Zacks Small-Cap Research

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LED Medical Diagnostics (V.LMD)

V.LMD: Surgical Margins May Offer Future Market Opportunity

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	01/20/2014
Current Price (02/01/2016)	$0.17
Target Price	**$1.25**

OUTLOOK

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

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

SUMMARY DATA

52-Week High	**$0.35**
52-Week Low	**$0.13**
One-Year Return (%)	**-46**
Beta	**1.69**
Average Daily Volume (sh)	**67,125**
Shares Outstanding (mil)	**112**
Market Capitalization ($mil)	**18**
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 2015 Estimate	**N/A**
P/E using 2016 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)
2014	$1055 A	$1590 A	$1629 A	$4688 A	$8962 A
2015	$2443 A	$3269 A	$1783 A	$5000 E	$12494 E
2016					$18877 E
2017					$26499 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.04 A	$0.00 A	-$0.03 A	-$0.01 A	-$0.08 A
2015	-$0.02 A	-$0.02 A	-$0.01 A	-$0.01 E	-$0.05 E
2016					-$0.03 E
2017					-$0.02 E

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

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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 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.

FINANCIAL MODEL

LED Medical Inc.

	2014 A	Q1A	Q2A	Q3A	Q4E	2015 E	2016 E	2017 E	2018 E
Revenue	$8,962	$2,443	$3,269	$1,783	$5,000	$12,494	$18,877	$26,499	$35,608
YOY Growth	*255.7%*	*131.6%*	*105.6%*	*9.5%*	*6.7%*	*39.4%*	*51.1%*	*40.4%*	*34.4%*
Cost of sales	$5,502	$1,814	$2,249	$1,453	$3,422	$8,939	$12,428	$16,650	$21,343
Gross Income	$3,460	$629	$1,020	$330	$1,577	$3,556	$6,448	$9,849	$14,265
Total Gross Margin	*38.6%*	*25.7%*	*31.2%*	*18.5%*	*31.5%*	*28.5%*	*34.2%*	*37.2%*	*40.1%*
SG&A	$8,906	$2,162	$2,197	$1,682	$2,733	$8,775	$10,312	$12,747	$14,570
% SG&A	*99.4%*	*88.5%*	*67.2%*	*94.3%*	*54.7%*	*70.2%*	*54.6%*	*48.1%*	*40.9%*
R&D	$255	$50	$65	$32	$87	$234	$644	$841	$994
% R&D	*2.8%*	*2.1%*	*2.0%*	*1.8%*	*1.7%*	*1.9%*	*3.4%*	*3.2%*	*2.8%*
Operating Income	($5,702)	($1,584)	($1,242)	($1,384)	($1,243)	($5,453)	($4,508)	($3,739)	($1,299)
Operating Margin	*-63.6%*	*-64.8%*	*-38.0%*	*-77.6%*	*-24.9%*	*-43.6%*	*-23.9%*	*-14.1%*	*-3.6%*
Total Other Income	($326)	$94	$36	$22	($20)	$88	($42)	$85	$0
Pre-Tax Income	($6,028)	($1,490)	($1,206)	($1,362)	($1,263)	($5,364)	($4,550)	($3,654)	($1,299)
Taxes (benefit)	$0.0	$0.0	($4.1)	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.3%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($6,028)	($1,490)	($1,202)	($1,362)	($1,263)	($5,364)	($4,550)	($3,654)	($1,299)
Net Margin	*-67.3%*	*-61.0%*	*-36.8%*	*-76.4%*	*-25.3%*	*-42.9%*	*-24.1%*	*-13.8%*	*-3.6%*
EPS	($0.08)	($0.02)	($0.01)	($0.01)	($0.01)	($0.05)	($0.03)	($0.02)	($0.01)
YOY Growth	*-42.3%*	*-59.1%*	*-1191.5%*	*-58.6%*	*99.2%*	*-29.0%*	*-37.6%*	*-27.2%*	*-65.4%*
Diluted Shares O/S	79,821	92,660	99,458	100,394	107,700	100,053	136,000	150,000	154,000

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