implants) and orthodontics. CBCT's ability to provide 3D images is viewed as a significant advantage to the 2D images provided by conventional extraoral imaging modalities. Unlike 2D X-rays, 3D imaging provides the benefit of viewing adjacent and anomalous structures which provides better accuracy and allows for improved visualization and treatment planning, particularly for more complex diagnoses.

A paper published in the October 2010 issue of The Journal of The American Dental Association titled *Practical Applications of Cone-Beam Computed Tomography in Orthodontics*¹ cites several advantages of CBCT over conventional 2D imaging in orthodontics which provide for improved diagnosis and planning. And relative to utility in implantology, in June 2012 the American Academy of Oral and Maxillofacial Radiology updated their guidelines for dental implant imaging, recommending CBCT as the preferred method for presurgical assessment of dental implant sites.

In September 2013 Millennium Research Group published a research study on dental imaging industry trends titled *Global Markets for Dental Imaging Systems 2014*. The authors expect growth in the dental implant market and increasing demand for higher quality images will drive future sales of CBCT systems, which they predict will expand at a CAGR of approximately 15% globally and 16% in the U.S. over the ten year period of 2012 - 2022. The report further notes that CBCT is the fastest growing segment in dental imaging and is expected to continue to be so as dental professionals

LED is looking to capitalize on the expected significant growth in demand for CBCT systems. In April the company announced that it entered an agreement with Ray Co, Ltd, a subsidiary of Samsung, to sell that company's RAYSCAN-Expert CBCT instrument in North America. And with roughly 60% of all CBCT systems residing in the U.S., the domestic market is where the lion's share of the business is.

RAYSCAN - Expert and Sample Images (SOURCE: rayscanamerica.com)



¹ Mah JK., et al. Practical Applications of Cone-Beam Computed Tomography in Orthodontics. JADA, Oct 2010 141,7S-13S

Film-Based Imaging Being Replaced By Digital Imaging...

According to the 2013 Millennium Research Group report the global market for dental imaging will grow from \$1.4B in 2012 to \$2.3B in 2022, a CAGR of 5.5% which will be driven in part by the transition of film-based to digital-based imaging. Other factors also expected to facilitate this growth are greater demand for technologies that can increase patient flow (which also relates to the switch from film to digital imaging) as well as growing popularity of cosmetic dentistry procedures, such as veneers and orthodontics.

Intraoral imaging is used for the detection of cavities, to look at the roots of the tooth and to evaluate the health of area around tooth. There are two types of digital intraoral imaging systems; photostimulable phosphor plate systems (PSP plate systems) and digital X-ray sensors. PSP plate systems are indirect and involves a small plate (that is used in place of film) that is inserted into the mouth and then removed and digitally scanned. Digital sensors are direct, meaning that the sensor sends the data directly to a computer. PSP plate systems are more economical in terms of upfront costs but have disadvantages to digital sensors including that while sensors provide immediate results, scanning time with PSP plate systems can take up to two minutes.

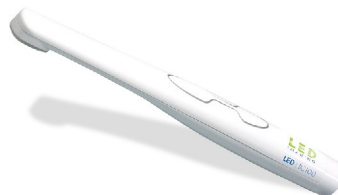
Millennium Research expects film based modalities to be replaced by digital systems and for PSP plate systems to increase at a CAGR of about 2.6% in the U.S. over the next ten years. However, as practitioners are increasingly demanding improved workflow and patient throughput, the minutes lost waiting for scanning via PSP will drive even greater interest in digital X-ray sensors. Another advantage of digital X-ray sensors is their easy integration with electronic medical record systems. Millennium expects these advantages to push the U.S. digital X-ray sensor market up at a CAGR of about 4.4% over the next ten years.

LED is also looking to participate in this market. In May 2014 the company announced the introduction of LED IS100, a digital intraoral sensor. LED will distribute the sensor in the U.S. The sensor is manufactured by Owandy, a France-based digital imaging company which has a presence in Europe but insignificant sales in the U.S., providing LED with a wide-open opportunity to exploit the domestic market. LED also introduced a intraoral camera, IC100.

Intraoral Sensor

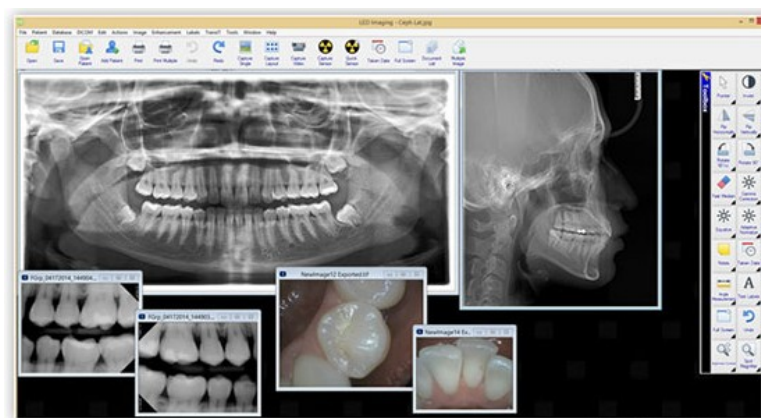


IC100 Intraoral Camera (SOURCE: leddental.com)



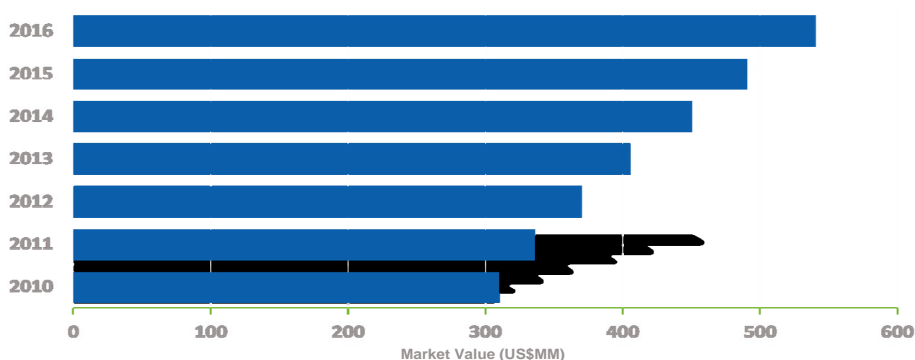
Imaging Software Ties In Intraoral / Extraoral Imaging

Imaging software is used to generate and store the images produced by intra- and extra-oral imaging modalities. In April LED announced the launch of open-architecture imaging software. The software is compatible not only with RAYSCAN-Expert but also with intraoral and extraoral devices from a variety of manufacturers. It also can be seamlessly integrated with any dental practice management suite.



Software is a key piece in patient diagnosis and treatment planning. It is also used for computer-aided design/computer-aided manufacturing (CAD/CAM), a rapidly growing area in dentistry. CAD/CAM is used to design dental restorations such as veneers, crowns and prostheses but is still considered to be in the early adoption phase, leaving significant room for growth. Millennium Research expects the global CAD/CAM market to grow from approximately \$320M in 2010 to \$540M in 2016 (9% CAGR).

GLOBAL DENTAL CAD/CAM SYSTEM MARKET* Market Forecast - \$540MM in 2016



SOURCE: Millennium Research Group

LED Making Rapid Progress in Tapping Imaging Market

The company has already made significant strides in tapping the digital imaging market since LED Imaging was formed in April 2014. They have signed partnership deals to distribute high potential digital imaging products throughout North America and commenced building a sales infrastructure to promote the products. LED is also in a somewhat unique and advantageous position in terms of distribution as they can leverage their already established VELscope customer base, which currently stands at approximately 8k dental practices.

And while the company has already brought several third-party digital imaging products under its distribution umbrella, management has indicated that they remain highly engaged with existing and other potential new partners with an eye on further expanding their dental imaging and technology product suite and expect their LED Imaging business to be a major driver of long-term growth of the company.

This early progress has already culminated in a significant increase in orders and revenue. 2014 revenue is expected to increase ~240% (from \$2.5M in 2013 to \$8.5M in 2014) and management's current guidance is for 2015 revenue growth of 75% - 90% (\$15M - \$16M).

VELscope Also Remains a Focus

And while LED has dedicated considerable energy on building its imaging division, reviving sales of the company's proprietary oral cancer screening device, VELscope, also remains a priority. VELscope continues to

hold the title of the world's leading adjunctive screening device for oral tissue abnormalities, including oral cancer. There are currently about 13k devices in use. But despite success in building a sizeable installed base, VELscope sales have recently lagged. Revenue fell from \$6.3M in 2012 to \$2.5M in 2013 in the midst of a change in distribution model.

Since then the new management team has implemented changes related to VELscope distribution and optimized sales and marketing. This has included changing their distribution - from one which was heavily reliant on a single distributor to one which now will include several sales organizations. LED has made considerable progress in this regard. Since late 2013, the company has penned new distribution agreements with eight distributors including "majors" Patterson Dental, Henry Schein and DenMat Holdings. Optimization of the distribution model along with expected forthcoming additional clinical evidence supporting the use of VELscope for oral cancer detection, is expected to culminate in a resurgence of growth in sales of the device. Early indications are that the revamped distribution strategy is already paying off. LED notes in their 1/21/2015 revenue preannouncement that much of ~\$6.0 million revenue growth (+240%) from 2013 to 2014 was driven by a significant increase in contribution from VELscope products.

Financial Model

With RAYSCAN-Expert retailing for approximately \$100k, the instrument could be a very significant revenue source for LED. LED's \$15M - \$16M revenue guidance for 2015 includes the expectation that sales of their digital imaging products show a much more substantial contribution compared to 2014. Furthermore, the company has indicated that they expect the digital imaging products will continue to be a significant contributor to total sales going forward.

Revenue fell 60% in 2013 but has since done an about-face, increasing 86% through the first three quarters of 2014 and expected to increase by 240% for the full-year 2014. We think it is now clear that the initial portion of the company's shift in strategy, which includes a major focus on expanding distribution and complementary revenue opportunities, has already been well established - and has been done in much more rapid fashion than we had initially anticipated it would be. The architects, namely David Gane and Lamar Roberts who came to LED from Carestream with highly relevant experience in the dental products industry sales, have made obvious substantive progress (in a very short period of time) with broadening the distribution footprint, revamping the sales strategy, growing the product portfolio and returning the company to positive revenue growth. For 2015 the company has provided revenue guidance of \$15M - \$16M, implying growth of 75% - 90%.

We model \$8.5 million of revenue in 2014. We think this grows to at least \$15 million in 2015, catalyzed by a greater (and full-year) contribution from the digital imaging suite of products. This includes RAYSCAN's cone beam computed tomography instrument which is expected to receive Health Canada approval by the current year-end. Continued investment in sales/marketing infrastructure and other costs related to the roll-out of the LED Imaging product suite as well as an increase in sales-related commissions will have the effect of pushing up operating expenses, although we model a flatter rate of growth in opex as compared to that of revenue.

OUTLOOK / VALUATION / RECOMMENDATION

We model \$8.5 million in revenue in 2014. Expansion of the product suite has ramped very rapidly and, along with a change in distribution model, has been the work of the new management team. This recent shift in strategy appears to already be the turning point for the company in terms of returning it to positive revenue growth. Revenue is up 86% yoy through the first nine months of 2014 and is expected to increase by 240% for the full year.

We expect moderate growth of the VELscope installed system base in the U.S. and accelerating growth in international markets. While we think the U.S. market remains the largest base for LED and at only about 6% penetrated, still provides significant upside for the company, international markets, which are almost completely untapped, offer potentially steep growth curve opportunities over the next several years. Current paid utilization is well below reasonable expectations but is likely at floor level with upside (potentially significantly so) possible now with a new and experienced sales team onboard and additional distribution expected in the near term. We model only somewhat modest increases in paid utilization over the next several years - we think this is a fair estimate given the lackluster consumables in the past but also giving credit for LED's change in strategy to take hold. The

modest increase in paid utilization, where the greater margin lies, is also reflected in our somewhat modest estimated uptick in gross margin over the next few years.

Meanwhile, the company will further capitalize on their distribution reach and leverage their sales infrastructure through a larger product portfolio. In December LED announced that they expanded their distribution reach for the RAYSCAN products, which had previously only included the U.S. market but will now also encompass Canada. The RAYSCAN agreement already looks like a winner for LED and the company expects to continue to look to add complementary products to their sales forces' bags. Per our discussions with management relative to the potential of the LED Imaging business, this segment holds great opportunity to grow over the long-term. This outlook appears to be supported by industry research indicating attractive growth on the horizon for digital dental imaging equipment and technology, We think 2014 revenue will pale in comparison to 2015 - which we expect will show significant growth in both the VELscope and LED Imaging businesses.

We value LED using a 10-year discounted cash flow model. We have revenue CAGR of about 50% from 2014 through 2018, then dropping to a low-double digit average through 2024. We also note that growth in the LED Imaging business could outpace our current estimates - these will also be subject to updating as the potential for these products becomes more clear. This could provide revenue upside to our model, particularly over the mid-to-long-term time frames. We use a 10% discount rate and 2% terminal growth rate. Based on DCF, LED is value at \$2.28/share - we round to \$2.25.

We are maintaining our Outperform rating.

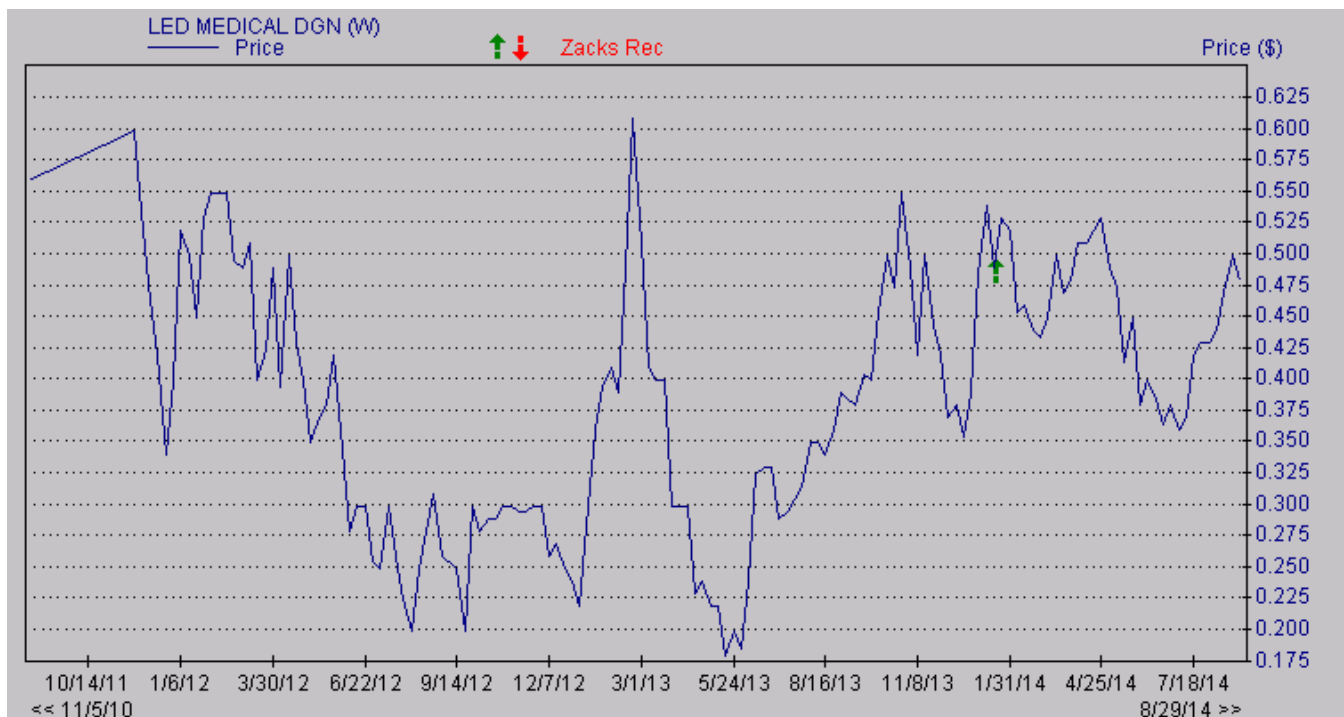
FINANCIAL MODEL

LED Medical Inc.

	2013 A	Q1A	Q2A	Q3A	Q4E	2014 E	2015 E	2016 E	2017 E
Revenue	\$2,519	\$1,055	\$1,590	\$1,629	\$4,207	\$8,481	\$15,045	\$26,499	\$35,617
<i>YOY Growth</i>	-60.1%	240.7%	46.9%	78.7%	1851.6%	236.6%	77.4%	76.1%	34.4%
Cost of sales	\$1,348	\$526	\$724	\$1,028	\$2,493	\$4,771	\$7,931	\$12,380	\$15,915
Gross Income	\$1,171	\$529	\$866	\$601	\$1,714	\$3,710	\$7,114	\$14,119	\$19,702
<i>VELscope related GM</i>				54.6%	54.2%	54.7%	55.3%	60.0%	61.2%
<i>Total Gross Margin</i>	46.5%	50.2%	54.5%	36.9%	40.7%	43.8%	47.3%	53.3%	55.3%
SG&A	\$4,369	\$1,478	\$2,251	\$2,362	\$3,250	\$9,341	\$10,050	\$12,980	\$15,100
<i>% SG&A</i>	173.4%	140.1%	141.6%	145.0%	77.2%	110.1%	66.8%	49.0%	42.4%
R&D	\$442	\$259	\$247	\$216	\$280	\$1,002	\$1,154	\$1,218	\$1,336
<i>% R&D</i>	17.6%	24.5%	15.6%	13.2%	6.7%	11.8%	7.7%	4.6%	3.8%
Operating Income	(\$3,641)	(\$1,207)	(\$1,633)	(\$1,977)	(\$1,816)	(\$6,632)	(\$4,090)	(\$79)	\$3,266
<i>Operating Margin</i>	-144.5%	-114.4%	-102.7%	-121.4%	-43.2%	-78.2%	-27.2%	-0.3%	9.2%
Total Other Income	(\$3,302)	(\$1,687)	\$1,715	(\$717)	\$20	(\$669)	\$60	\$70	\$85
Pre-Tax Income	(\$6,943)	(\$2,894)	\$83	(\$2,694)	(\$1,796)	(\$7,301)	(\$4,030)	(\$9)	\$3,351
Taxes (benefit)	\$12.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>Tax Rate</i>	-0.2%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Net Income	(\$6,955)	(\$2,894)	\$83	(\$2,694)	(\$1,796)	(\$7,301)	(\$4,030)	(\$9)	\$3,351
<i>Net Margin</i>	-276.0%	-274.3%	5.2%	-165.4%	-42.7%	-86.1%	-26.8%	0.0%	9.4%
EPS	(\$0.13)	(\$0.04)	\$0.00	(\$0.03)	(\$0.02)	(\$0.09)	(\$0.03)	(\$0.00)	\$0.02
<i>YOY Growth</i>	455.5%	14.3%	-102.2%	-3.2%	-5.2%	-31.5%	-66.7%	-99.8%	-35616.4%
Diluted Shares O/S	53,131	73,574	74,593	82,313	95,000	81,370	135,000	140,000	145,000

Brian Marcckx, CFA

HISTORICAL ZACKS RECOMMENDATIONS



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Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.

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- 16.0%, Hold/Neutral- 77.8%, Sell/Underperform – 6.0%. Data is as of midnight on the business day immediately prior to this publication.