

## Veriteq Corp

(VTEQ-OTC)

VTEQ: 10-K Filed, Maintaining Outperform Rating

<b>Current Recommendation</b>	<b>Outperform</b>
Prior Recommendation	N/A
Date of Last Change	02/11/2014
Current Price (04/16/14)	\$0.99
<b>Target Price</b>	<b>\$2.00</b>

### OUTLOOK

VeriTeQ's RFID technology is unique as it is the only one on the market which affords access to UDI information in-vivo, at the point of care and from outside of the body. The company will look to exploit the market for direct part marking of medical devices, demand for which is expected to accelerate as a result of a recent FDA mandate as well as a recent breast implant rupture scare. Commercialization is now underway via an agreement with a breast implant manufacturer. Similar agreements with other, larger breast implant manufacturers could be on the horizon. The RFID technology is also used for radiation dosimetry, a very large market with potential significant opportunity for VTEQ.

VTEQ has little operating history and will need to raise significantly more capital to fund operations. As such, an investment in the company is not without meaningful risk. Despite these and other risks, we feel the shares are undervalued. Our DCF-generated price target is \$2.00/share.

### SUMMARY DATA

52-Week High	\$4.30
52-Week Low	\$0.60
One-Year Return (%)	-24.94
Beta	2.43
Average Daily Volume (sh)	37,436

Shares Outstanding (mil)	9
Market Capitalization (\$mil)	\$10
Short Interest Ratio (days)	1.42
Institutional Ownership (%)	3
Insider Ownership (%)	75

Annual Cash Dividend	\$0.00
Dividend Yield (%)	0.00

5-Yr. Historical Growth Rates	
Sales (%)	N/A
Earnings Per Share (%)	N/A
Dividend (%)	N/A

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

Zacks Rank	N/A
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Risk Level	High,
Type of Stock	N/A
Industry	Med Instruments

### ZACKS ESTIMATES

#### Revenue

(in '000s of \$)

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2013					18 A
2014	72 E	99 E	121 E	155 E	447 E
2015					1062 E
2016					1906 E

#### Earnings per Share

(EPS is operating earnings before non recurring items)

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2013					-\$1.75 A
2014	-\$0.13 E	-\$0.12 E	-\$0.11 E	-\$0.10 E	-\$0.45 E
2015					-\$0.29 E
2016					-\$0.22 E

Zacks Projected EPS Growth Rate - Next 5 Years %	N/A
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## WHAT'S NEW...

### 2013 10-K Filed

VeriTeQ filed their 10-K for the period ending December 31, 2013 on April 15th. Initial revenue amounting to \$18k from sale of the Q Inside Safety Technology transponders to Establishment Labs (EL) was recorded in Q4. This was in-line with our \$24k estimate.

As a reminder, in October VTEQ announced that they made their first shipment to EL, for 2k transponders. Concurrent with the initial order the company noted that they expected follow-on orders to be received on a regular basis. Subsequent to 2013 year-end, VTEQ announced that they shipped another 8k microchips as well as a (undisclosed) number of handheld readers. We continue to look for modest yet sequential revenue growth throughout the current year as VTEQ records revenue from additional EL orders.

Operating expenses were \$6.6M in 2013, although only approximately \$3.9M of this was cash expense as the \$6.6M included ~\$2.1M in non-cash stock based compensation and ~\$600k in depreciation and amortization. Net loss and EPS were \$15.1M and (\$1.75). Total non-cash expense for the year aggregated to approximately \$10.8M (includes \$3.9M non-cash interest, \$600k D&A, and \$4.2M in revaluation of derivative securities). On a cash basis net loss and EPS were approximately \$4.3M and (\$0.50).

We have made some slight adjustments to our model following the 10-K filing - most of which reflects a moderate upward adjustment to near-term operating expenses. The changes resulted in no meaningful impact to our DCF-generated price target - which continues to calculate to approximately \$2.00/share. We are maintaining our Outperform rating.

## SNAPSHOT

VeriTeQ Corporation (VTEQ) went public in July 2013. The company is engaged in the development and sale of radio-frequency identification (RFID) technologies for use in implantable and reusable medical devices as well as radiation dose measurement technologies used during oncological procedures. VeriTeQ's patent-protected "Q Inside Safety Technology" is a unique device identifier (UDI) which includes an FDA-cleared passive RFID microchip, a handheld reader and an information database. The technology is unique as it is the only one on the market which affords access to UDI information in-vivo, at the point of care and from outside of the body. The technology directly evolved from implantable RFID used safely for decades in over 100 million pets as a means to identify them in the event they became separated from their owners.

In September 2013 FDA issued a Final Rule<sup>1</sup> ("Rule") which will require most medical devices sold in the U.S. to carry a UDI. The Rule, compliance deadlines of which will be phased in over several years and dependent on the type and class of the devices (beginning in September 2014), was issued (per FDA) to "improve the quality of information in medical device adverse event reports, which will help the FDA identify product problems more quickly, better target recalls and improve patient safety." Per the Rule, the UDI, an alphanumeric code that will be interpreted when matched to a database, will provide manufacturer and device-specific information. While implantable devices will only be required to carry the UDI on the label and package of the device, reusable or reprocessed medical devices will be required to have the UDI directly marked on the device itself.

Originally, the FDA was inclined to mandate direct part marking for all implantable devices. Acknowledging in the Final Rule that RFID technology (such as VeriTeQ's) was the only viable option they backed off and mandated direct part marking for reusable and re-processed medical devices. However, it is possible (although there is no current indication of this) that FDA may mandate direct part marking for all implantable devices in the future.

The reusable/reprocessed medical device market, which includes products such as sizers (used to size the area prior to implantation of the actual device) for breast implants, chin implants, heart valves and artificial joints represents a potentially very attractive market for VTEQ as these devices, per the Rule, will be required to carry a UDI directly on the product itself. We also believe that FDA's recent greater scrutiny relative to medical device safety may compel some manufacturers of implantable devices to voluntarily provide direct part marking of their devices, in addition to the requisite label/packaging marking, which would offer another large market opportunity for the company.

VTEQ's target markets are not just confined to those which are expected to grow necessarily as a result of the implementation of FDA's Final Rule, however. The company already has a development and supply agreement with manufacturers of breast implants (Establishment Labs, S.A.) and vascular ports (Medical Components, Inc.) whereby VeriTeQ's RFID microchip will be embedded in these products. Since October 2013 VTEQ has delivered 8,000 Q Inside Safety Technology transponders to Establishment Labs (EL) which will be used in EL's Motiva breast implants. The implants with the Q Inside Safety Technology received CE Mark in October 2013, allowing them to be sold in the European Union.

A recent massive recall of faulty breast implants in Europe prompted England to establish a national registry of all breast implant procedures and may compel other manufactures to take proactive action to ensure patient safety. This could potentially lead to VTEQ entering into additional arrangements with other, larger breast implant manufacturers in the near future.

VTEQ's radiation dosimetry technology can be used to measure radiation at the skin level and in the body at the tumor site in cancer patients undergoing external beam radiation procedures. The technology is already FDA cleared for this application, has clinical study experience with positive outcomes and is at least partially reimbursed by third-party payers. The market for radiation dosimetry is many times larger than the UDI application, although commercialization for dosimetry may take more time as the company focuses current resources on the direct part marking opportunity.

<sup>1</sup> Unique Device Identification System; Final Rule. Fed Register. Dept of Health and Human Svcs. Sept 24, 2013. <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM368961.pdf>

## BACKGROUND

During 2012 VeriTeQ acquired the intellectual property related to the company's bio-sensor technologies. The acquisitions included the VeriChip implantable microchip and related technology, as well as the radiation dosimetry technology, and gave VTEQ control of the patents and patents pending related to the RFID technology that is at the heart of their Q Inside Safety Technology. This includes U.S. patent 7,125,382 for an Embedded Bio-Sensor System.

### Partial List of VeriTeQ's Patent Portfolio

Patent No.	Title
7,125,382	Embedded Bio-Sensor System
6,402,689	Methods, Systems and Associated Implantable Devices for Dynamic Monitoring of Physiological and Biological Properties of Tumors
7,378,056	Methods, Circuits, and Compositions of Matter for In Vivo Detection of Biomolecule Concentrations Using Fluorescent Tags
7,011,814	Systems, Methods And Devices For In Vivo Monitoring Of A Localized Response Via A Radiolabeled Analyte In A Subject
7,479,108	Implantable Sensor Housing, Sensor Unit And Methods For Forming And Using The Same
7,495,224	Disposable Single-Use External Dosimeters For Use In Radiation Therapies
7,966,054	Disposable Single-Use External Dosimeters For Detecting Radiation In Fluoroscopy And Other Medical Procedures/Therapies
7,491,942	Disposable Single-Use Internal Dosimeters For Detecting Radiation In Medical Procedures/Therapies
7,010,340	Methods, Systems, and Computer Program Products for Providing Dynamic Data of Positional Localization of Target Implants
7,510,699	In Vivo Fluorescence Sensors, Systems, And Related Methods Operating In Conjunction with Fluorescently Labeled Materials
7,557,353	Single-Use External Dosimeters for Use in Radiation Therapies and Related Methods, Systems and Computer Program Products

The implantable RFID microchip technology was cleared by the FDA in 2004 (owned then by VeriChip Corporation) as the predicate Class II medical device in the industry. The initial application for the technology, commercialization for which was pursued immediately following FDA clearance, was for patient identification. Specifically the major initial focus was to enable a patient's medical records to be accessed via the microchip, which was implanted in the patient's arm and which could be identified by a handheld reader (used by medical staff) which would then link to a database containing the medical records. The application, called VeriMed, provided a means to access medical records of patients that were unconscious or otherwise unable to provide their medical history.

The original application of the implantable RFID microchip related to personal medical records whereby a patient's medical records could be accessed via the microchip, which was implanted in the patient's arm and which could be identified by a handheld reader (used by medical staff). This did not meet the expected commercial demand, however. While it addressed real needs and was seemingly promising from a business standpoint, privacy concerns proved a difficult barrier to overcome.

VeriTeQ's targets for the technology are for the identification of medical devices and for radiation dosimetry, areas with very large markets and absent of any risk of concerns of privacy. And while the technology has yet to be cleared by the FDA for use in specific devices, the (potentially higher) hurdle of U.S. regulatory approval for implantation within the human body has already been attained, an obvious significant benefit. It is also possible, although not yet clear, that FDA may not require regulatory approval to commercialize specific products (i.e. - breast implants, artificial joints, etc) with the chip inside given that both the chip and the products have already been approved for sale by the agency and the inclusion of the Q Inside Safety Technology does not alter the functionality of the medical device containing it.

#### **Q Inside Safety Technology: RFID Microchip, Handheld Reader and Information Database**

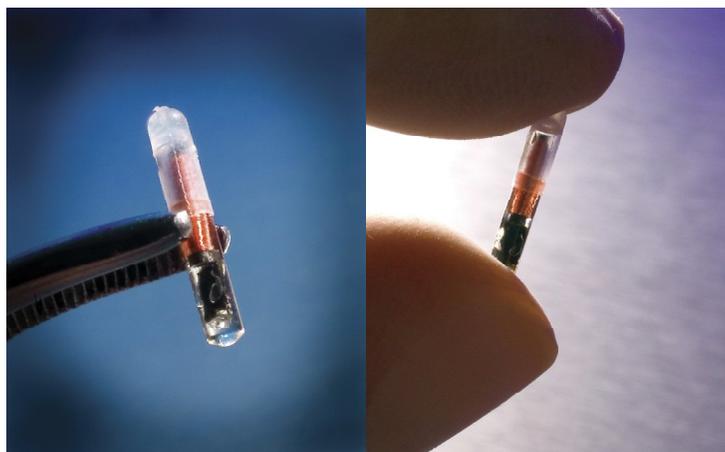
VeriTeQ's patent-protected "Q Inside Safety Technology" is a unique device identifier (UDI) which includes an FDA-cleared passive **RFID microchip**, a **handheld reader** and an **information database**. The technology is unique as it is the only one on the market which affords access to UDI information in-vivo, at the point of care

and from outside of the body. The technology directly evolved from implantable RFID used safely for decades in over 100 million pets as a means to identify them in the event they became separated from their owners.

The implantable RFID microchip is about the size of a grain of rice. It is passive, meaning that it does not generate power or a signal, and is low frequency. While this requires the reader to be in very close proximity (several inches) in order to read the microchip, it affords the benefits of maximum patient safety, maximum patient privacy and little to no interference with other transponders or electronics.

The RFID microchip holds a unique 15-digit number that is retrieved with VeriTeQ's handheld reader.

**VeriTeQ's RFID Microchip**



**VeriTeQ's Handheld Reader**

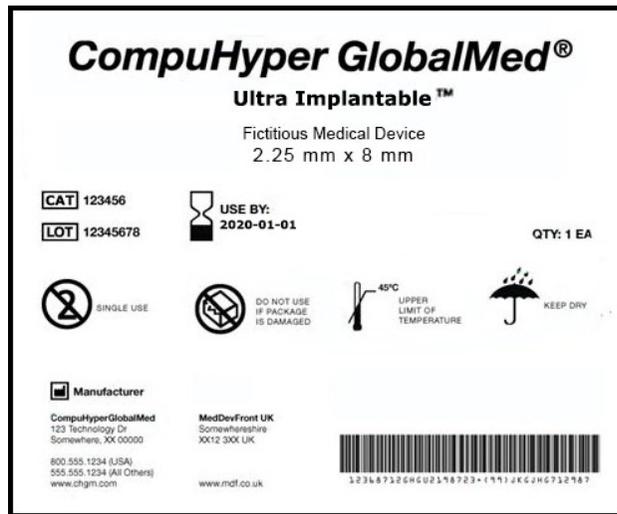


VeriTeQ is also developing application system software. Initial functionality will allow for integration and communication between the chips, readers and VTEQ's product partners' (i.e. - EL, MedComp) databases. Future functionality is expected to include the ability to link the Q Inside information to third-party electronic health record systems such as those in hospitals and clinics.

### **FDA Final Rule**

In September 2013 the FDA issued a final rule to establish a national system to identify medical devices during their distribution and use. The purpose of the unique identification (UDI) system is to be able to quickly and accurately identify a medical device and its safe and effective use in order to reduce errors as a result of misuse or misunderstanding of how the device is intended to be used. The UDI system will also provide a means of more accurate reporting of device-specific adverse events and help health care providers and the industry in taking any necessary remedial action. In the event of adverse event reports or recalls, the UDI system will facilitate the identification of the problem device, more efficiently target recalls and reduce the chance that patients receive devices which have been identified as having safety risks.

The UDI system will allow health care providers and the general public to identify a particular medical device from a UDI that will be on the package of the device, and in the case of reusable or reprocessed devices, on the device itself. The UDI will consist of two parts; a device identifier and a production identifier. The device identifier (DI) will identify the manufacturer and the specific version or model of the device. The production identifier (PI) will identify the lot/batch number, serial number, and the manufacturing and expiration dates. Below is an (fictitious) example of how a UDI might look on the packaging of a medical device - this is provided on the FDA's UDI web page.



The final rule also includes the establishment of the Global Unique Device Identification Database (GUDID), a repository of medical device identification information. Manufacturers will be required to submit device and labeling information to GUDID. GUDID will contain only the device identifier information. It will not store patient data.

The label above is a representative example of the UDI required on the packaging of most devices, including implantable devices. However, for reusable and reprocessed medical devices, the UDI final rule mandates that unique device identifier be located on the device itself (in addition to on the package). VeriTeQ's Q Inside Safety Technology directly addresses and fulfills this direct part marking requirement. In fact VeriTeQ believes their product is the only one in existence today that has the ability to meet the AIDC portion of FDA's mandate for direct part marking under the UDI legislation (we note, however, that there are other marking technologies that may qualify under the mandate which we discuss later).

**Compliance Timelines...**

The FDA has a set schedule for compliance of the UDI final rule based on device type and class. For non-reusable devices, Class III devices are mandated to be in compliance (i.e. - package must bear a UDI) within 12 months of the final rule publication date (by Sept 2014) - manufacturers may request a one-year extension, life-sustaining/life-supporting and implantable devices within two years (by Sept 2015), Class II devices within three years (by Sept 2016) and Class I devices within seven years (by Sept 2020).

For devices that are reusable and those intended to be reprocessed, life-sustaining/life supporting devices must be in compliance (i.e. - UDI must be marked directly on the device) within two years of the final rule publication date (by Sept 2015), Class III devices within three years (by Sept 2016), Class II devices within five years (by Sept 2018) and Class I devices within seven years (by Sept 2020).

**Summary of Compliance Dates for the UDI Final Rule**

Compliance Date	Requirement
1 year after publication of the final rule (September 24, 2014)	The labels and packages of class III medical devices and devices licensed under the Public Health Service Act (PHS Act) must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18. Data for these devices must be submitted to the GUDID database. § 830.300. A 1-year extension of this compliance date may be requested under § 801.55; such a request must be submitted no later than June 23, 2014. Class III stand-alone software must provide its UDI as required by § 801.50(b).
2 years after publication of the final rule (September 24, 2015)	The labels and packages of implantable, life-supporting, and life-sustaining devices must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18.

	<p>A device that is a life-supporting or life-sustaining device that is required to be labeled with a UDI must bear UDI as a permanent marking on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use. § 801.45.</p> <p>Stand-alone software that is a life-supporting or life-sustaining device must provide its UDI as required by § 801.50(b).</p>
	<p>Data for implantable, life-supporting, and life-sustaining devices that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300.</p>
3 years after publication of the final rule (September 24, 2016)	<p>Class III devices required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45.</p>
	<p>The labels and packages of class II medical devices must bear a UDI. § 801.20.</p> <p>Dates on the labels of these devices must be formatted as required by § 801.18.</p> <p>Class II stand-alone software must provide its UDI as required by § 801.50(b).</p>
	<p>Data for class II devices that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300.</p>
5 years after publication of the final rule (September 24, 2018)	<p>A class II device that is required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45.</p>
	<p>The labels and packages of class I medical devices and devices that have not been classified into class I, class II, or class III must bear a UDI. § 801.20.</p> <p>Dates on the labels of <u>all</u> devices, including devices that have been excepted from UDI labeling requirements, must be formatted as required by § 801.18.</p>
	<p>Data for class I devices and devices that have not been classified into class I, class II, or class III that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300.</p> <p>Class I stand-alone software must provide its UDI as required by § 801.50(b).</p>
7 years after publication of the final rule (September 24, 2020)	<p>Class I devices, and devices that have not been classified into class I, class II, or class III that are required to be labeled with a UDI, must bear UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45.</p>
<p><b>Compliance dates for all other provisions of the final rule.</b> Except for the provisions listed above, FDA requires full compliance with the final rule as of the effective date that applies to the provision.</p>	

SOURCE: [www.fda.gov](http://www.fda.gov)

### ***FDA UDI Mandate Offers Opportunity For VeriTeQ...***

The low-hanging fruit opportunity for VeriTeQ as it relates to the UDI final rule is the direct part marking mandate for devices that are reusable and intended to be reprocessed, although we believe the expanded opportunity extends beyond this. Since these reusable devices must be directly marked by September 24, 2015 and VeriTeQ's technology is already FDA cleared for human use (although not yet cleared for specific devices - although, again, FDA may not require this), VeriTeQ is in a potentially prime position to garner early and substantial market share of the reusable medical device market.

VeriTeQ's game plan to capitalize on the reusable mandate includes a focus on breast implant sizers which are used to size the area prior to implantation of the actual device and, after being sterilized, will be reused. VeriTeQ's Q Inside Safety Technology RFID transponder can be implanted within the silicone breast implant sizer which can then be scanned with a reader. This will satisfy the FDA's UDI mandate for reusable medical devices. Breast implant sizers are intended to be reused a maximum of ten times before being discarded. VeriTeQ estimates the breast implant sizer market at about 600k devices annually.

The potential expanded market opportunity for VeriTeQ as it relates to the UDI mandate are implantable medical devices. Under the UDI legislation implantable (i.e. - non-reusable/non-reprocessed) devices must only carry the device identifier on the packaging and are not mandated to have the device itself directly marked. Interestingly, however, is that this expanded market (i.e. - implantables) represents VeriTeQ's most near-term opportunity and where there is already demand for their technology in breast implants.

While the rule only requires the packaging of implantable (i.e. - non-reusable/non-reprocessed) devices to carry the UDI, manufacturers may have a real interest in having the UDI directly marked on the devices as well.

These reasons include providing consumers more safety and peace of mind that in the event of a recall or reports of adverse events that the implanted devices can be identified quickly and accurately and corrective action can be swift. As the device packaging, literature and warranty information oftentimes is discarded or misplaced, particularly if a length of time has passed since the device was implanted, patients may be unaware of the relevant information (i.e. - make, model, batch, serial #, etc) to identify which particular device is in their body. In a recall situation this can create unnecessary anxiety for patients that may not have the faulty device but are unsure of such and can increase the risk of adverse events in those patients which do have the device but for which corrective action was delayed due to the additional time consumed in identifying which patients received the particular device. Direct part marking would greatly reduce or eliminate these risks and VeriTeQ's technology has certain advantages over other direct part marking methods, particularly as it relates to breast implants and breast implant sizers.

### ***Breast Implant Recall Demonstrates Utility of Direct Part Marking of Implantables...***

As a recent example involving a massive recall of a widely used breast implant demonstrates, there's reason to believe direct part marking would provide patients with greater peace of mind and safety in the event of a recall. And being able to provide these benefits to patients is a direct benefit to manufacturers in the form of a competitive advantage. As such, manufacturers may have interest in over complying with the UDI mandate and directly marking the part in addition to the required UDI packaging requirement.

Poly Implant Prothese (PIP) was a French company and one of the largest producers of breast implants, producing approximately 100k implants annually. It was estimated that about 400k women had received PIP breast implants. In 2009 surgeons in France noticed a higher than average number of ruptures of the PIP implants and shortly afterwards, it was found that PIP had been using (unapproved and much cheaper) industrial grade instead of medical grade silicone in the implants. The ruptured implants put patients at significant health risk and the French government recommended that 30k women in France have the PIP implants removed.

News of the safety risks quickly spread and the implants were banned throughout the world. And while some breast implant recipients were aware of whether they had received the PIP implants, many others were not and no longer had the product documentation to verify what implants they had received. The anxiety and potential health risks due to the time consumed in identifying the implants that these patients endured could have been eliminated or greatly reduced had the implants had a direct part marking, such as VeriTeQ's Q Inside Safety Technology. Government regulators in England, as we detail below, have already taken action in this direction as a result of the PIP problem.

### ***England Will Track Breast Implant Procedures and Devices...***

The PIP issue prompted England to establish a national registry where every breast implant procedure carried out in the country will be logged. The type of implant used will also be recorded in the future. The registry, which just commenced piloting and which will become law later this year, is currently only in effect in England but Wales, Northern Ireland and Scotland are all considering joining.

The registry is a direct response to the PIP fiasco and an attempt to prevent a similar event. Dr. Dan Poulter, England's health minister, noted that, "For the first time, there will be proper training courses for cosmetic surgeons, and we shall be setting up a breast implant registry which will better track the quality of implants and, if required, enable us to act much more quickly to protect women and patients." Setting up such a registry has been strongly supported by the British Association of Aesthetic Plastic Surgeons.

We view this as another real opportunity for VeriTeQ. Their Q Inside Safety Technology could be an ideal way to track breast implants for the national registry.

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## **COMMERCIALIZATION**

VeriTeQ's plans for commercialization of their technology include for the identification of both implantable as well as reusable medical devices and also for radiation dosimetry. Initial commercialization, for identification of breast implants, just recently commenced through a development and supply agreement with Establishment Labs, S.A., a global breast implant manufacturer. The company also has a development and supply agreement with Medical Components (MedComp), Inc, a leading manufacturer of vascular ports, whereby MedComp will embed VeriTeQ's microchip in their vascular ports. The radiation dosimetry technologies were commercialized previously under prior ownership and are currently in the pipeline to be ramped up in the future.

### ***Establishment Labs Breast Implants Embedded With VTEQ's Microchip...***

In September 2012 VeriTeQ entered into a development and supply agreement with Establishment Labs, S.A. (EL), a global provider of breast implants under the Motiva Implant Matrix brand name. Under the agreement, EL will purchase VTEQ's Q Inside Safety Technology microchip and embed these in their Motiva breast implants.

EL has already tested the microchips to insure that they can be read through the implant and verified that the chips can withstand exposure to the silicone as well as adverse conditions such as high temperatures and the effects of sterilization.

In October 2013 EL received CE Mark to market their Motiva breast implant with VTEQ's microchip embedded inside of it. Based on comments by EL's management there is already demand for these microchip-embedded implants. Concurrent with the CE Mark announcement, EL's CEO noted that, "We are already on final talks with the biggest groups of clinics in Europe to provide the highest degree of safety, which patients have been rightly demanding after the recent breast implant scare in the EU."

In August 2013, in anticipation CE Mark would be forthcoming, EL placed their first order of 2,000 microchips, which were delivered in October. In mid-January 2014 VeriTeQ announced that they delivered another 6,000 microchips to EL. VeriTeQ sells each microchip for approximately \$10 - \$12. Even with some margin priced in, the EL implants with VTEQ embedded technology are expected to remain competitively priced.

In early March 2014 VTEQ announced that they also began shipping the handheld readers to EL and further noted that patients had begun receiving the Motiva chip-enabled implants. EL's breast implants are now the only ones in the world to be identifiable while implanted in the body. Through the use of a VeriTeQ handheld reader (which is expected to sell for ~\$500 each), The Q Inside Safety Technology allows retrieval of implant-specific data such as serial number, manufacturer name, date of manufacture, lot number, volume, size, and other data. Had the PIP implants been embedded with VTEQ's technology, patients and health care providers would have been able to quickly and accurately identify which patients had received the faulty implants which would have facilitated immediate corrective action. The aforementioned breast implant registry in England is expected to require the type of implant used to be logged in the future - VTEQ's microchip embedded in the implants should offer an efficient solution to meet that mandate.

### **EL Motiva Breast Implant With VeriTeQ's RFID Microchip Embedded Inside**



### ***Follow-On Agreements Could Be Even More Important...***

While the EL agreement is important from a near-term revenue perspective for VeriTeQ, the greater significance may lie in the facilitation of similar agreements with other, much larger, breast implant manufacturers.

There is no publicly available data on market share among breast implant manufactures although we estimate EL may only hold low-single digit share. The majority of the market is dominated by Mentor Corp. (part of Johnson & Johnson) and Allergan, Inc., which combined we estimate hold 80% - 90% of the worldwide breast implant market. The rest of the market is less concentrated and includes Nagor and Eurosilicone (two European manufacturers, both of which are owned by GC Aesthetics) which sell breast implants in Europe and in 50+ countries but not in the U.S. In the U.S. there are only five silicone breast implants approved by the

FDA<sup>2</sup> which includes two from Allergan, two from Mentor and one from Sientra, a small and relatively new entrant to the breast implant market which is based in California.

As the agreement with EL is non-exclusive, VTEQ's game plan will be to pursue similar partnerships with other breast implant manufacturers. VTEQ's investor presentations have noted discussions with at least two breast implant manufacturers regarding testing the Q Inside Safety Technology with their respective breast implants and/or breast implant sizers. If an agreement is penned with a breast implant manufacturer of significant size, this could exponentially and instantly expand VTEQ's reachable breast implant market opportunity.

As VTEQ's chip is already FDA cleared for human use, it is currently unclear whether FDA would require formal approval of a silicone breast implant with the chip inside. Due to safety concerns FDA has historically taken a somewhat conservative stance on silicone breast implants, including a 14-year ban (which was lifted in 2006) and requiring manufacturers to conduct post-marketing surveillance safety studies. The agency's relatively aggressive oversight of breast implants along with the renewed concerns borne out of the PIP scandal may bode well for regulatory support of initiatives and products such as VTEQ's which are designed to address these concerns. So in the event FDA requires regulatory approval of the implants with the chip inside, we think there is reason to believe the approval process could be swift. We also expect that the manufacturers would take ownership of the regulatory process and related obligations.

#### ***MedComp Vascular Ports Embedded With VTEQ's Microchip...***

VTEQ's 2012 acquisition of the VeriChip and related patents from PositiveID Corp also included the rights to a development and supply agreement with MedComp, a leading manufacturer of vascular access catheters. Under the agreement, MedComp will embed VTEQ's microchip in their vascular ports. The microchip will allow the ports to be easily identified when implanted in a patient, which also helps ensure the correct medication dosage. The current method for identifying the size (which determines the flow rate) of the port is by the clinician feeling the port through the patient's skin, which introduces the risk of error. Vascular ports are considered implantable, non-reusable devices and therefore are not mandated under the FDA UDI legislation to have the UDI directly marked on the part.

The initial term of the agreement is for five years and totals over \$3 million over that timeframe but which has been contingent on MedComp receiving FDA clearance of the vascular port with the embedded microchip. However, it is currently unclear whether FDA will actually require clearance of the ports with the chip inside as both the chip and the ports are both FDA cleared.

VTEQ's January 2014 investor presentation notes that studies are expected to begin at three hospitals; Northwestern Memorial (Chicago), New York-Presbyterian and either the Cleveland Clinic or MD Anderson Cancer Center (Houston). It's currently unclear as to the scope or status of these studies.

VeriTeQ estimates the vascular port market at approximately 800k procedures per year, with roughly 50% of those done in the U.S.

#### ***Add'l Applications Include Other Medical Devices and Radiation Dosimetry...***

VeriTeQ expects their product to have applicability in other reusable and implantable devices including artificial hips (~ 460k procedures/yr worldwide), artificial knees (~1.1M procedures/yr worldwide) and spacers for these and other artificial joints. In addition to medical devices, VeriTeQ sees a real potential opportunity in radiation dosimetry.

VeriTeQ acquired radiation dosimetry measurement technology and related intellectual property from the investor group SNC, which purchased the intellectual property marketed by Sichel Technologies, Inc. This includes external (called "OneDose") and implantable (called "DVS SmartMarker" - which VTEQ has rebranded as "Q Inside SmartMarker" ) radiation dosimetry sensors which measure the amount of radiation a patient receives when undergoing external beam radiation therapy. The utility of the dosimetry technology is to ensure the patient does not receive a harmful level (per-treatment and cumulatively) of radiation, to optimize the amount of radiation at the tumor site and to help identify the specific location of the tumor. The external dosimeter measures the amount of radiation penetrating a patient at skin level while the implantable dosimeter measures radiation at the tumor site. The implantable sensor can also be used as a marker for the location of the tumor in the body which is useful for the radiologist as a cancer patient will typically need to undergo multiple treatment sessions.

<sup>2</sup> FDA Approved Silicone Gel-Filled Breast Implants.

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm063871.htm>

SmartMarker was evaluated (when owned by Sixel) in a multi-center clinical trial in patients with breast cancer (n=38 patients) and prostate cancer (n=31). The study was conducted at four sites; Wake Forest University School of Medicine, Duke University School of Medicine, Rex Cancer Center and Texas Cancer Clinic. Objectives were to assess safety and, secondarily, to assess the ability of the dosimeters to measure the delivered radiation dose (daily fractionated photon irradiation) at the site of implantation. In total, 126 internal dosimeters were implanted. A manuscript of the study, titled *The Observed Variance Between Predicted and Measured Radiation Dose in Breast and Prostate Patients Utilizing an in-vivo Dosimeter*, was published in October 2008 in the International Journal of Radiation Oncology, Biology and Physics. Results showed the device to be safe and well-tolerated. In terms of measuring radiation dose, DVS showed that the cumulative radiation dose delivered to the tumor site was as much as 20% to 42% different than what was expected (i.e. - expected based on the radiation dose plan). The trial investigators concluded that, "The DVS was not associated with significant adverse events or migration. The dosimeter can measure dose *in situ* on a daily basis. The accuracy and utility of the DVS [SmartMarker] complements current IGRT (image guided radiation therapy) and IMRT (intensity modulated radiation therapy) techniques."<sup>3</sup>

Management notes that their One Dose external sensor is the only wireless, pre-calibrated, disposable surface sensor on the market that can instantly provide measurement of radiation dose delivered at skin level. It is FDA cleared for use in cancer patients being treated with external beam radiation. VeriTeQ views the ~1.1 million patients that receive external beam radiation therapy in the U.S. each year as the initial target market for their external sensor. The expanded market could include (assuming requisite regulatory approvals) patients undergoing CT scans (~75M/year in the U.S.) and fluoroscopy procedures (~5M/year in the U.S.).

Similarly, VeriTeQ's internal sensor is the only implantable wireless sensor on the market that confirms radiation dose delivered directly to the tumor. It is FDA cleared for use in prostate and breast cancer radiotherapy settings. Future goals could include pursuit of regulatory approval for use in other tumor types including lung, colorectal and pancreatic.

Data collected by their bio-sensor is stored in VeriTeQ's information platform and provides radiologists information about the exact dosage received per treatment as well as the total amount of radiation over the course of a treatment regimen. Both sensors are FDA cleared and CE Marked and the company notes that they are also reimbursed by Medicare and many private insurers. Specific to the One Dose external sensor, reimbursement per patient averages approximately \$260 - \$380 (with ~ 4-6 dosimeters used per patient).

**VeriTeQ's Implantable Dosimeter**



**VeriTeQ's External Dosimeter**



VeriTeQ also notes that they are actively looking at other areas where their sensor technology would have potential utility including for the measurement of blood oxygen, glucose, temperature and others.

#### **Data Opportunity...**

In addition to the opportunity with their Q Inside Technology, VeriTeQ expects to generate revenue from an information and data platform. VeriTeQ is building a technology platform that they envision will support better informatics and new data analytics through which superior evidence-based healthcare data will flow to patients and hospital systems. In addition to the direct benefits of incorporating medical device and treatment information into the patient care model and electronic health records, VeriTeQ believes that their technologies and the various applications that can be created from their implementation will ultimately develop new healthcare metrics and analytics created by the union of these and other interdisciplinary data sources. The company's expectations are that these metrics will link what was once deemed disparate data together in a truly patient centric system through software and infrastructure development. Depending on the ultimate success of the data and information platform, this could potentially evolve to be the company's largest revenue generator

<sup>3</sup> Scarantino Charles W., et al. The Observed Variance Between Predicted and Measured Radiation Dose in Breast and Prostate Patients Utilizing an in-vivo Dosimeter. Int Journal of Rad, Onc, Bio and Phys. 2008 October: 72(2): 597-604

over time. We note, however, that as development is still in the relatively early stages, that we do not currently model any contribution from this potential opportunity.

## COMPETING TECHNOLOGIES

### ***Other Marking Techniques Available But All Have Drawbacks...***

Direct part marking on the device itself can be achieved by means other than RFID tags. In fact direct part marking is already commonplace in other industries such as the automotive industry and for suppliers to the Department of Defense. The most common direct part marking techniques are dot peening, laser marking, electrochemical etching and ink jet printing. All of these techniques can produce linear (1D) bar codes as well as DataMatrix 2D bar codes, the latter which can hold a relatively large amount of data and therefore may be considered more practical than linear bar codes as it relates to the UDI mandate.

**Dot Peen**



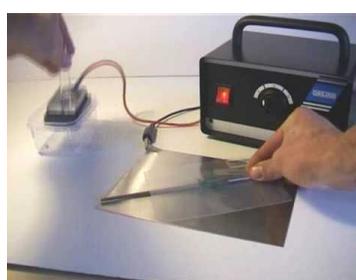
dapramarking.com

**Laser**



ticona-photos.com

**Electrochemical**



youtube.com

**Wire Marked By Ink Jet**



durable-tech.com

Dot peening involves a very hard (typically carbide or diamond) stylus striking the metal surface of the product that is being marked, imprinting it with a code or symbol. Drawbacks of dot peening include that it is generally a lower throughput method, it has limitations with very small products, it is less precise than some other techniques and may not be suitable for some materials.

Laser marking uses a laser to engrave a code on a product. Laser marking can produce relatively high throughput, high resolution marks and can be used with small products. Some potential drawbacks of laser marking is that the laser equipment can be relatively expensive, the mark produced by the laser may not be as deep as with dot peening (which can make the mark less resistant to scratches or wear) and lasers may not be suitable for some materials.

Electrochemical etching involves transferring a mark or code from a stencil to the surface of the product to be marked by passing an electric current through the stencil which is treated with electrolytes. Electrochemical etching is typically used for parts and products more fragile in nature and of unique shape. It is relatively low throughput and not typically used for large manufacturing batches.

Ink jet printing stain the part being marked with a specialized ink. Ink jet printing can have relatively high throughput and good readability. Drawbacks are that the surface of the part may need to undergo a preparation process and, since the mark is not etched, there can be higher risk compared to the other techniques of degradation due to scratching or wear.

In addition to the unique limitations of each of these marking techniques, there are other drawbacks that are consistent among them. The drawback that all of these direct part marking techniques suffer from is that, in the case of implanted medical devices, the marks, which must be read with imaging equipment, are not always clearly visible or discernable. Some materials, such as breast implants, are also not suitable for any of these techniques, save potentially ink-jet printing (which, as noted, has its own unique limitations). In the case of reusable devices, the device oftentimes must be thoroughly cleaned of bodily fluids so as to be able to read the mark. And since these reusable devices are subject to considerable handling and potentially multiple sterilization processes over their usable lifetimes, there is more risk that the inked, etched or engraved mark becomes degraded and harder or impossible to read over time.

In contrast to these other direct marking techniques, VeriTeQ's technology suffers from none of these limitations, either unique to each method or shared among them.

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## FINANCIAL CONDITION

As of the most recent reporting period (ending 12/31/2013) the company had approximately \$13k in cash and short-term investments and another \$882k in restricted cash. Subsequent to 2013 year-end, \$145k of restricted cash was allowed to be transferred to the operating (non-restricted cash) account. Additional of the restricted cash will be released pro-rata as convertible debt converts to equity.

Cash burn (ex changes in working capital) was approximately \$4.1M in 2013. VTEQ will need to raise additional capital to fund ongoing operations.

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## OUTLOOK

Our outlook and related financial model reflects our estimates and assumptions related to the various markets that VTEQ is targeting with their Q Inside Safety Technology. As commercialization for any of the targeted applications has either only recently commenced (in the case of breast implants) or is in earlier stages (vascular ports, artificial joints, dosimetry), there are a number of unknowns that we needed to account for. We have made what we believe to be reasonable best-guesses for unknowns related to areas such as regulatory approvals, launch timelines, third-party interest and competitive technologies, pricing and margins, and rates of adoption, among others (which also includes the assumption that VTEQ successfully raises additional capital to fund ongoing operations). Our outlook and model are subject to change based on developments over time.

### ***Breast Implants and Sizers***

The breast implants market is where we expect substantially all of the near-term opportunity to lie for VTEQ. Establishment Labs has now placed orders for a total of 8k of VTEQ's RFID tags. The company noted in October, with the announcement of the initial 2k order, that follow-on orders could be expected on a (roughly) monthly basis. As such, and with the expectation that EL integrates the chip into other of their breast implant models, we think there will be ongoing orders throughout 2014 and likely beyond. We have modeled a somewhat measured increase in orders from EL throughout 2014. The totality of our modeled revenue in 2014 represents revenue generated from orders from EL.

VTEQ has indicated in recent investor presentations that (since November 2013 or earlier) another breast implant manufacturer of significant size was testing the feasibility of the Q Inside Safety Technology for integration in their silicone implants. The company also notes in the same November presentation that they have been in discussions with "two leading global breast implant manufacturers" relative to their needs to comply with the FDA Final Rule as it relates to their breast implant sizers.

As VTEQ's chip is already FDA cleared for human use, it is currently unclear whether FDA would require formal clearance of a silicone breast implant with the chip inside. Depending on regulatory requirements, commercialization in the U.S. for use in breast implants and/or sizers could potentially come in the relatively near-term (<12 months) or could be a much longer timeframe (>24 months, particularly if PMA is necessary). We do, however, believe FDA has interest in programs, policies and products aimed at improving safety of breast implants which may bode well for the agency supporting technologies such as VTEQ's. The recently established national registry in England to track breast implants provides additional support for the notion that there is real interest throughout the globe (albeit not mandated by FDA) to improve safety of breast implants. As such, combined with the fact that the chip has already been FDA cleared for human use, we think it is reasonable to expect that VTEQ will have the ability to access the U.S. market in the not too distant future.

Our modeled revenue beginning in late 2015 includes the assumption that VTEQ enters into agreements for integration of their chip with other breast implant manufacturers and gains any potential requisite FDA clearances for commercialization in the U.S. While this is speculation on our part, we feel that this is a reasonable assumption based on our reasoning above as well as that competing product marking methods (i.e. - dot peening, laser marking, ink jet marking, electrochemical etching) are either unsuitable for breast implants (and breast implant sizers) or functionally inferior to VTEQ's technology for this application. We think this drives

increasing demand for VTEQ's Q Inside Safety Technology from the breast implant industry which is reflected in our modeled step up in revenue growth from 2015 to 2016 and order flow picking up throughout 2016.

Access to the U.S. would greatly expand the potential market for VTEQ in breast implants. Approximately 1.2 million breast augmentation procedures are done every year worldwide with almost 300k of those done in the U.S. (see table for top 20 countries performing breast augmentation procedures). And as the U.S. breast implant market is highly concentrated between J&J and Allergan, VTEQ could potentially quickly ramp commercialization in the U.S. with agreements with these companies. Entry into the U.S. market could also facilitate expansion into other countries and continents, including Mexico and South America. And combined with the distribution reach already afforded by Establishment Labs, we think VTEQ's footprint for the breast implant application could encompass as much as 75% (which we view as the total reachable market) of the total market within a few years. There are approximately 32k plastic surgeons in the world - if we assume 75% of these will fall within VTEQ's reachable market, one reader per plastic surgeon and each reader is replaced every three years, the total reachable reader market is approximately 72k readers annually.

VTEQ disclosed selling prices of ~\$10 - \$12 per chip (two chips per procedure) with expected gross margins of ~70%. The scanners are expected to be sold for ~\$500 with gross margins of ~50%. This implies a total reachable annual market size worth approximately \$19.8M (900k procedure reachable mrkt x 2 chips/procedure x \$11 avg selling price) in sensor chips revenue and \$36.0M (72k readers/year x \$500 avg selling price) in readers revenue.

Our model assumes VTEQ captures approximately 2% of their reachable breast implant market by the end 2016 and just under 5% by the end of 2017. We currently model approximately \$1.3M and \$2.7M in revenue related to this breast implant application in 2016 and 2017, respectively. This is arguable conservative and will be updated if and when warranted.

#### Breast Augmentation Procedures By Country in 2011<sup>4</sup>

Rank		Annual Procedures	% of Total WW Procedures	Rank		Annual Procedures	% of Total WW Procedures
1	U.S.	284,351	23.6%	11	Spain	25,135	2.1%
2	Brazil	148,962	12.4%	12	India	24,859	2.1%
3	Mexico	72,712	6.0%	13	Russia	20,572	1.7%
4	Italy	62,055	5.1%	14	Canada	20,375	1.7%
5	China	56,840	4.7%	15	U.K.	19,031	1.6%
6	Japan	52,220	4.3%	16	Turkey	14,680	1.2%
7	France	41,484	3.4%	17	Venezuela	14,389	1.2%
8	Colombia	38,779	3.2%	18	Argentina	13,429	1.1%
9	Germany	36,816	3.1%	19	Greece	11,623	1.0%
10	S. Korea	35,325	2.9%	20	Taiwan	10,038	0.8%

We do not currently model any revenue from the breast implant sizers market. While discussions with manufacturers relative to integration of Q Inside into their implant sizers is an obvious positive step, we feel it's too early to gauge substantive interest at this point. We also note that FDA lists breast implant sizers as "unclassified" devices and the deadline for meeting the UDI mandate for unclassified devices that are intended to be reused is not until September 2020. This means these manufacturers may not gear up to integrate direct part marking into the manufacturing process of their devices until several years from now. We will update our model if and when there is sufficient evidence that there is greater traction from these manufacturers relative to substantial interest in using VTEQ's technology in their breast implant sizers as well as potential timing of when purchase orders would commence.

#### **Vascular Ports**

VTEQ's acquisition of the VeriChip and related patents in 2012 also included a development and supply agreement with MedComp, a leading manufacturer of vascular access catheters. Under the agreement, MedComp will embed VTEQ's microchip in their vascular ports. The microchip will allow the ports to be easily

<sup>4</sup> International Society of Aesthetic Plastic Surgery International Survey on Aesthetic/Cosmetic Procedures Performed in 2011

identified when implanted in a patient and will also help ensure the correct medication dosage. The initial term of the agreement is for five years and totals over \$3 million over that timeframe but is contingent on MedComp receiving FDA clearance (anticipated to be 510k) of the vascular port with the embedded microchip. However, it is currently unclear whether FDA will actually require clearance of the ports with the chip inside as both the chip and the ports are both FDA cleared.

VTEQ's January 2014 investor presentation notes that studies are expected to begin at three hospitals; Northwestern Memorial (Chicago), New York-Presbyterian and either the Cleveland Clinic or MD Anderson Cancer Center (Houston). It's currently unclear as to the scope or status of these studies.

We believe, given the supply and development agreement that is already in place, that MedComp represents a potentially meaningful revenue generating opportunity for VTEQ. However, we will not model any contribution from this relationship until there's more obvious clarity to MedComp's timelines and vested interest in pursuing commercialization in the near-term.

If successfully integrated and commercialized with MedComp's catheters, VTEQ expects to pursue agreements with other vascular port manufacturers.

### **Artificial Joints and Spacers**

We see no obvious hook for VTEQ to gain near term access to the artificial joint market. Given that the final rule did not mandate that implantables must have the UDI mark directly on the part, doing so would be completely voluntary on the part manufacturers. But while it's probably too early to gauge how compelled implantable manufacturers may be in that regard to what would essentially be over compliance, it's possible that orthopedic device manufacturers may follow the lead of makers of breast implants, such as Establishment Labs and potentially others which voluntarily are either going forward with, or considering, integrating VTEQ's Q Inside transponder with their products.

It is probably reasonable to assume that implantable device manufacturers are at least contemplating direct part marking in light of the PIP scandal and the potential related litigation risk that could follow, particularly if there was not a reliable and effective way to track and identify specific implanted devices in the event of a recall. In addition, FDA's decision to implement an identification and tracking system is a clear indication that the agency is encouraging measures to improve safety and information flow for all medical devices - which perhaps will compel a more proactive approach from manufacturers, including those of orthopedic implants.

However, as there is little evidence that orthopedic device manufacturers are currently aggressively pursuing this, along with the fact that there are other potentially viable direct marking methods available that could be used if these manufacturers do pursue direct part marking, we feel it is too early to model any potential financial contribution from artificial joint manufacturers. Regulatory approval may also need to be attained prior to commercialization of an implanted device integrated with VTEQ's transponder.

Relative to artificial joint spacers, orthopedic spacers are either unclassified or Class I devices, both of which must have the UDI directly on the part by September 2020. This provides a long runway for manufacturers to implement a game plan for compliance and they may seek compliance by using VTEQ's technology or one of the other competing methods such as laser marking or dot peening (either of which might be suitable for orthopedic implants). Given that it is several years until compliance is required and no indication that these manufacturers are considering one method more seriously than any other, we feel it is prudent to refrain from modeling any contribution from this potential source for now. We reiterate however, that our model will be updated if and when appropriate which could include a contribution from the orthopedic device channel as well as others if circumstances warrant.

### **Biosensors**

VTEQ's biosensor products benefit from already being FDA cleared, having clinical trial experience with positive results (and published in a peer-reviewed journal) and being covered by at least some level of third party reimbursement. We also view the opportunity with the biosensor products as holding the most upside potential given the relatively large target markets for the products.

The target market for the external sensors is the ~1.1M people that receive external beam radiation therapy in the U.S. each year. The expanded market could include (assuming requisite regulatory approvals) patients undergoing CT scans (~75M/year in the U.S.) and fluoroscopy procedures (~5M/year in the U.S.). VTEQ disclosed selling prices of ~\$500 per external sensor kit for each patient. Gross margins are expected to be ~80%.

The target market for the internal sensors is the ~82k patients which undergo external beam radiation treatment for breast or prostate cancer in which a gold seed is used. Gold seeds are non-radioactive pellets implanted near the tumor and used as a marker in order to more accurately deliver the radiation dose. VTEQ's implanted sensor serves a similar purpose but, unlike gold seeds, VTEQ's biosensor also measures the radiation dose delivered. VTEQ disclosed selling prices of ~\$1,200 per internal sensor kit for each patient. Gross margins are expected to be ~80%.

We expect commercialization of the biosensors would initially focus on awareness building which may potentially include investigator led studies at a small number of hospitals in order to build on the clinical experience of the devices. The company's general game plan is to sell the technology directly and through distributors to radiation oncologists and medical dosimetrists. However, commercialization of the biosensors is likely not a near-term event as this will undoubtedly require additional financial resources and VTEQ is currently focused on the launch of the direct part marking applications.

Our model assumes a soft launch towards the back half of 2015 with a combination of a small sales force and initial distribution agreement(s). As a placeholder we assume less than one percent penetration of both the external (excluding the external sensor expanded markets) and internal sensor markets by the end of 2017. We currently model approximately \$3.2M in revenue from the biosensors in 2017. This is subject to updating depending on how developments unfold. We also note that the size of potential biosensor market, at approximately \$650M annually (in just the U.S. alone), is more than 10 times as large as what we characterize as VTEQ's worldwide reachable breast implant market. As such, and depending on VTEQ's success in penetrating the biosensor market, this could prove to be the area that holds the most upside opportunity for the company, particularly over the long term.

## VALUATION / RECOMMENDATION

VeriTeQ is just now on the very front of the initial commercialization of their Q Inside Technology and has very limited operating history. As such, and as we indicated in our Outlook section above, construction of near-to-long term forecasts and a related financial model entails assumptions based on available current information, best-guesses and management's publicly available guidance. While we believe our assumptions are reasonable and defensible, there is significant risk that the inputs built into our outlook for the company unfold differently than our forecast - some of this uncertainty is detailed in our risk factors section below.

The two sole current contributors to our modeled revenue are from the breast implant and dosimeters applications. Revenue from any other sources or from the expanded markets from the breast implant and dosimeter applications that may materialize would be incremental, and provide potential upside, to our model. Our model assumes approximately 5% penetration of the worldwide breast implant market by the year 2018, growing to 10% by 2023. We model the dosimeter application (both internal and external biosensors) to capture just under 1% of their respective target markets (this does not include what we characterized as potential extended markets, that is, CT and fluoroscopy) by the year 2018, growing to just under 3% by 2023. Our forecasted gross margins are generally in-line with the publicly available guidance provided in the company's recent investor presentations.

Our modeled operating expenses assume breast implant-related sales are handled largely through distribution agreements. We look for aggregate SG&A spend to increase with introduction of the dosimeter application, reflecting an assumption of combination distributor/in-house sales force.

We value VTEQ using a 10-year DCF model. We look for revenue of approximately \$1.1M in 2015, \$8.4M in 2018 and \$31.6M in 2024. We use a 10% discount rate and 2% terminal growth rate. Based on our 10-year DCF VTEQ is valued at \$1.98/share. We round to \$2.00/share.

## RISK FACTORS

A number of unknowns exist, several of which, depending on the outcomes, could have a materially negative impact on VeriTeQ's future. As such, an investment in VeriTeQ comes with meaningful risk. Factors that should be considered include;

- **Tight Cash Position:** Balance sheet is light on cash, particularly as compared to the burn rate. VTEQ will require significantly more capital and need to raise funds to execute on even its near-term plans (i.e. - roll out with EL). Additional capital raises could be dilutive to the current shareholder base. Cash flow break even may not materialize for several years, if ever.
- **Good Start With EL But Need To Expand Opportunities:** The agreement is a good start for commercialization of the technology but EL's relatively small production/sales volume is not enough to sustain VTEQ's operations for the long-term. Therefore VTEQ will need to expand to additional opportunities such as agreements with other, larger breast implant manufacturers, integration of the chip into orthopedic implants, commercialization of biosensors, etc.
- **Competing Products/Technologies:** Our report does not cover the comprehensive list of potential competitive products, methods and technologies. The rapid pace of technological innovation in the med-tech space means a novel and more robust method for direct part marking and/or dosimetry could potentially come to market in the short-term.
- **Model-Based Assumptions Could Prove Inaccurate:** Our model assumes VTEQ pens an agreement with at least one more breast implant manufacturer and commercializes via this agreement(s) by year-end 2015 - if that does not materialize, our breast implant-related revenue forecast beginning in late 2015/early 2016 may end up being too optimistic. Similarly, we assume a meaningful contribution from the biosensor products beginning in 2017 - if the biosensor products fail to make it to market or underperform our forecast, our model could prove too optimistic.

Also related to model-based assumptions, we are using best-guesses relative to product (chips, biosensors, readers) gross margins which are based on management's expectations (per recent investor presentations). If our modeled gross margins prove liberal, our forecasted operating and net income may also prove too optimistic.

## FINANCIAL MODEL

### VeriTeQ Corporation

	2013 A	Q1E	Q2E	Q3E	Q4E	2014 E	2015 E	2016 E	2017 E
Total Revenues	\$18.0	\$71.8	\$99.4	\$121.4	\$154.6	\$447.1	\$1,061.5	\$1,905.7	\$5,833.3
<i>YOY Growth</i>	-	-	-	-	758.7%	2384.0%	137.4%	79.5%	206.1%
Cost of Goods Sold	\$7.0	\$36.4	\$50.4	\$61.6	\$78.5	\$227.0	\$476.6	\$748.2	\$2,012.5
Gross Income	\$11.0	\$35.3	\$48.9	\$59.8	\$76.1	\$220.2	\$584.9	\$1,157.5	\$3,820.8
<i>Gross Margin</i>	61.1%	49.2%	49.2%	49.2%	49.2%	49.2%	55.1%	60.7%	65.5%
SG&A	\$6,589.0	\$1,640.0	\$1,690.0	\$1,705.0	\$1,750.0	\$6,785.0	\$7,092.0	\$7,188.0	\$7,216.0
<i>% SG&amp;A</i>	36605.6%	2285.4%	1700.9%	1404.0%	1132.2%	1517.5%	668.1%	377.2%	123.7%
R&D	\$0.0	\$0.0	\$0.0	\$0.0	\$50.0	\$50.0	\$200.0	\$350.0	\$450.0
<i>% R&amp;D</i>	0.0%	0.0%	0.0%	0.0%	32.3%	11.2%	18.8%	18.4%	7.7%
Operating Income	(\$6,578.0)	(\$1,604.7)	(\$1,641.1)	(\$1,645.2)	(\$1,723.9)	(\$6,614.8)	(\$6,707.1)	(\$6,380.5)	(\$3,845.2)
<i>Operating Margin</i>	-36544.4%	-2236.2%	-1651.6%	-1354.7%	-1115.4%	-1479.4%	-631.8%	-334.8%	-65.9%
Chge in derivative value	(\$4,164.0)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Total Other Income (Expense)	(\$8,499.0)	(\$40.0)	(\$40.0)	(\$40.0)	(\$40.0)	(\$160.0)	(\$200.0)	(\$200.0)	(\$150.0)
Pre-Tax Income	(\$15,077.0)	(\$1,644.7)	(\$1,681.1)	(\$1,685.2)	(\$1,763.9)	(\$6,774.8)	(\$6,907.1)	(\$6,580.5)	(\$3,995.2)
Tax expense (benefit)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>Tax Rate</i>	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Net Income	(\$15,077.0)	(\$1,644.7)	(\$1,681.1)	(\$1,685.2)	(\$1,763.9)	(\$6,774.8)	(\$6,907.1)	(\$6,580.5)	(\$3,995.2)
<i>YOY Growth</i>	-	-	-	-	-	-	2.0%	-4.7%	-39.3%
<i>Net Margin</i>	-83761.1%	-2291.9%	-1691.9%	-1387.7%	-1141.2%	-1515.2%	-650.7%	-345.3%	-68.5%
EPS	(\$1.75)	(\$0.13)	(\$0.12)	(\$0.11)	(\$0.10)	(\$0.45)	(\$0.29)	(\$0.22)	(\$0.11)
<i>YOY Growth</i>	-	-	-	-	-	-	-	-	-
Diluted Shares O/S	8,607	12,200	14,200	16,000	18,000	15,100	24,000	30,000	35,000

Brian Marekx, CFA

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## MANAGEMENT

### **Scott R. Silverman**

#### *Chairman and CEO*

Mr. Silverman has been Chairman and CEO of VeriTeQ since its inception in December 2011. He served as Chairman and CEO of PositiveID Corporation (OTCBB:PSID) from 2008 to August 2011, and Chairman and CEO of VeriChip Corporation (NASDAQ:CHIP) from December 2006 to July 2008. He was Chairman of Digital Angel Corporation from 2003 to 2007. From 2003 to 2006, Silverman served as Chairman and CEO of Applied Digital Solutions (NASDAQ:ADXS). Prior to his role as Chairman and CEO of Applied Digital he held other senior positions with the company. Silverman is an attorney licensed to practice in NJ and PA, and has more than 15 years of executive experience with technology companies. He is a graduate of the University of Pennsylvania and Villanova School of Law.

### **Randolph K. Geissler**

#### *President*

Mr. Geissler has been President of VeriTeQ since July 2012 and is also currently the CEO of Geissler Corporation. He specializes in managing companies and technologies focused on RFID, optical imaging and artificial antibodies. His vision and implementation are directly responsible for bringing the implantable microchip from "just an idea" to its highly successful status of more than 80 million microchips implanted in animals worldwide for identification and tracking. He previously served as CEO of Geissler Technologies (2004 - 2008) when he sold the company's expansive product development pipeline. Prior to that, he served as CEO of Digital Angel Corporation (AMEX: DOC) (2000 - 2003) and Destron Fearing (Nasdaq: DFCO) (1993 - 1999), a company he founded. He took his company public (two times) and has broad experience in product development, electronic miniaturization, application of advanced technologies in new markets, and creating marketing alliances; plus extensive experience in establishing strategic intellectual property and patent portfolios.

### **Michael Krawitz**

#### *Chief Legal and Chief Financial Officer*

Mr. Krawitz was most recently the Chief Executive Officer of Pear Energy, a renewable energy company that finances renewable energy and energy efficiency projects. He has worked previously with VeriTeQ's Chairman and CEO, Scott R. Silverman, most recently as a member of the Company's Board of Directors. Mr. Krawitz earned a bachelor of arts degree from Cornell University and a juris doctorate from Harvard Law School.

### **Caryn Mills**

#### *Director of Strategic Alliances*

Ms. Mills joined the VeriTeQ team in September 2013, bringing 15-plus years of extensive experience in pharmaceutical and medical device sales, marketing and business development. Prior to joining VeriTeQ, Ms. Mills held top producing sales, management, marketing and business development positions with medical device and pharmaceutical companies including Schering Plough Pharmaceuticals (December 1998-July 2005), King Hospital Surgical Division (July 2005- January 2011), and Covidien Surgical Solutions (January 2011-August 2013). Ms. Mills is responsible for identifying and advancing new partnerships with implantable medical device manufacturers to help them meet federal regulations requiring unique device identification ("UDI"), by using the Company's FDA cleared radio frequency identification microchip "Q inside" within their devices. Ms. Mills will also be responsible for bringing to market the Company's dosimeter technologies for use in radiation therapy treatment.

### **Allison Tomek**

#### *Sr. VP, Investor Relations & Corporate Communications*

Ms. Tomek has served as Sr. VP, IR and Corporate Communications of VeriTeQ since its inception and has served as Sr. VP, Investor Relations & Corporate Communications of PositiveID since 2009. She joined PositiveID in January 2007 as VP. From January 2007 to June 2008 she was VP of Investor Relations at Applied Digital Solutions and Digital Angel. From 2003 to 2006, Tomek was Director of Investor Relations and Corporate Communications at Andrx Corporation (NASDAQ:ADRX), a pharmaceutical manufacturer and distributor, and held investor relations positions at RailAmerica (NYSE:RRA) from 2001 to 2003. Tomek is the former President of the National Investor Relations Institute – South Florida chapter and a current member of the chapter's Board.

## HISTORICAL ZACKS RECOMMENDATIONS



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