Zacks Small-Cap Research

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# LED Medical Diagnostics (V.LMD)

## V.LMD: China VELscope Launch, New RAYSCAN System Could Be Needle Movers

We have revenue CAGR of about 18% from 2015 through 2019, then dropping to a low-double digit average through 2025. We use a 10.5% discount rate and 2% terminal growth rate. Based on DCF, LED is value at approximately $0.70/share.

| | |
|---|---|
| Current Price (11/30/2016) | $0.08 |
| **Valuation** | **$0.70** |

## OUTLOOK

LED Medical's VELscope is the world's leading device used for oral cancer screening with 13k units sold and ~30 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. Recent greater international focus should provide incremental revenue growth. Recent entry into China offers significant revenue opportunity.

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. New RAYSCAN Alpha Plus Imaging System has the potential to add to their success which includes several upgrades to the legacy system.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$0.20** |
| **52-Week Low** | **$0.06** |
| **One-Year Return (%)** | **-56** |
| **Beta** | **-0.61** |
| **Average Daily Volume (sh)** | **92,578** |
| **Shares Outstanding (mil)** | **113** |
| **Market Capitalization ($mil)** | **9** |
| **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 2016 Estimate** | **N/A** |
| **P/E using 2017 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) |
|---|---|---|---|---|---|
| 2015 | $2443 A | $3269 A | $1783 A | $5640 A | $13135 A |
| 2016 | $2153 A | $3661 A | $2489 A | $5335 E | $13638 E |
| 2017 | | | | | $16955 E |
| 2018 | | | | | $21438 E |

**Earnings per Share**

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

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

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## Q3 2016 Financial Results: *Operating Loss Continues To Improve…*

LED reported financial results for the third quarter ending September 30th. Revenue, as expected following the company's preannouncement in October, came in at $2.5M, representing yoy growth of 40% (from $1.8M in Q3 2015) and largely in-line with our prior-to-preannouncement estimate of $2.3M. And while Q3 revenue declined 32% sequentially (from $3.7M in Q2 2016), we remind investors that the third quarter has historically been a relatively weak period for dental-related products and services due to summer vacations and holidays. Meanwhile, revenue through the first nine months of 2016 was $8.3M, an increase of 11% from the prior year comparable period. We continue to model sequential revenue growth from Q3 to Q4 given that the final quarter of the year is typically the strongest for dental imaging products.

Also noteworthy as it relates to revenue is that no customer accounted for 10% or more of total revenue in any of the first three quarters of 2016. By contrast, one customer accounted for 10% of total revenue through the first nine months of 2015. The reduced customer concentration reduces A/R risk and may have the added benefit of helping to smooth revenue volatility.

While gross margin, which can swing based on product mix, narrowed from 29% in Q2 to 25% in Q3, it was well ahead of the 19% posted in Q3 2015. We continue to believe that while growth in the digital imaging segment as a percentage of total sales may limit significant upside in gross margin, we think higher sales volumes in that business along with even incremental growth in the VELscope segment offers potential for further GM widening. The proprietary VELscope business, which carries relatively beefy margins, could benefit from several recent potential catalysts including launch of the device in China and publication of additional clinical data supporting the use of the technology for the early diagnosis of oral cancer.

Operating expenses have also shown improvement, recently trending down, particularly as they relate to revenue levels. This has resulted in consistent improvement in operating losses. Operating expenses were just $1.5M in Q3, or 59% of total revenue and despite the moderate gross margin, the relatively low expense level helped to push operating loss to its lowest level since Q4 2012. Operating loss through the first nine months of 2016 was $3.9M, improved from $4.2M and $4.8M in the comparable periods of 2015 and 2014, respectively. Additional cost-control measures, coupled with expectations of continued revenue growth and incremental upside in gross margins should push the company closer to profitability

Cash used in operating activities was $297k and $1.8M ($761k and $3.5M ex-changes in working capital) in the three and nine months ending September 30th. LED ended Q3 with $342k in cash and equivalents. Subsequent to quarter end the company issued CDN$500k 12%, 24-month senior secured debt (along with 750k common shares) to Bloom Burton Healthcare Lending Trust via private placement. They also had an A/R balance of approximately $936k, 87% of which is current (<30days) and 92% of which is less than 60 days old. As we have previously noted, we continue to expect LED to look to raise additional capital in the near-term.

**LED had some recent operational-related "wins" in both their dental imaging and VELscope segments which have the potential to provide meaningful revenue tailwinds as the company heads into 2017.**

**As it relates to digital imaging**, we think the recent launch of the RAYSCAN Alpha Plus Imaging System, announced in late September, 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 of this year 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, earlier this month LED announced the launch of VELscope Vx in China. While the device received regulatory approval in that country in August of last year, 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. 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 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 notes that Prospect Dentech has 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 at DenTech China which (per dentech.com) is billed as "China's leading professional event for the dentistry technology industry" and is now on its 21st 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.

***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 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

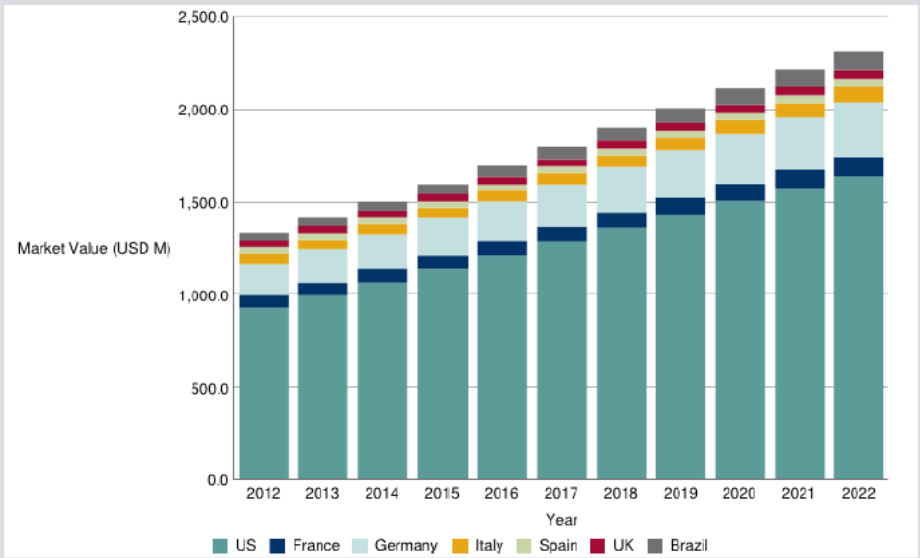
Cancer Research in 2006. This was one of the first studies offering substantial evidence that VELscope can significantly improve on normal white light visualization of detection of oral cancer.

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 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

[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.

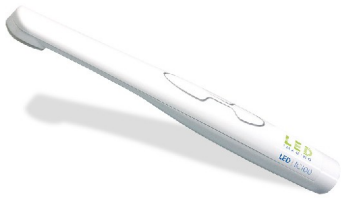
Millennium Research expects film based modalities to be replaced by digital systems and for PSP plate systems to increase at a CAGR of about 2.6% in the U.S. over the next ten years. However, as practitioners are increasingly demanding improved workflow and patient throughput, the minutes lost waiting 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 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.



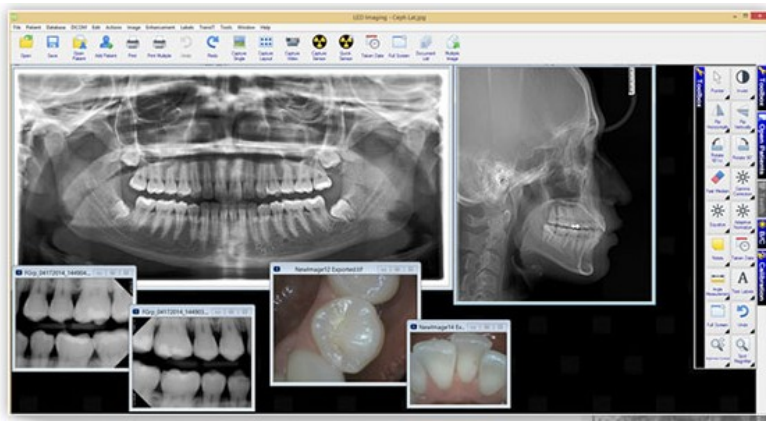
Then in March 2016 they announced that their new Tuxedo digital intraoral radiography system received FDA 510(k) clearance, allowing it to be sold in the U.S. Tuxedo is as billed as providing some of the highest image quality of any intraoral sensors on the market.

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***

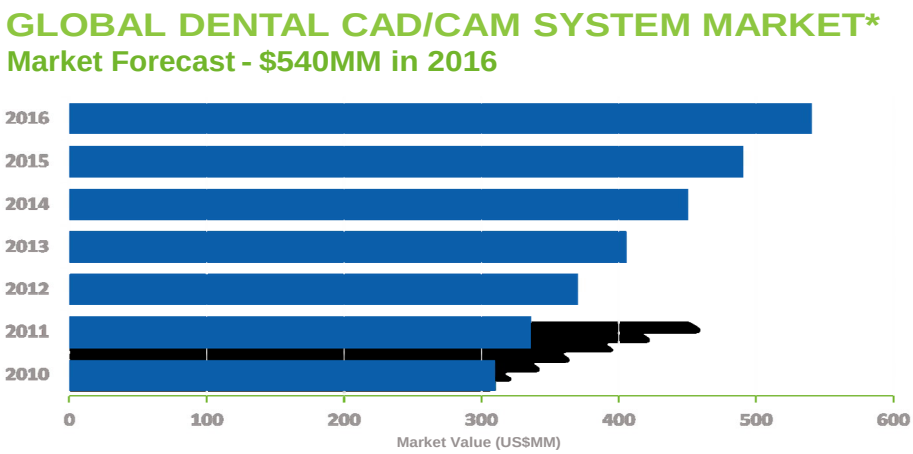
Imaging software is used to generate and store the images produced by intra- and extra-oral imaging modalities. In April 2014 LED announced the launch of open-architecture imaging software. The software is compatible not only with RAYSCAN-Expert but also with intraoral and extraoral devices from a variety 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).



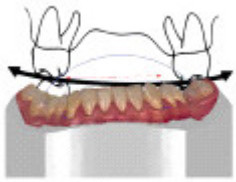
*SOURCE: Millennium Research Group*

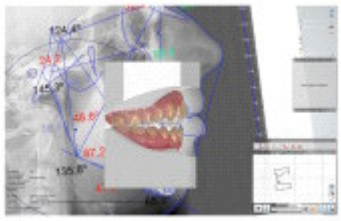
And LED made even more recent additions to its product portfolio, building on its quest to become a one-stop shop for dental imaging and related products and a full-product provider for practices converting from film to digital imaging.

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.

This early progress has already culminated in a significant increase in orders and revenue. Revenue grew 256% to $9.0M in 2014 and another 47% in 2015 to $13.1M. We currently model $13.6M in revenue for 2016, implying growth of 4% from 2015.

## 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 fell from $6.3M in 2012 to $2.5M in 2013 in the midst of a change in distribution model (more recent figures have not been disclosed).

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 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 which is scheduled for April 2017. 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 at DenTech China which is billed as "China's leading professional event for the dentistry technology industry" and is now on its 21st 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

Revenue fell 60% in 2013 but has since done an about-face, increasing 256% in 2014 and another 47% in 2015. 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.

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.

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 less than 10% 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. We think the Chinese market could provide meaningful revenue growth opportunity for VELscope Vx. 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.

Meanwhile, the company will further capitalize on their distribution reach and leverage their sales infrastructure through a larger product portfolio. 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. We think the recent launch of the RAYSCAN Alpha Plus Imaging System, announced in late September, 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.

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 value LED using a 10-year discounted cash flow model. We have revenue CAGR of about 18% from 2015 through 2019, then dropping to a low-double digit average through 2025. 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 10.5% discount rate and 2% terminal growth rate. Based on DCF, LED is value at approximately $0.70/share.

## FINANCIAL MODEL

LED Medical Inc.

| | 2015 A | Q1A | Q2A | Q3A | Q4E | 2016 E | 2017 E | 2018 E | 2019 E |
|---|---|---|---|---|---|---|---|---|---|
| Revenue | $13,135 | $2,153 | $3,661 | $2,489 | $5,335 | $13,638 | $16,955 | $21,348 | $25,470 |
| *YOY Growth* | *46.6%* | *-11.8%* | *12.0%* | *39.6%* | *-5.4%* | *3.8%* | *24.3%* | *25.9%* | *19.3%* |
| Cost of sales | $9,561 | $1,618 | $2,590 | $1,872 | $3,806 | $9,886 | $10,999 | $13,207 | $15,324 |
| Gross Income | $3,573 | $536 | $1,071 | $617 | $1,528 | $3,752 | $5,957 | $8,141 | $10,146 |
| *Total Gross Margin* | *27.2%* | *24.9%* | *29.3%* | *24.8%* | *28.6%* | *27.5%* | *35.1%* | *38.1%* | *39.8%* |
| SG&A | $8,584 | $2,480 | $2,063 | $1,420 | $2,305 | $8,268 | $9,800 | $10,695 | $12,175 |
| *% SG&A* | *65.4%* | *115.2%* | *56.3%* | *57.1%* | *43.2%* | *60.6%* | *57.8%* | *50.1%* | *47.8%* |
| R&D | $189 | $50 | $20 | $37 | $45 | $152 | $530 | $611 | $710 |
| *% R&D* | *1.4%* | *2.3%* | *0.5%* | *1.5%* | *0.8%* | *1.1%* | *3.1%* | *2.9%* | *2.8%* |
| Operating Income | ($5,200) | ($1,995) | ($1,011) | ($840) | ($821) | ($4,667) | ($4,374) | ($3,166) | ($2,739) |
| *Operating Margin* | *-39.6%* | *-92.6%* | *-27.6%* | *-33.7%* | *-15.4%* | *-34.2%* | *-25.8%* | *-14.8%* | *-10.8%* |
| Total Other Income | $20 | ($57) | ($71) | ($16) | ($48) | ($192) | ($175) | ($159) | ($181) |
| Pre-Tax Income | ($5,180) | ($2,052) | ($1,083) | ($855) | ($869) | ($4,859) | ($4,549) | ($3,325) | ($2,920) |
| Taxes (benefit) | ($4.1) | $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 | ($5,176) | ($2,052) | ($1,083) | ($855) | ($869) | ($4,859) | ($4,549) | ($3,325) | ($2,920) |
| *Net Margin* | *-39.4%* | *-95.3%* | *-29.6%* | *-34.4%* | *-16.3%* | *-35.6%* | *-26.8%* | *-15.6%* | *-11.5%* |
| EPS | ($0.05) | ($0.02) | ($0.01) | ($0.01) | ($0.01) | ($0.04) | ($0.03) | ($0.02) | ($0.02) |
| *YOY Growth* | *-33.9%* | *13.6%* | *-20.3%* | *-44.1%* | *-24.1%* | *-16.0%* | *-23.9%* | *-31.4%* | *-16.1%* |
| Diluted Shares O/S | 101,208 | 112,319 | 112,514 | 112,787 | 114,600 | 113,055 | 139,000 | 148,000 | 155,000 |

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## CHART




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