Zacks Small-Cap Research

May 2, 2017

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# LED Medical Diagnostics (V.LMD)

## V.LMD: Apteryx, Other Catalysts Offer Upside In 2017

Our $0.70 target price and valuation is under review and, along with our model, will be updated after LED files historicals for the pro forma combination of LED Medical and Apteryx – which is expected to occur in the coming weeks.

| | |
|---|---|
| Current Price (05/02/2017) | $0.08 |
| **Valuation** | **$0.70** |

## OUTLOOK

While 2016 ended with somewhat of a whimper, there are reasons to believe 2017 will return the company back to growth. In addition to the renewed ability to build imaging-related product inventory, other potential growth catalysts including VELscope disposable sales and initial contribution from recently acquired Apteryx offer additional upside. In fact as it relates to Apteryx, management noted that integration is going well and that they "expect Apteryx to contribute significantly to revenue, EBITDA and cash flow growth this fiscal year and for the foreseeable future." And Apteryx, as we discuss, brings other potential benefits to LED including a recurring revenue stream and synergies in product portfolios and customer call points – which means LED's existing business lines may also directly benefit from the marriage of the two companies. We note that our model still does not reflect contribution from Apteryx (or any potential synergies) nor for the equity raises commensurate with the acquisition. We will incorporate forecasted effects of the Apteryx acquisition into our model following LED's filing of pro formas – which we think will happen within the coming weeks. But, even without any assumed Apteryx contribution, we still model revenue growth in 2017.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$0.19** |
| **52-Week Low** | **$0.05** |
| **One-Year Return (%)** | **-53** |
| **Beta** | **0.35** |
| **Average Daily Volume (sh)** | **17,000** |
| **Shares Outstanding (mil)** | **373** |
| **Market Capitalization ($mil)** | **28** |
| **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 2017 Estimate** | **N/A** |
| **P/E using 2018 Estimate** | **N/A** |
| **Zacks Rank** | **N/A** |

| | |
|---|---|
| **Risk Level** | **N/A** |
| **Type of Stock** | **Large-Growth** |
| **Industry** | **Med/Dental-Supp** |

## ZACKS ESTIMATES

**Revenue**
(in '000)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2016 | $2153 A | $3661 A | $2489 A | $1865 A | $10169 A |
| 2017 | $1977 E | $3192 E | $3006 E | $5431 E | $13605 E |
| 2018 | | | | | $17117 E |
| 2019 | | | | | $20652 E |

**Earnings per Share**

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2016 | -$0.02 A | -$0.01 A | -$0.01 A | -$0.01 A | -$0.05 A |
| 2017 | -$0.01 E | -$0.01 E | -$0.01 E | -$0.01 E | -$0.04 E |
| 2018 | | | | | -$0.03 E |
| 2019 | | | | | -$0.02 E |

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

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## Q4, FY2016 Financials: *2016 Ends On Whimper, But Apteryx and Other Catalysts Offer Upside In 2017…*

LED reported financial results for their fourth quarter and full year ending December 31st. Despite seasonality of dental capital equipment sales typically favoring Q4, the quarter was relatively weak for LED with revenue at the lowest level of any period in 2016 and contracting by 67% yoy and 25% from Q3. The company pointed to inability to purchase sufficient inventory due to lack of capital as a reason for the disappointing top-line number – which missed our $5.3M estimate by about 65%. As a reminder, while we were modeling a mid-single digit contraction from Q4 2015, we had also expected LED would again be able to take advantage of the characteristically strong demand for dental equipment that is typical of the final quarter of the year.

On the brighter side, LED's cash balance was recently shored up via the sale of debt and equity - which happened concurrently with the Apteryx acquisition. While $7M of the ~$11M (gross U.S) raise was allocated to the acquisitions' upfront payment, much of the remainder will be used to fund operations – presumably including to beef up their inventory (balance of which fell by a relatively large $4.9M in 2016).

Revenue for the full year was $10.2M, down 23% from 2015. Prior to Q4, revenue had increased 11% through the first nine months of 2016 from the comparable year-earlier period – so had it not been for such a poor showing in Q4, 2016 could have been another revenue growth year for the company.

But while 2016 ended with somewhat of a whimper, there are reasons to believe 2017 will return the company back to growth. In addition to the renewed ability to build imaging-related product inventory, other potential growth catalysts including VELscope disposable sales, which LED noted continued to grow in 2016, and initial contribution from recently acquired Apteryx offer additional upside. In fact as it relates to Apteryx, management noted in their shareholder letter that the integration is going well and that they "expect Apteryx to contribute significantly to revenue, EBITDA and cash flow growth this fiscal year and for the foreseeable future." And Apteryx, as we noted in our recent investor note (and discuss in more detail below), brings other potential benefits to LED including a recurring revenue stream and synergies in product portfolios and customer call points – which means LED's existing business lines may also directly benefit from the marriage of the two companies.

We note that our model still does not reflect contribution from Apteryx (or any potential synergies) nor for the equity raises commensurate with the acquisition. As noted in our update just following the acquisition, we will incorporate forecasted effects of the Apteryx acquisition into our model following LED's filing of pro formas – which we think will happen within the coming weeks. But, even without any assumed Apteryx contribution, we still model revenue growth in 2017.

And as it relates to VELscope, we think (as we discuss in more detail below) the recent entry into China, coupled with additional and recently published clinical evidence supporting use and clinical utility of the device, are both potential near-term growth drivers for that business.

**Gross margin**, similar to revenue, was not a highlight in Q4 – in fact, at just 13.7% it was at the lowest level since at least Q4 2013. LED attributed the relative weakness to lower margin imaging sales from competitive pricing pressures as well as to "a significant year-end inventory adjustment." It is not clear what exactly the inventory adjustment relates to and we note that there was not a descriptive non-cash item related to such that ran through the cash flow statement. Nonetheless, GM, which was 24.4% for the full year (vs. 27.2% in 2015) should have room to improve in 2017, particularly in the event of meaningful sales from Apteryx.

While we won't know exactly what to expect in terms of margins from the company until more financial information becomes available, given that Apteryx is primarily involved in software development (i.e. typically a high-margin business), we think it is reasonable to believe LED's overall gross margins may benefit from the acquisition.

And while imaging product sales have always carried relatively low (reseller-type) margins, LED's proprietary VELscope and related disposables margins are believed to be much healthier. In fact LED notes in their current filings that VELscope margins have been running at about 56%. So with expectations that VELscope sales continue to grow, coupled with contribution from Apteryx, we could see a meaningful improvement in gross margins as soon as the current year.

**Operating expenses** in Q4 remained at roughly the same level as in Q3 – at about $1.5M. And, if we had to point to one part of the income statement that was moderately positive, it would be OpEx level – which remained

well below the $2.3M quarterly average during the first half of 2016. Full-year OpEx in 2016 was $7.6M – improved from $8.8M in 2015. So while revenue and gross margin contracted by 23% and 280 basis points from 2015 to 2016, these were more than offset by the $1.2M lower operating expenses – the net result was operating loss improving (albeit barely) from $5.2M to $5.1M over the same period.

**Cash** used in operating activities was $648k and $2.5M ($1.3M and $4.7M ex-changes in working capital) in the three and twelve months ending 12/31/16. LED exited the year with $875k in cash and equivalents. Subsequent to year-end and concurrent with the Apteryx acquisition, the company raised ~$10.9M (CDN$14.4M) in gross proceeds via the sale of equity and debt. We estimate that net proceeds after issuance and IB expenses was approximately $10.1M (U.S.) which, after the upfront cash payment to Apteryx, left LED with approximately $3.1M (in addition to already existing cash).

## Apteryx Brings Diversified/Synergistic Portfolio, IP, Expanded Customer Base and Profitability

In September 2015 LED Medical announced their intent to acquire "100% of a growing and profitable technology company to complement LED's existing business and provide a platform to assist LED in achieving its strategic and long-term business objectives." The press release further noted that, "The potential transaction, if successfully negotiated and closed, would be significantly additive to revenues, and immediately accretive to EBITDA and net earnings and bring additional Intellectual Property to the Company."

LED mentioned little after that regarding the potential acquisition until this January when they announced their intent to acquire Apteryx, Inc., an Ohio-based company which develops and sells software primarily for the dental industry. The deal closed in February.

Apteryx looks like it could be a great fit for LED given that there appears to be some potential significant synergies among the companies' product portfolios and customer call points. Apteryx brings the dental imaging and database software that supports LED's digital imaging hardware – providing a one-stop-shop for dental practices. Apteryx's software licensing and recurring revenue business model will also provide welcome diversity and smoothing to LED's capital product sale revenue stream – which is typically highly seasonal and based on the dental industry's capex purchasing patterns.

And beyond the current benefits, which apparently also includes profitable operations, Apteryx brings a sizeable patent portfolio and software development experience which can be expected to be leveraged for future growth including from further expansion of their product offerings.

**Terms:**

- $10.25M acquisition price for 100% of Apteryx:
    - $7M cash at closing
    - $1.8M (33.9M shares @ C$0.07, ~$0.053) worth of LED stock at closing
    - $1.2M cash paid in tranches over 18 months
    - $450k in cash or LED stock (LED's option) in 24 months
- Apteryx will operate as a stand-alone subsidiary of LED
- Apteryx's founder and CEO, Kevin Crucs, will continue to run operations and joins LED's management team

**Concurrent financing:**

Concurrent with the acquisition LED raised approximately C$14.4M (~$10.9) via the sale of equity and debt. Equity raise C$13.3M (~$10.0M) includes the sale of approximately 215M common shares (@ C$0.06/share) with 50% warrant (24mths, C$0.10 strike) coverage. Insiders of LED, including directors and officers, bought 9.2M of the shares sold. Debt raise via the sale of C$1.15M (~$870k) senior secured debentures (24mths, 12%) with ~2.4M common shares attached.

LED's recent quarterly cash burn has averaged ~$1M but with the addition of Apteryx's operations, which LED indicates generates positive cash flow, this level of cash burn could come down. And while LED will also pay an additional $1.2M cash to Apteryx over the next 18 months, we think their cash balance could represent a fairly lengthy runway to fund operations depending on contribution from Apteryx. We will know much more about Apteryx's financials, including cash flow, when LED files historicals for the pro forma combination.

**Apteryx**

Apteryx, located in Akron, Ohio, was founded in 1995 by Kevin Crucs. The company develops software primarily for the dental and medical imaging markets. The company's competitive positioning includes development of

custom software applications to meet the needs of their customers and to do so in a relatively short turnaround time. Per the company's website, "Apteryx specializes in image processing; synthetic imaging and generation; data and image compression; encryption and data security; neural networking; check processing systems, network and communication applications and services; tools and utility applications and services; real-time video imaging; hardware and peripheral integration; proficient in several programming languages for a number of different hardware platforms; design and implementation of several networking and distributed systems applications for inventory management and other large-scale programs; large-scale software projects."

**Apteryx 's Product Portfolio:** Their products are sold through resellers (such as LED Medical) as well as through their own website. Their suite of products are compatible with hardware of many different manufacturers and designed for businesses of all sizes - from small, single-office practices to large, multi-office organizations. The following product descriptions are from Apteryx's website (www.apteryx.com):

- **XrayVision**: was first launched in 1996 and has become the industry's leading open-architecture digital image management program. XrayVision will capture, enhance and display all of your dental images. Supporting image capture from the majority of the different digital intraoral sensors available today, XrayVision also integrates with phosphor plate scanners, digital panoramic and cephalometric imaging, flatbed scanners, intra-oral and extra-oral cameras, 3D conebeam tomography and many other digital sources.
- **XVWeb**: In addition to being a web application used to view the images, XVWeb is a fully-functional DICOM server that can accept images from any DICOM-compliant imaging software. Although any DICOM-enabled application can be utilized, Apteryx DCV and XrayVision4 are specifically designed to work seamlessly with XVWeb.




- **XVlite**: XVlite will capture, enhance and display all of your dental images. XVlite supports image capture from a majority of the different digital hardware in today's market. XVlite incorporates the latest advancements in imaging technology and Apteryx's patented STB (Secure Tagged Block) file format, an unmodifiable, secure and "loss-less" imaging format. XVlite also exports to a number of common image file formats, including TIFF, JPEG, and BMP for universal viewing.
- **XrayVision DCV**: XrayVision DICOM Capture View, known as DCV, is a DICOM-based dental imaging suite that is scalable to any size organization. DCV is used to standardize the capture, storage, retrieval, and viewing of images across an entire organization. DCV supports most all imaging devices utilized in dentistry, including: Intra-oral sensors, Phosphor Plate Scanners, Panoramic / Cephalometric units, 3D / CAT scan, Tomography, Intra-oral Cameras, Extra-oral Cameras, Endo scopes, and Flatbed Scanners. DCV can act as a full enterprise standalone PACS or can serve as the capture modality that will automatically forward to an existing PACS. DCV's open architecture enables the freedom to use a wide variety of capture devices, while maintaining the industry standards. The US Army and US Navy currently use DCV as their global solution for managing all of their dental clinics worldwide, which allows for centralized storage of all images to provide global access to patient information. XrayVision DCV has numerous bridging capabilities from a standard command line integration, data extraction and auto importing patient demographic, barcode scanning, DICOM Worklist, HL7, and custom data bridges.

**Highlights of Apteryx Acquisition:**

- Immediately accretive: expected to be significantly accretive to revenue, EBITDA and net income in 2017
- Software margins: while LED has yet to provide specifics, software margins are typically significant and we would expect the Apteryx margins to be substantially better than LED's current ~25%
- Recurring revenue: software licensing and recurring revenue business model provides diversity and smoothing to LED's capital product sale revenue stream which is typically highly seasonal
- One-stop-shop: LED can now provide a full digital imaging product solution, including software and hardware
- Synergies: complementary products which share similar customer call points should provide operational synergies
- Familiarity: the companies' management have known each other for ~15 years and LED is a customer of Apteryx's products. The long affiliation provides for operational and relationship related risk-mitigation, particularly given that Kevin Crucs joins as part of LED's management team
- Expands customer base: immediately bolts on a significantly greater installed base to cross-sell to

- Growth opportunity: Apteryx brings a sizeable patent portfolio and software development experience which can be expected to be leveraged for future growth including from further expansion of their product offerings. Per LED's 3/8/17 press release Apteryx has 23 U.S. and 41 international patents

**Our comments:**
We note that oftentimes M&A transactions in the micro-cap space prove shortsighted given a tendency to overemphasize a goal of product extension and underweight the importance of operational synergies. Operational friction from poor fit often has unfortunate symptoms including bloated (and duplicative) expenses, lack of unified strategy and direction, and stressed managerial relationships (among others) which is rarely a recipe for success and future growth.

We think LED's acquisition of Apteryx is one of the exceptions where product and operational fit were carefully (and wisely) and appropriately balanced. And the fact that there has been a long courtship between the two parties prior to consummation of the marriage should lend itself to mitigation of any relationship or personality-related risks. So while we will wait to opine on the potential financial impact and influence on LED's valuation until after the pro forma historicals are filed, we are encouraged by what we think appears to be the makings of an operationally healthy and (hopefully) financially beneficial transaction.

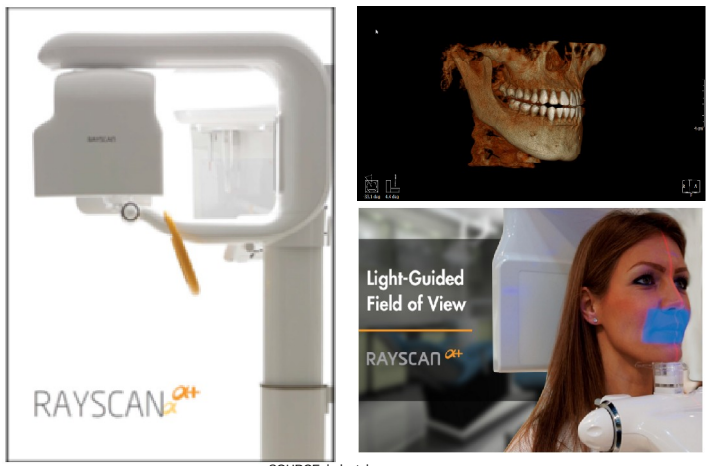
Our model has not been updated to reflect contribution from Apteryx nor for the equity and debt raises commensurate with the acquisition. As noted, we will incorporate Apteryx into our model following LED's filing of pro formas – which we expect will happen within the next few weeks. Our model updates could also influence our valuation of LED Medical.

**While much of the current excitement lies with the integration and expected meaningful contribution of Apteryx, LED's existing business lines remain poised for continued growth. The company had some recent operational-related "wins" in both their dental imaging and VELscope segments which have the potential to provide meaningful revenue tailwinds into 2017.**

**As it relates to digital imaging**, we think the recent launch of the RAYSCAN Alpha Plus Imaging System, announced in late September 2016, should be a meaningful revenue contributor given the success of the legacy RAYSCAN system. This next-gen product has the potential to add to their success which includes several upgrades to the legacy system. Functionality includes;

- Light-guided field-of-view superimposed on patients face which simplify and optimize patient positioning
- Customizable FOV (field of view) from 4x3cm to 16x10cm while many systems only allow for a limited number of preset field of view options
- Provides for 3D images among the highest resolution in the industry
- Only CT and cone beam system utilizing remote control functionality allowing clinician to interact with patient and control the system simultaneously
- Cephalometric module allows for both scanning and single-shot image capture – affording even less risk of distortion and lower radiation exposure

**Rayscan Alpha Plus Imaging System**




SOURCE: ledental.com

The addition of RAYSCAN Alpha Scan Plus is just the latest of a fairly regular flow of new products into LED's digital imaging product portfolio. This includes the addition of the Tuxedo digital intraoral radiography system which in March 2016 received FDA 510(k) clearance, allowing it to be sold in the U.S. Tuxedo is billed as providing some of the highest image quality of any intraoral sensors on the market. Tuxedo, like most of LED's imaging portfolio, looks to exploit the rapid digital imaging market growth driven by the shift from analog dental film and imaging.

And while the digital imaging segment has been responsible for much of the company's recent revenue growth, we think there are several potential catalysts that could facilitate additional growth of the **VELscope Vx business**. These include additional distribution and entry into new geographic territories (including China) as well as additional published clinical data supporting the use of autofluorescence in the early diagnosis of oral cancer as well as in improving survival of patients undergoing oral cancer surgery.

***VELscope Launches In China, Distributed By Largest Dental Equipment Supplier in China…***
Relative to expansion of the commercial VELscope footprint, in November 2016 LED announced the launch of VELscope Vx in China. While the device received regulatory approval in that country in August 2015, LED still needed to line up distribution and tie up remaining loose ends – these were finalized, including an exclusive distribution agreement with Biocare Health Supply which was penned in June 2016. British Columbia-based Biocare Health Supply is partnered with National Medicines Prospect Dentech Co of Beijing. Prospect Dentech will supply VELscope Vx to dentists and other clinicians in China and Hong Kong. Per LED's June 2016 press release, "Prospect Dentech is the largest oral medicine, dental equipment and materials distributor in China with on-site sales teams in the majority of the capitals of each province of China. It is the only subsidiary of Sinopharm focusing on sales and distribution of dental products, including technologies from major global manufacturers such as Acteon, Yoshida, Sunstar and Kavo Sybron. Sinopharm is China's largest pharmaceutical group."

LED also noted that Prospect Dentech initiated an aggressive marketing campaign around VELscope which includes targeting their network of Key Opinion Leaders in China. The official China launch of VELscope happened in October 2016 at DenTech China which (per dentech.com) is billed as "China's leading professional event for the dentistry technology industry".

Given the relatively massive population of China (plus Hong Kong), the modernizing of health care systems and practices and higher incidence of oral cancer in that region of the world, we think entry into these geographic areas could provide meaningful revenue growth opportunity for VELscope Vx. And, the indicated distribution reach and related capabilities, contacts and customer "Rolodex" of Prospect Dentech provides additional support in that regard.

***Additional Clinical Data Published Supporting Role of Autofluorescence in Diagnosis of Oral Cancer…***
Approximately two dozen clinical and case studies using VELscope have been performed and respective manuscripts published in peer-reviewed publications since 2006. In addition, several studies that pre-date these have been done using natural tissue fluorescence for the detection of oral cancer with largely positive results, indicating tissue fluorescence has significant utility in oral cancer detection applications (refer to our January 24, 2014 Initiation report on LMD.V for a more in-depth discussion of VELscope/autofluorescence clinical data).

Most recently, a meta-analysis of 24 prior studies encompassing almost 2,800 oral lesions assessing the use of autofluorescence in the diagnosis of oral cancer was published online in July 2016 in Scientific Reports, a journal affiliated with Nature. The goal of the study, titled "Accuracy of Autofluorescence in Diagnosing Oral Squamous Cell Carcinoma and Oral Potentially Malignant Disorders: A Comparative Study with Aero-Digestive Lesions" (Luo et al.), was to assess the accuracy of autofluorescence in diagnosing oral squamous cell carcinoma (OSCC) and oral potentially malignant disorders (OPMD) as well as to investigate the applicability of technology for general practice.

Investigators determined that sensitivity and specificity of autofluorescence in detection of OSCC (the most common form of oral cancer) and OPMD (which may precede oral cancer) were 0.89 and 0.80, respectively. In addition, it was found that (this relatively high accuracy) could be improved further with additional algorithms. The investigators concluded that, "With relatively high accuracy, autofluorescence could be potentially applied as an adjunct for early diagnosis of OSCC and OPMD".

Studies such as this, as well as the surgical margin study (discussed below), supporting the use of VELscope / autofluorescence for diagnosis of oral cancer is critical, in our opinion, to facilitate further and more widespread adoption of the technology. As such, the more clinical data demonstrating the benefits of VELscope, particularly as it relates to use as an adjunct to conventional oral exams, the greater opportunity for related revenue growth both in the U.S. and internationally.

**Surgical Margins Study Published Online in *JAMA – Otolaryngology – Head and Neck Surgery* :**
Results of a 246-patient retrospective study assessing the utility of fluorescence visualization (FV) via VELscope in reduction of locoregional recurrence of cancer and improving overall survival in patients undergoing oral cancer surgery was recently published online in the *Journal of the American Medical Association – Otolaryngology – Head and Neck Surgery.*

FV was used to determine surgical margins. It is important to determine exactly where the lesion should be excised as the majority of oral cancer surgeries inadvertently leave some cancerous tissue behind, due in large part to the fact that some tissue is beneath the surface and not visible to the naked eye of the surgeon. Patients 18 years and older diagnosed with high grade lesions or squamous cell carcinoma of less than 4cm and which underwent oral surgery were included. 154 of the 246 underwent surgery with FV guidance while the other 92, the control group, underwent conventional surgery. There were no significant differences between the FV and control groups in age, smoking history, anatomical site of the lesion, tumor size, and previous oral cancer.

Results: The use of fluorescence visualization in determining surgical margin significantly reduced the rate of localized cancer recurrence in high grade and early stage oral cancers.

Per JAMA Otolaryngology Head Neck Surg. Published online January 14, 2016. doi:10.1001/jamaoto.2015.3211 (http://bit.ly/1WXRldE): Among the 156 patients with squamous cell carcinoma , the 92 patients in the FV group showed significant reduction in the 3-year local recurrence rate, from 40.6% (26 of 64 patients) to 6.5% (6 of 92 patients) (P□<□.001). Among the 90 patients with high-grade lesions, the 62 patients in the FV group showed a reduction in local recurrence rate from 11 of 28 patients (39.3%) to 5 of 62 patients (8.1%) (P□<□.001). The data also indicated that, compared with conventional surgery, the FV-guided approach for squamous cell carcinoma was associated with less regional failure (14 of 92 patients [15.2%] vs 16 of 64 [25.0%]; P□=□.08) and death (12 of 92 patients [13.0%] vs 13 of 64 [20.3%]; P□=□.22), although these differences were not statistically significant.

This study provides additional validation of the utility of VELscope in identifying the presence of cancer. And while commercial use VELscope has been mostly to aid dentists with identification of oral mucosal abnormalities, including those associated with oral cancer, there is a growing body of evidence to suggest it may have broader applications. This includes with identifying surgical margins.

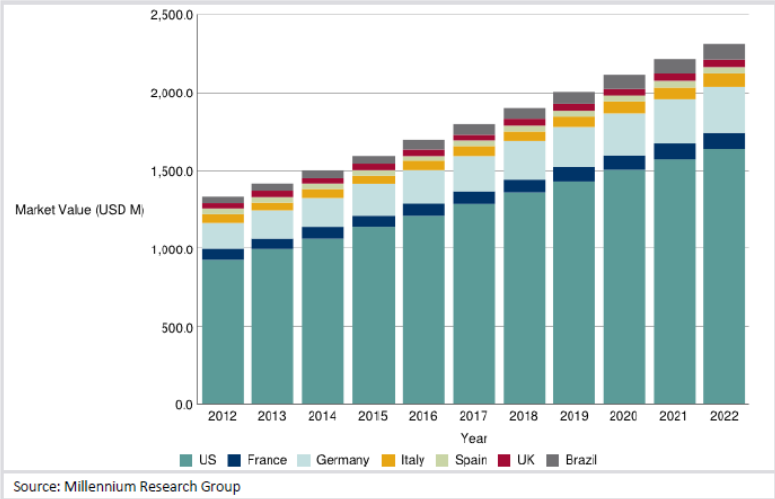
Along with this recently published study, Dr. Catherine Poh was also the lead investigator of *Fluorescence Visualization Detection of Field Alterations in Tumor Margins of Oral Cancer Patients,* a study published in Clinical Cancer Research in 2006. This was one of the first studies offering substantial evidence that VELscope can significantly improve on normal white light visualization of detection of oral cancer.

The study compared VELscope to assessment under normal lighting to determine the surgical margins. The respective margins determined by normal light and by VELscope were marked with a surgical pen. 122 oral mucosa biopsies were obtained from 20 surgical specimens (20 from the clinically apparent tumors, 36 from the margins determined to be abnormal by VELscope, and 66 from margins determined to be healthy by VELscope). Results showed that 32 of the 36 abnormal identified margins did indeed show histological changes (7 squamous cell carcinoma, 10 severe dysplasia, and 15 mild-to-moderate dysplasia). Meanwhile 65 of the 66 healthy identified margins were indeed normal with one showing mild-to-moderate dysplasia. Of the 20 clinically apparent tumors, 19 had abnormal margins that extended beyond what was clinically apparent (i.e. apparent under normal light). In addition, the investigators found that if a conventional 10mm clearance of the clinical tumor had been used, 50% of the tumors in the study would have had cancer or dysplasia at the margin, 30% of which showed severe dysplasia or carcinoma in situ (i.e. abnormal cells that may become cancer).

Dr. Poh notes in the January 26, 2016 press release that they are now working with head and neck surgeons in Canada to conduct a larger surgical margin study. The JAMA article also notes that “An ongoing multicenter, phase 3, randomized surgical trial has completed accrual, and the data will be used to validate the results of this study.” If and when a larger, randomized trial completes – and assuming positive results, this potentially could eventually lead to broader indications for VELscope and open it up to an additional and sizeable market.

## LED Exploiting Growth in Dental Digital Imaging

Market research supports LED's 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).




***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 $360^0$ 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 CBTC 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 G*lobal 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 began to capitalize on the expected significant growth in demand for CBCT systems in 2014 when the entered an agreement with Ray Co, Ltd, a former 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.

Then in September 2016 LED announced the launch of the RAYSCAN Alpha Plus Imaging System (product video: https://youtu.be/WEyP6T1OBdg). While LED does not break out revenue by product, it is clear that the RAYSCAN line has been a significant contributor to the company's recent sales growth. This next-gen product

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

has the potential to add to their success which includes several upgrades to the legacy system. Functionality includes;

- Light-guided field-of-view superimposed on patients face which simplify and optimize patient positioning
- Customizable FOV (field of view) from 4x3cm to 16x10cm while many systems only allow for a limited number of preset field of view options
- Provides for 3D images among the highest resolution in the industry
- Only CT and cone beam system utilizing remote control functionality allowing clinician to interact with patient and control the system simultaneously
- Cephalometric module allows for both scanning and single-shot image capture – affording even less risk of distortion and lower radiation exposure

**Rayscan Alpha Plus Imaging System**




SOURCE: ledental.com

***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.

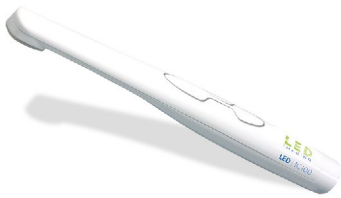
LED is also participating in this market. In May 2014 the company announced the introduction of LED IS100, a digital intraoral sensor, which the company is distributing in the U.S. The sensor is manufactured by Owandy, a France-based digital imaging company which has a presence in Europe but insignificant sales in the U.S.,

providing LED with a wide-open opportunity to exploit the domestic market. LED also introduced two intraoral cameras, IC100 and IC200.

***Intraoral Sensor***



***IC100 Intraoral Camera*** *(SOURCE: leddental.com)*



Ray Co.and LED Dental expect a fairly regular flow of new product introductions and in April 2015 launched RIOSensor Digital Radiography System.



Then in March 2016 they announced that their new Tuxedo digital intraoral radiography system received FDA 510(k) clearance, allowing it to be sold in the U.S. Tuxedo is as billed as providing some of the highest image quality of any intraoral sensors on the market.

As noted above, the most recent addition to the dental imaging segment was the RAYSCAN Alpha Plus Imaging System, launch of which was announced in September.

***Imaging Software Ties In Intraoral / Extraoral Imaging***

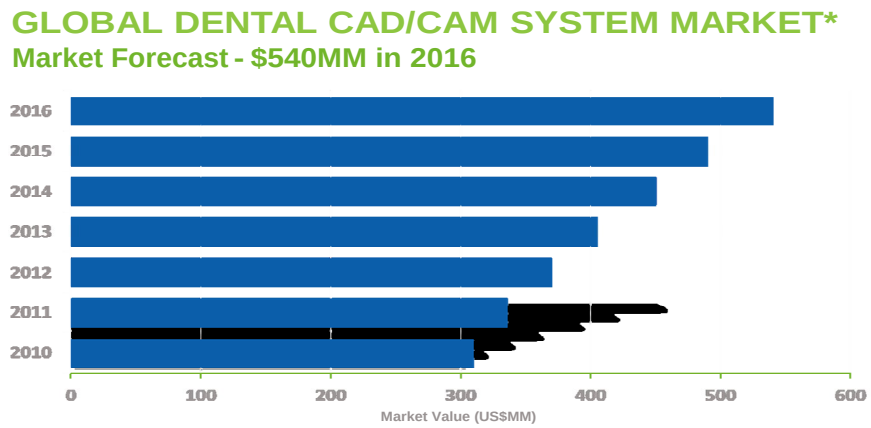
Imaging software is used to generate and store the images produced by intra- and extra-oral imaging modalities. In April 2014 LED announced the launch of open-architecture imaging software. The software is compatible not only with RAYSCAN-Expert but also with intraoral and extraoral devices from a variety of manufacturers. It also can be seamlessly integrated with any dental practice management suite.

***LED Imaging Software*** *(SOURCE: leddental.com)*



And as a complement to their software, April 2015 LED announced the launch of "LED Imaging Cloud" which provides dentists secure and easily accessible cloud storage of patient records and clinical data. Similar to personal and business computing, onsite data storage of medical and dental records via hard drives and servers is undergoing a rapid and massive shift to the cloud given the benefits of ease of access from any location, security and greater capacity. LED Imaging Cloud is compatible with both 2D and 3D data, allows for housing of all patient records on all workstations in one location and can be integrated with most imaging systems.

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).




*SOURCE: Millennium Research Group*

LED, with the acquisition of **Apteryx** in February 2017, has positioned themselves to directly benefit from the growth in dental imaging software. Apteryx looks like it could be a great fit for LED given that there appears to be some potential significant synergies among the companies' product portfolios and customer call points. Apteryx brings the dental imaging and database software that supports LED's digital imaging hardware – providing a one-stop-shop for dental practices. Apteryx's software licensing and recurring revenue business model will also provide welcome diversity and smoothing to LED's capital product sale revenue stream – which is typically highly seasonal and based on the dental industry's capex purchasing patterns. And beyond the current benefits, which apparently also includes profitable operations, Apteryx brings a sizeable patent portfolio and software development experience which can be expected to be leveraged for future growth including from further expansion of their product offerings.

**Apteryx 's Product Portfolio:** Their products are sold through resellers (such as LED Medical) as well as through their own website. Their suite of products are compatible with hardware of many different manufacturers and designed for businesses of all sizes - from small, single-office practices to large, multi-office organizations. The following product descriptions are from Apteryx's website (www.apteryx.com):

- **XrayVision**: was first launched in 1996 and has become the industry's leading open-architecture digital image management program. XrayVision will capture, enhance and display all of your dental images. Supporting image capture from the majority of the different digital intraoral sensors available today, XrayVision also integrates with phosphor plate scanners, digital panoramic and cephalometric imaging, flatbed scanners, intra-oral and extra-oral cameras, 3D conebeam tomography and many other digital sources.
- **XVWeb**: In addition to being a web application used to view the images, XVWeb is a fully-functional DICOM server that can accept images from any DICOM-compliant imaging software. Although any DICOM-enabled application can be utilized, Apteryx DCV and XrayVision4 are specifically designed to work seamlessly with XVWeb.
- **XVlite**: XVlite will capture, enhance and display all of your dental images. XVlite supports image capture from a majority of the different digital hardware in today's market. XVlite incorporates the latest advancements in imaging technology and



Apteryx's patented STB (Secure Tagged Block) file format, an unmodifiable, secure and "loss-less" imaging format. XVlite also exports to a number of common image file formats, including TIFF, JPEG, and BMP for universal viewing.

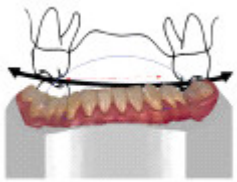
- **XrayVision DCV**: XrayVision DICOM Capture View, known as DCV, is a DICOM-based dental imaging suite that is scalable to any size organization. DCV is used to standardize the capture, storage, retrieval, and viewing of images across an entire organization. DCV supports most all imaging devices utilized in dentistry, including: Intra-oral sensors, Phosphor Plate Scanners, Panoramic / Cephalometric units, 3D / CAT scan, Tomography, Intra-oral Cameras, Extra-oral Cameras, Endo scopes, and Flatbed Scanners. DCV can act as a full enterprise standalone PACS or can serve as the capture modality that will automatically forward to an existing PACS. DCV's open architecture enables the freedom to use a wide variety of capture devices, while maintaining the industry standards. The US Army and US Navy currently use DCV as their global solution for managing all of their dental clinics worldwide, which allows for centralized storage of all images to provide global access to patient information. XrayVision DCV has numerous bridging capabilities from a standard command line integration, data extraction and auto importing patient demographic, barcode scanning, DICOM Worklist, HL7, and custom data bridges.

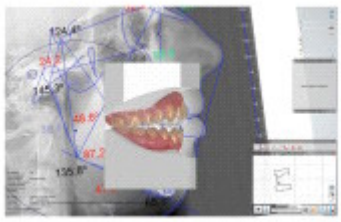
And LED made even more recent additions to its product portfolio, building on its quest to become a one-stop shop for dental imaging and related products and a full-product provider for practices converting from film to digital imaging.

In mid-June 2015 the company announced that they will distribute 3Shape's 3D intraoral digital impression and desktop scanner to the orthodontic market. The TRIOS 3 digital impressioning system further beefs up the company's burgeoning digital imaging product portfolio and provides more headway towards exploiting the high potential opportunity in the orthodontics space which has seen growing demand for higher quality imaging.

***3Shape Trios Scanner and sample images***







In August 2015 LED penned an agreement with EnvisionTec to distribute that company's EnvisionTec 3D printers. The printers are used by dental and orthodontic practitioners and laboratories to make a variety of implants, materials and tools including crowns, bridges, models, surgical guides and other dental and orthodontic products. The addition of a 3D printer to LED's product portfolio further enhances their ability to be a one-stop for dental imaging and related products and a full-product provider for practices converting from film to digital imaging. And with 3D being one the fastest growing segments in dental and orthodontics, their burgeoning product portfolio continues to strengthen their position to leverage one of the most attractive areas in the industry.

*EnvisionTec 3D Printer*



**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 put in place 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 13k 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.

## 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. While LED does not break out VELscope versus imaging related sales in their public filings, they have recently noted that VELscope sales continue to grow and carry a relatively hefty 56% gross margin.

Management recently 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 includes several sales organizations. Optimization of the distribution model along with additional clinical evidence supporting the use of VELscope for oral cancer detection (including the recently published surgical margin study and OSCC/OPMD study), is expected to culminate in additional growth in sales of the device.

And LED has recently begun looking at more “ways to expand adoption and the user base". This included partnering with the Oral Cancer Foundation in that organization’s recent initiative to promote more oral cancer screening. Under the relationship, LED provides a VELscope free of charge to dental practices that agree to perform at least three daily oral screenings over three years. While LED provides the instrument at no cost, they will charge the practices for the single-use consumable (i.e. disposable caps), which is where most of the margin is.

LED also recently partnered with London Drugs, a pharmacy chain in Canada, in a Vancouver-based oral mucosal screening program. LED recently announced that the program, which screened 167 patients, found approximately 20% of those examined showed oral mucosal abnormalities and were referred to a dental clinician for further examination. Almost all (96%) of the participants, which were asked to complete a survey, said that they would recommend screening to a friend or family member and 86% said that they would continue with

regular oral cancer screenings. In addition, London Drugs was so satisfied with the outcome of the screening program that they committed to another one. While these small screening programs are not intended to be a source of revenue for LED, they do provide potentially important feedback from patients and clinicians in terms of the desire for better screening options. As such, these types of programs have the potential to increase awareness and possibly drive further adoption and pull-through demand at both the dental practice level as well as at the patient level.

***Clinical Data Key to Maximizing VELscope Opportunities…***
Clinical data supporting the use of VELscope in the diagnosis of oral cancer and in improving patient outcomes will be key to maximizing the potential growth and adoption of VELscope, in our opinion. Approximately two dozen studies assessing the utility of VELscope/autofluoresence in oral cancer applications have been published, most of which support the utility of the technology, particularly as an adjunct to conventional oral examination. These, as well as future studies, are what KOL's and other clinicians will look to when evaluating VELscope and in their decision-making process when considering whether the technology is "right" for their particular practice. As such, the more clinical data that helps to confirm the ability of VELscope to improve upon oral cancer screening and diagnosis, clearly the better opportunity to grow the user base and the related revenue. The two recently published studies (as detailed above) should help in that regard.

***Entry Into China Could Provide Meaningful Growth Opportunity…***
As we have noted in our recent coverage of LED Medical, we think that while the U.S. has been the major market to-date for VELscope that much of the growth opportunity lies outside North America. Management has put more efforts towards exploiting this given that the ex-U.S. market represents about two-thirds of the total market opportunity. The recent entry into the Chinese market was a major milestone in our opinion.

VELscope Vx received regulatory approval in China in August 2015 and after nailing down distribution with the largest dental equipment supplier in China (Prospect Dentech), officially launched VELscope Vx in October 2016 at DenTech China which is billed as "China's leading professional event for the dentistry technology industry" and is now on its 21$^{st}$ year.

Given the relatively massive population of China (plus Hong Kong), the modernizing of health care systems and practices and higher incidence of oral cancer in that region of the world, we think entry into these geographic areas could provide meaningful revenue growth opportunity for VELscope Vx. And, the indicated distribution reach and related capabilities, contacts and customer "Rolodex" of Prospect Dentech provides additional support in that regard.

We expect LED will look to gain marketing approval in other international territories, particularly spots in Europe and Asia. Following gaining requisite regulatory approvals, the next step will be to consummate distribution agreements in those regions of the world.

## OUTLOOK / VALUATION

Our $0.70 target price and valuation is under review and, along with our model, will be updated after LED files historicals for the pro forma combination of LED Medical and Apteryx.

## FINANCIAL MODEL

LED Medical Inc.

Model will be updated for Apteryx acq following filing of historicals for the pro forma combination of LED Medical and Apteryx

| | 2016 A | Q1E | Q2E | Q3E | Q4E | 2017 E | 2018 E | 2019 E | 2020 E |
|---|---|---|---|---|---|---|---|---|---|
| Revenue | $10,169 | $1,977 | $3,192 | $3,006 | $5,431 | $13,605 | $17,117 | $20,652 | $23,460 |
| *YOY Growth* | *-22.6%* | *-8.2%* | *-12.8%* | *20.8%* | *191.1%* | *33.8%* | *25.8%* | *20.7%* | *13.6%* |
| Cost of sales | $7,690 | $1,482 | $2,363 | $2,220 | $3,998 | $10,062 | $11,667 | $13,399 | $14,701 |
| Gross Income | $2,479 | $495 | $829 | $786 | $1,433 | $3,543 | $5,450 | $7,253 | $8,759 |
| *Total Gross Margin* | *24.4%* | *25.0%* | *26.0%* | *26.1%* | *26.4%* | *26.0%* | *31.8%* | *35.1%* | *37.3%* |
| SG&A | $7,461 | $1,552 | $2,132 | $1,936 | $2,308 | $7,928 | $8,798 | $9,438 | $10,111 |
| *% SG&A* | *73.4%* | *78.5%* | *66.8%* | *64.4%* | *42.5%* | *58.3%* | *51.4%* | *45.7%* | *43.1%* |
| R&D | $132 | $32 | $28 | $36 | $31 | $127 | $452 | $626 | $688 |
| *% R&D* | *1.3%* | *1.6%* | *0.9%* | *1.2%* | *0.6%* | *0.9%* | *2.6%* | *3.0%* | *2.9%* |
| Operating Income | ($5,114) | ($1,089) | ($1,331) | ($1,186) | ($906) | ($4,512) | ($3,800) | ($2,811) | ($2,041) |
| *Operating Margin* | *-50.3%* | *-55.1%* | *-41.7%* | *-39.5%* | *-16.7%* | *-33.2%* | *-22.2%* | *-13.6%* | *-8.7%* |
| Total Other Income | ($259) | ($162) | ($162) | ($154) | ($152) | ($630) | ($529) | ($174) | ($164) |
| Pre-Tax Income | ($5,373) | ($1,251) | ($1,493) | ($1,340) | ($1,058) | ($5,142) | ($4,329) | ($2,985) | ($2,205) |
| Taxes (benefit) | $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 | ($5,373) | ($1,251) | ($1,493) | ($1,340) | ($1,058) | ($5,142) | ($4,329) | ($2,985) | ($2,205) |
| *Net Margin* | *-52.8%* | *-63.3%* | *-46.8%* | *-44.6%* | *-19.5%* | *-37.8%* | *-25.3%* | *-14.5%* | *-9.4%* |
| EPS | ($0.05) | ($0.01) | ($0.01) | ($0.01) | ($0.01) | ($0.04) | ($0.03) | ($0.02) | ($0.01) |
| *YOY Growth* | *-7.1%* | *-77.4%* | *17.7%* | *-15.9%* | *-28.4%* | *-13.3%* | *-29.0%* | *-34.2%* | *-34.6%* |
| Diluted Shares O/S | 113,130 | 116,430 | 118,000 | 126,000 | 138,840 | 124,818 | 148,000 | 155,000 | 175,000 |

*Brian Marckx, CFA*

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## CHART




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