Zacks Small-Cap Research

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E-Qure Corp (EQUR-OTC)

EQUR: Regulatory Delays From Both Sides Of The Atlantic!

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	08/07/2015
Current Price (11/23/2015)	$0.27
Target Price	**$1.00**

OUTLOOK

EQUR has developed an effective, low cost, easy-to-use device for chronic wound management, which addresses a market worth about $6 billion annually.
Management is in the final preparation phase to resubmit the IDE to the regulatory agency involving their BST device so they can initiate pivotal studies in the U.S.
Regulatory delays in EU, Argentina and Israel are adding uncertainty surrounding launch timelines for the BST device in these regions.
As per the third quarter financial update, the company's cash balance of $1 million (as of September 30, 2015) gives it some cushion to fund its planned operations into mid-2016.

SUMMARY DATA

52-Week High	**$3.07**
52-Week Low	**$0.20**
One-Year Return (%)	**-84.83**
Beta	**-1.14**
Average Daily Volume (sh)	**44**
Shares Outstanding (mil)	**22**
Market Capitalization ($mil)	**6**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**80**
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 2015 Estimate	**-4.5**
P/E using 2016 Estimate	**-5.4**
Zacks Rank	**N/A**

Risk Level	**High**
Type of Stock	**N/A**
Industry	**Med Instruments**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014					$0.0A
2015	$0.0A	$0.0A	$0.0A	$0.0E	$0.0E
2016					$0.37E
2017					$261.0E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014					(2.41)A
2015	(0.01)A	(0.01)A	(0.01)A	(0.01)E	(0.03)E
2016					(0.05)E
2017					(0.04)E

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

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WHAT'S NEW

EQUR: Regulatory Delays From Both Sides Of The Atlantic!

Update on Q3 2015 Financials

On November 16, 2015 EQUR reported financial and operational results for the third quarter of 2015.

The company did not report any revenues for this period. EQUR's net loss came in at $0.14 million (a loss of $0.01/share). R&D expenses continued to be minimal at $54,000. There has been reduced activity and lower costs related to operations as the company is in the final preparation phase to resubmit the IDE to the regulatory agency involving their BST device in the U.S. Consequently, research and development expenses have been low but are expected to increase once clinical trials commence. At a cash burn rate of close to $0.7 million annually, we think the $1 million cash on hand (as of September 30, 2015) gives the company some cushion to fund the company's planned operations into mid-2016.

Meanwhile in Europe, the application to renew the CE Mark for the BST device is still in the review phase. We had hoped that the renewal would come through before the end of 2015. However, the process has dragged out longer than expected. Meanwhile, the company entered into a distribution agreement in mid-2015 with Rubifarm S.A. (Argentina), and Chemipal (Israel) for the marketing and distribution of the BST device in their respective countries. Both distributors specialize in selling medical devices. As per the commercial terms of the agreement with both distributors, the devices will be rented out to hospitals and clinics at a small monthly rate to cover service and repairs, while the distributor will sell disposable electrodes on "treatment days" basis. The company is awaiting marketing approvals in both Argentina and Israel. Although management suspects that these regions have a sizeable wound care market, the rate of device adoption is rarely immediate and any new technology is prone to delays in uptake. The strategy chosen depends heavily on the market potential in ex-U.S. regions. Regulatory delays in EU, Argentina and Israel are adding uncertainty surrounding launch timelines for the BST device. If and when the approvals are granted, we assume the BST device would have a soft launch initially. Whether the sales from these regions results in a meaningful addition to EQUR's revenues in the long term remains to be seen.

In the U.S., EQUR has had pre-IDE meetings, is prepared to commence clinical trials and is maintaining sufficient cash balance to bear OpEx. Management is still expecting to complete trials and file the PMA before end of 2016. Should management be correct, they should be on track to launch their product in 2017. Having a CE Mark as well as FDA approval definitely expands the opportunity for the BST device in other global regions; a winning recipe that could steepen the revenue curve for the product in the out years. However, the company's efforts will take a while to bear fruit.

Valuation

We think the BST device is the primary value driver for EQUR. The successful development of the BST device is critical for EQUR as chronic wound management market offers opportunities for substantial revenues. In this regard, the clearance from FDA represents an important milestone for EQUR in achieving its long-term goal.

In January 2015 EQUR had laid out a systematic process to complete the application for U.S. regulatory clearance so that clinical trials employing their BST device could commence in 1H 2015. Management had met with representatives of the FDA to discuss their clinical development strategy. FDA had asked for additional information related to the BST device's technology and safety. Management then took part in the Pre-Submission (Q-sub) program, which allows the company to obtain feedback from the agency pertaining to the application prior to re-submission.

As per our previous update, we had anticipated that IDE approval would happen by the end of Q2 2015 and the multi-center clinical trials employing the BST device would begin in Q3 2015. Obviously those timelines were also missed. Management is currently preparing the documents to re-file the IDE, so they can initiate pivotal studies in the U.S. Assuming that the company re-files for approval before the end of 2015 and FDA provides their consent to commence the clinical trial within about 30 days of re-filing, it's possible that patient screening could start sometime in Q1 2016. Assuming those timelines are hit and everything goes to plan, the study and data analysis could be completed by Q3 2016. However, based on the regular delays to-date, there is reasonable risk that these revised forecasts could also be missed.

Unlike Europe's regulatory agency that approves devices based on safety alone, which results in shorter approval timelines, the FDA's approval process is a rigorous one and very time intensive as it only markets devices that are proven safe and effective. Although there is uncertainty regarding the trial results, (whether they turn out favorable), we do believe there is reasonable probability of success in these trials given the device has demonstrated strong proof of concept. More

importantly, positive data from the study would validate EQUR's technology. If the BST device's safety and efficacy can be repeated in these trials and U.S. studies do not continue to be hampered by delays , we expect the company to be in a position to file the PMA during 2H 2016, and the FDA approval could be granted sometime in 2017. For this reason, we view this investment currently as a binary play through the success of the pivotal trial.

The biggest factor that dictates revenue estimates besides market penetration that can potentially be achieved in the first year and beyond is the delays associated with obtaining regulatory approvals.

- The temporary delay in obtaining marketing clearance in the regions outside the U.S. has caused us to push out revenue expectations in these regions. Management anticipates commencing initial sale of their device in EU, Argentina and Israel as they already have distribution agreements in place.

- Further, delays in obtaining IDE approval to initiate pivotal trials will delay study results. Additionally, if FDA has multiple reviews and revises the trial size to prove efficacy in a larger set of population, then time to file PMA and time of device launch could further be delayed. If marketing is approved in the U.S., we project sales to begin sometime in 2017 and the next obvious step is to look at what the revenue numbers could be in the coming years. While an exact price for the product has not been declared yet, the company has stated that it will have the ability to price the BST device roughly in line with other similar treatments in the market.

We conservatively model steady growth in revenue as device launches and gains market share. We expect the company to gain operating leverage in the out years. As the market penetration increases over the years, we expect revenue to gain momentum and result in a positive EPS of $0.05 in 2020. Given the uncertainties discussed above, we have also revised our discount rate to 18%. We have updated our financial model and revised our outlook to reflect a meaningful downward revision to our price target from $2.50/share to $1.00/share.

We would like to remind investors not to be turned off by the revision to our valuation. The adjustments we have made to guidance are more to reflect the delays associated with progress and developmental goals in the business. Our financial estimates are subject to change based on the status of regulatory approvals as well as results of the clinical trial as they come through. We maintain our Buy rating on EQUR but have downwardly revised our price target based on the aforementioned regulatory delays.

BACKGROUND

E-QURE Corp. (Electric Quick Ulcer Remedy), a publicly traded company (OTCQB: EQUR) headquartered in New York, is a premier provider of innovative medical devices in the field of active advanced wound management. The key shareholders are the founders themselves, Ron Weissberg, Ohad Goren and Itsik BenYesha. The company has about 21 million shares outstanding and a market cap of about $25M.

Chronic wounds affect about 2% of the population in the U.S. which translates to about 6.5 million patients. Treatment of such non-healing wounds imposes an economic burden to the already increasing health care costs. The company's BST (Bioelectrical Stimulation Therapy) technology is an active advanced wound management device that is designed to produce an electrical stimulation, combining electrical noise and a pulse train to the wound site. This specific mode of electrical stimulation activates sensory nerves in humans via stochastic resonance and accelerates the body's mechanism of wound healing. The safety and efficacy of BST therapy was evaluated in controlled randomized studies at several centers internationally and the results were favorable. The BST device has been approved as a non-invasive electrical stimulation device for hospital, nursing home, and in-home care treatment of chronic wounds in Europe, Canada and Australia.

In July 2014, EQUR entered into an alliance with The Austen Bioinnovation Institute in Akron (ABIA) to spearhead their clinical trial program. Pivotal studies are required for obtaining regulatory approval from the U.S. Food and Drug Administration (FDA) which will enable EQUR to distribute the device in the U.S. The goal is to complete clinical trials and launch the product in 2017. The advanced wound care market has many big players with well-established innovative technologies enjoying a significant market share. Although EQUR faces strong barriers to entry, we believe that based on the lower cost of the device and ease of application as compared to the existing methodologies, the company can take some market share from the legacy technologies such as the Hyperbaric Oxygen Treatment (HBOT) and Negative Pressure Wound Treatment (NPWT, aka vacuum assisted closure devices or V.A.C.). We expect product launch in the U.S. to commence sometime in 2017 pending FDA approval and until then EQUR will need sufficient capital and concentrated efforts to reach targeted milestones.

INDICATION: Stage III and IV ULCERS

While stage I (painful skin surface) and stage II (tenderness and pain from an open wound area) ulcers can be treated with conventional treatments such as topical gels/ointments and bandages, stage III and IV ulcers require professional medical intervention, which often includes advanced wound care, as they have caused deep tissue injury.

Pressure Ulcer: A pressure ulcer, also known as decubitus ulcer or bed sore, is a localized injury to the skin and/or underlying tissue and often affects the elderly and stroke victims as well as paraplegics who suffer from impaired mobility. Continuous pressure at the skin surface compromises blood circulation and causes vascular occlusion resulting in ischemic and hypoxic tissues. Moisture (e.g., perspiration, incontinence) and/or friction cause local abrasion and breaks in the superficial layers of the skin thereby triggering ulceration.

Venous Stasis Ulcer: In immobile patients, venous valve dysfunction from trauma or venous thrombosis causes ineffective pumping of blood by the calf muscle. Chronic venous stasis causes pooling of blood in the venous circulatory system resulting in further capillary damage and activation of inflammatory processes. Activation of leukocytes, damage of endothelial cells, aggregation of platelets, and intracellular edema, and fibrin deposition in the interstitial space limits the diffusion of oxygen and nutrients to the surrounding tissue and contribute to venous ulcer development and impaired wound healing. Venous ulcers occur most commonly in the leg.

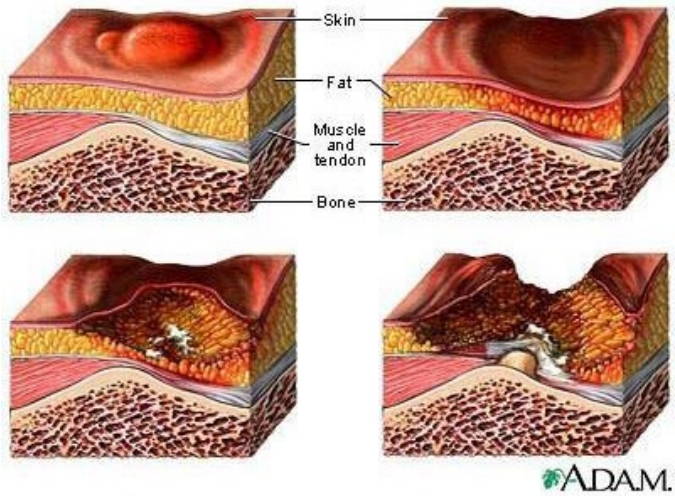
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Pressure and venous ulcers that remain unresponsive to treatment can cause considerable tissue loss and result in the exposure of subcutaneous fat along with the presence of some slough in stage 3 ulcers. Areas having significant adipose tissue can develop extremely deep pressure ulcers. Stage 4 ulcers have significant tissue loss resulting in exposure of bone, tendon or muscle.

Diabetic Foot Ulcer: A diabetic foot ulcer occurs on the bottom of the foot in diabetic patients. Nerve damage, vascular disease and elevated blood glucose levels can cause insensitivity in the foot, lead to poor blood circulation, increased pressure, and trauma resulting in subsequent erosion of underlying subcutaneous tissue.

PHYSIOLOGY OF WOUND HEALING

A wound results in the disruption of the skin surface, extending to the dermis, subcutaneous fat, fascia, muscle or even the bone. Normal wound healing results in the closure of the skin surface and the associated tissue structures return to normal anatomical structure, function and appearance within a reasonable period of time. The wound is termed chronic when the normal healing progression fails to proceed normally within the expected time to produce anatomic and functional integrity, and the wound persists for longer than 30 days.



(Source: ADAM)

Pathophysiological factors and micro-organisms compromise the otherwise highly regulated process of chronic wound healing. Local conditions favor bacterial growth rather than the tissue's defense mechanisms. Bacterial infection delays the healing at the site of injury[1]. Normal wound healing is a continuous, dynamic process that is comprised of four phases of hemostasis, inflammation, proliferation and remodeling. The proliferation and remodeling phases occur alternatively throughout the wound healing process. Interruption in this flow results in impaired healing or lead to non-healing chronic wounds.

Hemostasis: During the first step in the healing process blood vessels constrict to stop bleeding, form a blood clot and reduce exposure to bacteria.

Inflammatory phase: This is the second stage in wound healing and the body's early defense system against microbial invasion. The body responds to the wound by triggering the inflammatory response and promotes tissue regeneration.

Proliferation phase: This is also known as the active growth phase and is characterized by angiogenesis, collagen deposition, granulation tissue formation, wound contraction and epithelialization.

Maturation (Reconstruction) phase: The healing process involves remodeling and realignment of the collagen tissue to produce greater tensile strength.

The human biological cell is also an electrical component that operates on the electrochemical physiology principle of DC exchange of ions. Injury to the outermost layer or epithelial layer disrupts the body's naturally occurring electrical current therefore creating an electrical field termed as the "current of injury". Electrical stimulation is believed to restart

[1] Bowler PG, (2002), Wound pathophysiology, infection and therapeutic options. Ann Med;34(6):419-27

or accelerate wound healing by imitating the natural electrical current that occurs at the site of injury. (Source: E-Qure.com)

CURRENT TREATMENT IN ADVANCED WOUND CARE

The primary objective in wound management is to restore the skin tissue to its normal physiologic state and relieve pain. This is achieved by clearing the wound site of devitalized tissue, foreign bodies, bacterial load, inflammation, and by maintaining adequate tissue perfusion. Therapeutic strategies that target chronic inflammatory processes are critical to wound closure as poor healing in chronic wounds is associated with uncontrolled inflammation and abnormal pathophysiological conditions. Although surgical debridement has been considered the most rapid and effective technique for removing devitalized tissue, conventional therapies include topical cleaning agents, bandages, antibiotics (systemic or local), compression therapies, systemic medications, and/or nutritional supplements[2]. The conventional treatment for chronic wounds is termed standard of care. These products have the benefit of a long shelf life and are relatively uncomplicated to administer. When some wounds show little or no improvement even after 30 consecutive days of standard treatment advanced wound therapies are often prescribed.

Active wound care products comprise of growth factors, skin substitutes, wound matrixes, and manufactured human skin, in addition to providing moist environment at the wound site, contribute to tissue repair either by delivering bioactive compounds or by promoting the body's own mechanisms to heal. Alternative therapies for chronic wound care include the use of negative pressure, hyperbaric oxygen, electrical stimulation TENS devices, ultrasound, and ultraviolet light. The following section describes the alternative therapies in detail. It is important to note that the efficacy of the alternate therapies including BST is benchmarked against standard of care.

ELECTRICAL STIMULATION (ES): Electrical stimulation is known to enhance the body's natural healing mechanisms. Chronic wounds that are most frequently addressed using electrical stimulation for wound healing are: pressure, venous, arterial and diabetic ulcers or any hard to heal wounds. Currently there is no ES treatment cleared for marketing by FDA. Few ES devices that are marketed in the rest of the world have an electrode located inside the wound. Electrical stimulation was shown to accelerate the process of non-healing ulcers and superior to standard care of treatment [3,4,5,6].

NEGATIVE PRESSURE WOUND THERAPY (NPWT): This therapy involves creating a tightly sealed dressing around a wound and using a suction pump to apply negative pressure evenly across the wound surface in a continuous or intermittent manner. This process is proposed to enhance wound healing by increasing granulation tissue and local perfusion, reducing tissue edema, decreasing bacterial load, and stimulating cellular proliferation via induction of mechanical stress. The device is attached to the patient during the entire course of the therapy. Currently, negative pressure therapy is the most widely used treatment for patients with diabetic foot ulcers[7].

HYPERBARIC OXYGEN (HBOT): Specialized compression chambers capable of delivering increased concentrations of oxygen (usually 100% oxygen) under elevated atmospheric pressure are applied at the wound site. Many key aspects of ulcer healing are oxygen dependent and raising arterial oxygen tension and the blood-oxygen level delivered to a chronic ulcer is thought to supply a missing nutrient, promote the oxygen dependent steps in ulcer healing, up-regulate local growth factors, and down-regulate inhibitory cytokines. Even though it has been proven through clinical studies that HBOT significantly reduced the risk of major amputation and possibly improved the chance of healing in patients with diabetic foot ulcers, the system requires an expensive technology (a full course of treatment in the U.S. typically costs $50,000 to $200,000 depending on the type of insurance) and is time-consuming (an average of 60 total hours inside the chamber)[5].

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[2] Bowler PG, (2002), Wound pathophysiology, infection and therapeutic options. Ann Med;34(6):419-27

[3] Thakral, G., LaFontaine, J., Najafi, B., Talal, T. K., Kim, P., & Lavery, L. A. (2013), Electrical stimulation to accelerate wound healing. Diabetic foot & ankle, 4.

[4] Houghton, P. E., Campbell, K. E., Fraser, C. H., Harris, C., Keast, D. H., Potter, P. J.,and Woodbury, M. G. (2010), Electrical stimulation therapy increases rate of healing of pressure ulcers in community-dwelling people with spinal cord injury. Archives of physical medicine and rehabilitation, 91(5), 669-678.

[5] R. Rivkah Isseroff and Sara E. Dahle. (2012), Advances in Wound Care. 1(6): 238-243.

[6] Barnes, R., Shahin, Y., Gohil, R., and Chetter, I. (2014). Electrical stimulation vs. standard care for chronic ulcer healing: a systematic review and meta□analysis of randomised controlled trials. European journal of clinical investigation, 44(4), 429-440.

[7] Greer N, Foman N, Dorrian J, et al. (2012), Advanced Wound Care Therapies for Non-Healing Diabetic, Venous, and Arterial Ulcers: A Systematic Review. Washington (DC): Department of Veterans Affairs;

SKIN SUBSTITUTE: Bioengineered skin substitutes have emerged as a new and alternative therapeutic option. The skin substitutes are intended to stimulate the injured skin to regenerate healthy and functional tissue thereby restoring the physiological and mechanical functioning of a normal skin.

PRODUCT

E-QURE's BST device



(Source: E-Qure.com)

E-QURE's BST device offers a specific type of electrical stimulation, based on the principle of stochastic resonance. The BST technology is comprised of a single channel electrical stimulator, composed of a main unit with the circuits and the user interface, and two electrodes which are applied on the healthy skin surrounding the wound. Since this device is designed to work with alternate current (AC) rather than direct current (DC), the placement of the electrodes is not on the surface of the wound but at about 3 to 5 cm from the border of the wound touching the healthy skin only. The electrical current impulses "The current of injury" measured during the natural healing process of healing wounds is absent or weak when the ulcers becomes chronic. A unique patented waveform signal that mimics the naturally occurring pulses of healing wounds (The Current of Injury) is transmitted to the skin surface around the wound site. The stimulation mode is a low-frequency (2Hz) periodic pulse sequence composed of two integrated waveforms, a rectangular pulse train (periodic) and a stochastic (random) signal. The integrated signals are filtered using a low pass filter at 2500 Hz. This combination of stochastic signal with the rectangular pulses enables both the stimulation of sensory nerves and direct stimulation of the ulcer tissues. The increased electrical activity has been shown to accelerate granulation tissue, epithelial and vascular growth and cell proliferation on the periphery of the wounds. The nervous system interprets the transmitted pulse from the damaged area and initiates healing activity to the wound tissues. The healing of the chronic wound is visible as new granulation tissue and skin are generated within the initial days / weeks of treatment. The recommended treatment with the BST device is for it to be performed thrice daily for 30 minutes. The BST device is designed for both hospital-oriented treatment as well as in-home care and is user friendly, very easy to operate.

Clinical Trials using the BST Technology: The BST technology is non-invasive, painless and efficient. Its effectiveness in curing chronic wounds has been demonstrated in several clinical studies including a multi-center, double blind, and controlled clinical trial against standard wound therapies comprising of hydrocolloids, hydrogels foams, alginate and other dressings. It effectively accelerated wound closure and reduced wound size of non-healing pressure wounds of stage II, III and IV. The results were shown to be statistically significant. Patients with dressings having trace of metals (such as silver) or metal based ointments were excluded from clinical studies as the metal particles posed a threat of unnecessary interaction with the electrical field generated by the BST device.

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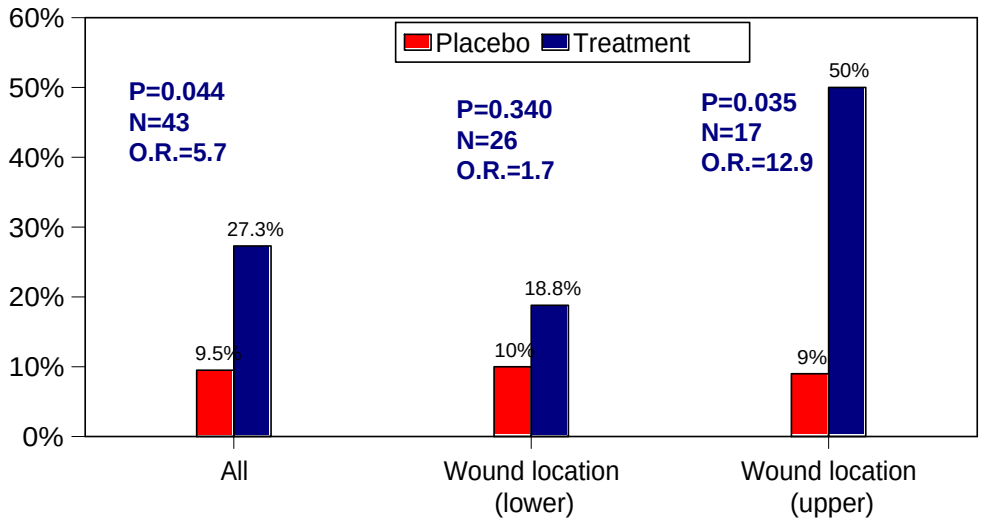


(Source: E-Qure.com)

Randomized Controlled study with BST device in Israel:
A multi-center, randomized, double-blinded, placebo controlled study was conducted in 2002-03 using the BST technology in a patient population of 63 (28 patients in the placebo group and 35 patients in the treatment group) at 12 medical centers and hospitals in Israel. The mean age of patients enrolled in the study was 72±19 years. Hospitalized or institutionalized patients with chronic non-healing stage III pressure ulcers (more than 30 days of an open wound) whose ulcer duration was less than 24 months were considered for the study. The location of the ulcer other than on the head, upper back or chest were chosen for treatment and had dimensions of 1 to 50 cm2. The placebo group as well as the patient group underwent surgical debridement as required, followed by a hydrocolloid or collagen dressing and pressure relief. All patients were treated for 8 weeks. Twenty minute treatment sessions were performed twice per day during the 56 days of the study. There were ten assessment days (1, 7, 14, 21, 30, 45, 57, 90, 120 and 147) during which the ulcer was assessed. The efficacy evaluation was based on the results observed during and at the end of the treatment, i.e. – through day 57 with a follow-up period of 90 days following the last treatment. The efficacy of the treatment was evaluated with complete wound closure as the primary endpoint and any progression towards closure as the secondary endpoint. A total of 25 patients terminated participation due to medical complications and other reasons.

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Figure 1: Percentage of patients with complete ulcer closure during the study period, by treatment group & Wound location



* Adjusted for Area (Baseline)

(Source: E-Qure.com)

The mean healing rate (complete ulcer closure) in the BST group was 27.3%, which was three times that of the placebo control group (9.5%). 50% of patients who had ulcers above the knee in the BST group achieved complete wound closure compared to 9% in the control group. A positive trend in complete closure was indicated for ulcers below the knee (18% for BST group and 10% in the placebo group), although this effect did not reach statistical significance. The average decrease in wound area from day 1 to day 45 was found to be 45% in the treatment group and 10% in the placebo group and was not statistically significant. The mean progression of the wound edges by contraction of the wound and formation of new skin from day 1 to day 45 was 4.6mm in the active group and 2.3mm in the placebo group and was statistically significant (P = 0.033). The efficacy and significance of epithelial growth and area reduction, were both higher on day 45 compared to the intended follow-up on day 57. The BST treatment was found to be safe and no adverse effects were reported [8].

The graph above shows treatment using the BST technology was twice as effective as the placebo for all wound sizes. For leg ulcers, BST's effectiveness was 2 times greater than the placebo, and for the treatment of upper body ulcers, BST was five times more effective.

The trial results showed that the average size of the ulcer that closed using the BST treatment was substantially bigger than the average size of the ulcer that closed in the placebo group. In order to perform statistical analysis on the trial data that comprised of patients having variable wound sizes, wound geometry was considered as a factor influencing the closing of the wound. A parameter termed "critical path" was defined as the distance traversed by the epithelia for complete closure from the periphery to the center of the wound. This model took into account the area and shape of the ulcer as both have an impact on the distance that should be covered by epithelia in order for the wound to close completely. The results that were obtained following this analysis revealed that for a specific ulcer to close, the odds of full closure in the treatment group was 5.7 times that of the odds of closure in the placebo group (P=0.04). Although achieving 100% wound closure is the goal of wound healing, being able to achieve a reduction in the wound area in the treatment group (twice the placebo group) is quite significant to the patient since reduction in wound area implies that the wound is showing signs of healing albeit at a slower than normal pace. This randomized, double-blinded, placebo-controlled, multicenter trial demonstrated that application of the BST therapy, three times daily for 60 days is safe and stimulates rapid healing of chronic, non-healing stage III pressure ulcers in geriatric patients. This is the first well-controlled trial to demonstrate a statistically significant difference in both the number of patients healed and the healing rates in patients with chronic wounds treated with the BST technology.

[8] Ohry A, Goren O. The effects of BST electrostimulation on healing of pressure ulcers: results of a multi-center, double blind, randomized, placebo controlled study. *EWMA J* 2007 oral abstract no. 66.

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Study conducted at the University of Turin, Italy



A



B



C

Figure A: Pre-treatment wound dimension 3cm×2 cm. Figure B: Bioelectrical stimulation therapy (BST) device applied close to the wound area. Figure C: Wound dimension 2•5cm×1•5 cm after 30 days of treatment [9].

[9] Fraccalvieri, M., Salomone, M., Zingarelli, E. M., Rivarossa, F., & Bruschi, S. (2014). Electrical stimulation for difficult wounds: Only an alternative procedure?. *International wound journal*.



D



E

Figure D: Wound dimension 1•5cm×1•5 cm after 50 days of treatment. Figure E: After One hundred and twenty days of treatment

A study was conducted in a 22-month period between July 2008 and May 2010 using the BST device at the University of Turin, Italy. The criteria for inclusion in the study were patients with chronic wounds, ranging from 0.8 to 12cm^2 in size, not responding to surgery, traditional and advanced wound care therapies for at least 3 months. The average age of the patients was 69 years. The patients were treated with the BST device for 30 minutes, thrice every day. The patients were taught to use the device so that the treatment could be provided at home without external help. All patients had a weekly follow-up. The standard wound care with medications was continued throughout the study period.

The first group was evaluated for the wound healing and composed of patients with wounds that were not responding to conventional therapies for at least 3 months. The second group was evaluated for the effect of electric therapy on pain control and composed of patients with severe pain with Visual Number Scale (VNS)>8, requiring heavy use of painkillers.

Results:

In the wound healing group, 71% of patients showed progress from chronic wounds to acute wounds in an average time of 34 days. At the end of the follow-up period, 87% of the wounds were completely closed in an average time of 97 days (range 10–150 days), while 13% were still in reepithelialisation.

45%of patients reported complete disappearance of pain, 36% reported a reduction in pain after 7 days of treatment 19% reported a reduction of pain from 9.5 to 2.5 after 7 days and stopped morphine-like painkillers after 2 weeks of treatment.

Study conducted at the Difficult Wounds Unit, San Luca Hospital, Turin, Italy
Another study that proved the BST device's effectiveness on recalcitrant ulcers of various etiologies was conducted at San Luca Hospital, Turin, Italy in 2009-2010. The study was an open-label, observational, case series and recruited patients with chronic, non-healing wounds, who had previously undergone standardized as well as advanced treatments such as debridement, tissue engineering or topical negative pressure, and whose wounds had neither reduced in size nor demonstrated signs of healing such as epithelialization, granulation or scar formation. The study group comprised nine patients with a total of 11 non-healing ulcers. The wound was a stage IV pressure ulcer and had been at least 1.5 years and up to 20 years old. The patients were treated with BST device for 30 minutes, three times a day for a total of 60 days. The wounds were followed up on day 0 as well as on days 15, 30, 45, 60 and 90. The follow-up observation continued for 30 more days for recurrence and/or progression of wound healing. Standard wound care (dressings), including pressure relief, debridement and/or antibiotics, and compression therapy were administered when necessary.

Results: The study demonstrated that applying BST Therapy to hard-to-heal pressure ulcers, post-actinic, ischemic and postsurgical ulcers, for 60 consecutive days reduced the wound surface area to less than half its original size in eight out of the nine subjects. The mean area of the wounds reduced in size by 82.5% and 45% of those exhibited closure within the 60 days of commencing the treatment. In three of these five ulcers, complete closure was observed between 45 to 60 days of treatment. The remaining two ulcers healed at 90 days (30 days after the end of treatment)[10]. From the table below it is evident that the time to heal recalcitrant ulcers was 90 days or less regardless of the duration the wound remained chronic and unhealed (130 months in patient 4, 240 months in patient 7, about 45 days in patients 1 and 9).

Patient No.	Stage (start)	Stage (End)	Wound Surface Area (cm^2) (start)	Wound Surface Area (cm^2) (End)	Wound Closure (%)	Wound duration (months)	Wound Appearance (End)	Time Elapsed
1	IV	Heal	4.4	0	100	45	Scar	90
2a	IV	Heal	4.1	0	100	27	Scar	60
2b	IV	Heal	2.1	0	100	27	Scar	54
3a	IV	II	3.7	2.5	32	19	Epitelization	90
3b	IV	II	4.4	0.6	86	23	Epitelization	90
4-Pre CVA	*IV*	*IV*	*14.7*	*12.6*	*14*	130	*Granulating*	*15-Stopped Due to CVA*
4-Post CVA	IV	II	16.4	0	100	131	Scar	90
5	IV	IV	3.5	1,7	51	38	Bone exposure	90
6	*III*	*III*	*0.9*	*1.7*	*Paraplegic*	28	*Granulating*	*60*
7	IV	IV	5.7	1,4	75	240	Granulating	90
8	*II*	*II*	*8.8*	*8.9*	*Stopped The study*	30	*Withdrawn Due to Irritation*	*15-stoped Due to Irritation*
9	III	Heal	3.7	0	100	46	Scar	90
10	IV	Heal	0.4	0	100	18	Scar	45

(Source: E-Qure.com)

Although this study was done with a small sample size (eight subjects with 10 wounds), noteworthy is that the wounds had been present for many months or years and had not responded to standard or advanced care treatments. The capability of the BST device to stimulate healing of hard-to-heal ulcers (wounds that had not responded to standard or advanced tissue engineering treatments) was particularly evident from 55.5% of the patients who achieved complete wound closure. One of the participants with an 18-month-old post-surgical lesion achieved complete closure after 45 days of treatment and the wound stayed healed. Another patient with grade IV pressure ulcers (with durations of 19 and 23 months) showed reduction in the surface areas by 32% and 86% respectively.

The potential effect of the BST device is compelling as the therapy has shown to facilitate complete wound closure on patients with grade IV pressure ulcers that have not healed in many years.

[10] Ricci, E., and Afaragan, M. (2010). The effect of stochastic electrical noise on hard-to-heal wounds. wounds, 21, 23.





A **B**

Figure A and B: Photographs showing the progression towards healing Before treatment (A) and After 60 days of treatment with BST device (B). Figures 4 and 5 illustrate the reduction in wound area recorded for individual patients during the 90 day treatment period.

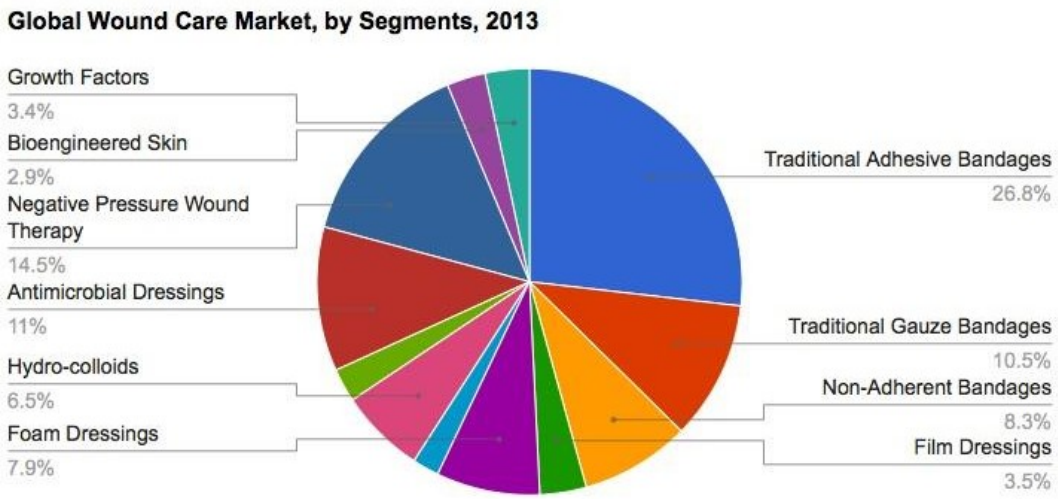
THE UNMET NEED

It has been estimated that the annual cost for the treatment of chronic, non-healing wounds exceeds $50 billion in the U.S. The economic burden is growing rapidly due to increasing health care costs, an aging population and a sharp rise in the incidence of diabetes and obesity, which leads to an increase in acute and chronic conditions such as diabetic foot ulcers, venous ulcers, and pressure ulcers[11].

The global market for products in wound management (traditional and advanced, source: MedMarket) stood at approximately $12.5B in 2012, and is expected to reach $22B in 2021. The global market for advanced wound care (moist dressings and physical therapies) had an estimated value of US$6.2 billion in 2013. North America accounts for the largest share of the advanced wound care market. Despite the competition in the wound care market and the rising demand by the government to reduce spending on healthcare, the future growth is expected to be driven by favorable demographic factors[12]. Growth is especially expected in Europe, Asia and other areas outside of the U.S. where the penetration of advanced care, and especially active care, is a fraction of the penetration in America.

[11] Sen, C. K., Gordillo, G. M., Roy, S., Kirsner, R., Lambert, L., Hunt, T. K., Longaker, M. T. (2009). Human Skin Wounds: A Major and Snowballing Threat to Public Health and the Economy. Wound Repair and Regeneration□: Official Publication of the Wound Healing Society [and] the European Tissue Repair Society, 17(6), 763–771.

[12] Source: ReportsnReports - The Global Market for Advanced Wound Care Products 2014



(Source: MedMarket Diligence, 2013)

It is estimated that 45% of 85 year olds are expected to develop chronic wounds in the next decade. The U.S. population continues to age. Circulatory diseases and diseases rendering the aged non-ambulatory are associated with non-healing wounds and generally affect Americans that are older than 65 years of age. Adding to this pool is the prevalence of obesity that is sharply rising in the U.S. Obesity-related changes to skin structure and function impedes wound healing.

An estimated 2.5 million patients are treated annually for pressure ulcers in the U.S. acute care facilities. The total annual cost to treat of pressure ulcers is estimated to be more than $11 billion per year[13]. According to the Centers for Medicaid and Medicare Services (CMS), the average length of stay in the hospital for treatment of a pressure ulcer is 13 days and the associated cost for hospital stay related to pressure ulcers is more than $40,000. It is estimated that about 30% of hospitalized patients in long-term care facilities experience a pressure ulcer due to commonly associated co-morbid conditions such as spinal cord injury, stroke, or other acute illness. The failure to prevent pressure ulcers in long-term care settings has resulted in increasing litigation costs to healthcare facilities. Additionally, the rising threat from diabetes resulting in diabetic foot ulcers and other foot complications are responsible for 20% of the 3 million hospitalizations every year. Many of these patients eventually undergo leg/foot amputations as a result of infection caused by unhealed foot ulcers.

As efficient advanced wound care and closure products with high degree of effectiveness in managing chronic wounds with quicker healing times are becoming increasingly prevalent, traditional wound care and closure products are being substituted with these. The need to reduce healthcare costs, and the rising demand for products that enhance therapeutic outcomes are the primary drivers for advanced wound care & closure products. The devices segment of the active advanced wound care therapy comprises of negative pressure wound therapy devices, pressure relief devices, electrical stimulation devices, oxygen and hyperbaric oxygen equipment, electromagnetic therapy devices, and ultrasound devices. The NPWT devices market is witnessed highest growth thus far due to the favorable reimbursement scenario for such devices prevailing in the market. Although the mature markets (U.S. and Europe) are saturated with major industry players, the emerging economies comprising Brazil, Russia, India, and China represent the next big opportunity for the leading players. Therefore, we believe growth in these markets will be driven by low cost and easy to use models such as EQUR's BST device[14].

[13] Baharestani M, de Leon J, Mendez-Eastman S, et al. Consensus Statement: A Practical Guide for Managing Pressure Ulcers with Negative Pressure Wound Therapy Utilizing Vacuum-Assisted Closure.- Understanding the Treatment Algorithm. Advances in Skin and Wound Care. 2008 Jan;21(Suppl1):1-20.

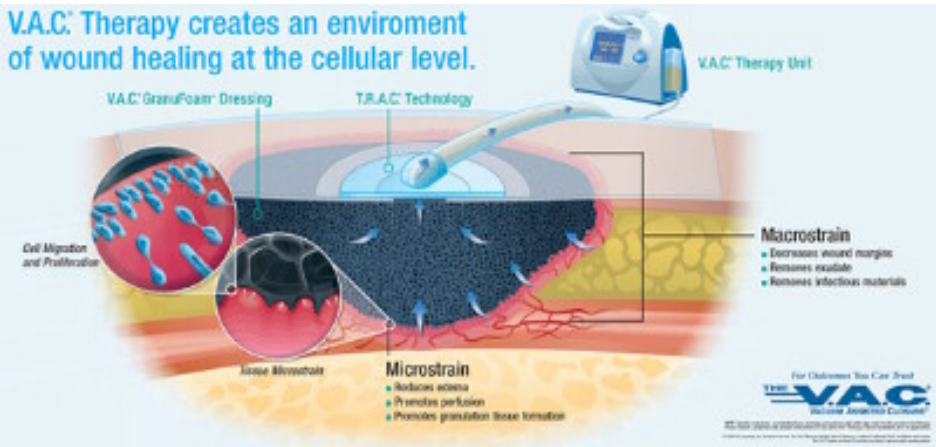
[14] Source: Woundcare market by type- Global forecast upto 2019, By MarketsandMarkets

COMPETITION

Smith and Nephew, Kinetic Concepts (KCI), 3M, Covidien, and ConvaTec are some of the major players in the global advanced wound care and closure market. The advanced wound management market is focused on the treatment of chronic wounds of the older population and other hard-to-heal wounds such as burns and certain surgical wounds and is therefore also expected to benefit from demographic trends. Management estimates that Smith & Nephew had an 18% share of the advanced wound management segment as at the end of 2011. Worldwide competitors in advanced wound management in 2013 include Coloplast (4%), Convatec (8%), Mölnlycke (12%), Smith and Nephew (20%) and Kinetic Concepts (19%), others (37%), who are active exclusively in the NPWT market (Smith and Nephew annual report 2013).

KCI VAC system: In 1996, KCI introduced an innovative approach to the treatment of serious, complex wounds through the use of sub-atmospheric or negative pressure. KCI's proprietary Vacuum Assisted Closure®, or V.A.C.® Therapy System has revolutionized the advanced wound care market and remains the most sought after treatment for managing complex, hard-to-heal wounds. The V.A.C. therapy systems address approximately 3 million patients worldwide. V.A.C. therapy utilizes a Granufoam dressing that is conformed to the wound bed. When sealed and placed under negative (vacuum) pressure, the system promotes wound healing process, reduces edema, prepares the wound bed for closure, promotes the formation of granulation tissue and removes infectious materials. The V.A.C. therapy has been the subject of more than 850 peer-reviewed articles.

About 55% of KCI's NPWT business is done in in-home care, 30% in hospitals, and 15% in assisted living facilities. Advanced wound care sales rose after KCI obtained Medicare reimbursement for the V.A.C. therapy for home-use in addition to hospital care. Although the V.A.C. therapy system constitutes 80% of the KCI's sales with a growth rate of 5%, this has recently shown signs of slowing due to pricing and competitive pressures (primarily from Smith & Nephew). Despite this, V.A.C. therapy pumps have been able to maintain approximately 83% market share with their strong product line, continuous technological enhancements and efforts in developing physician confidence.



(Source: KCI.com)

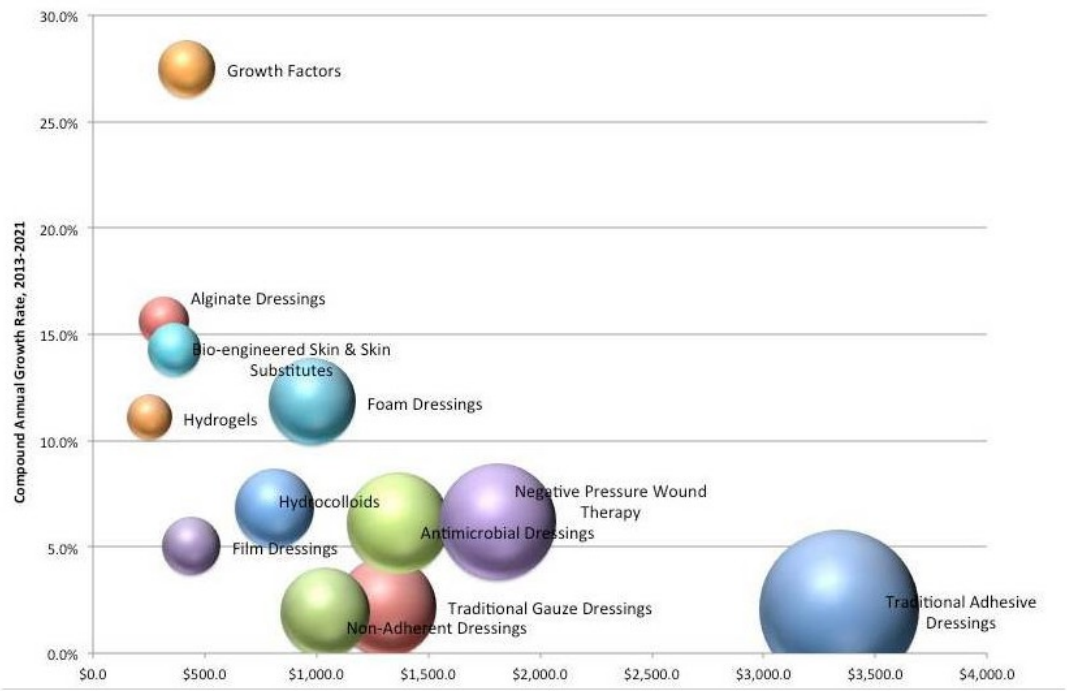
Smith & Nephew's NPWT devices: Smith & Nephew is the second largest shareholder in this market. The company's innovative products include dressings with an indicator to intimate the care specialist about the need to change the dressing, thereby reducing the frequency of hospital visits (increase interval between dressing changes), reduce wastage and save resources (nurse's time). The company also produces a line of gauzes that use NPWT to stimulate blood vessel growth beneath the wound. The company is currently conducting studies that employ living cells as a spray-on therapy to stimulate healing using the body's own cellular mechanisms.

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(Source: smith-nephew.com)

In 2011, the company introduced PICO, the first single-use NPWT system. The innovative design offers the clinical benefits of NPWT with a simplified product, thus allowing for an entirely disposable and cost effective system. The design has allowed increased access to therapy, reduced service and support costs, and significantly improved cost effectiveness compared to the traditional NPWT therapy. The PICO pump is connected to a dressing which conforms to the body contour. It can be easily applied and removed, thereby minimizing skin trauma. It also manages the fluid away from the wound through a unique combination of absorbency and evaporation techniques. The PICO pump provides therapy for up to 7 days. In a study conducted in South Africa in 2013 to study the functionality and dressing performance of the PICO system, revealed that 55% of wounds closed by the end of the 14-day study and 40% of wounds progressed towards closure[15].



(Source: E-Qure.com)

[15] Hudson, D. A., Adams, K. G., Huyssteen, A. V., Martin, R., & Huddleston, E. M. (2013). Simplified negative pressure wound therapy: clinical evaluation of an ultraportable, no□canister system. International wound journal.

E-QURE's BST DEVICE VS. COMPETITORS

New therapies that aim to promote healing in pressure ulcers and accelerate healing time are slow acting and resource intensive. The clinical trials using the above mentioned formidable competitors have been performed using standard of care as the control.

Clinical Trial Results: Although the studies have been conducted to prove efficacy, there are considerable differences among these trials including duration of study, location and severity of wounds, wound size, patient comorbid conditions, patient compliance with the treatment protocol, and the studies' endpoints. In spite of the small study size and based on the available research studies we found that the BST technology has demonstrated 45% wound closure, more than 75% reduction in wound size and 45% complete disappearance of pain after 60 days of administering the treatment in 30 minute sessions for 3 times per day.

A clinical, prospective, randomized, controlled trial study was designed in the Netherlands from 2002-2004 to study the treatment and cost effectiveness of KCI's V.A.C. therapy. After applying the negative pressure continuously and having changed the dressing 3 times per week, the results indicated that the skin surface reached the primary endpoint (tissue granulation in this case) in 16 days after which the patients required graft to seal the wound. Despite the significant differences shown using V.A.C. therapy over standard wound dressings for patients with cardiovascular disease and/or diabetes, a very important disadvantage of V.A.C. technique is its limitation of use in patients who have low tolerance to pain that may arise during treatment with NPWT and in patients who are allergic to the adhesive used to seal the foam dressing[16]. Trial patients encountered pain during dressing changes and the bacterial load increased. Although the costs associated were significantly higher when using the V.A.C. therapy, the overall cost was lower due to faster healing times. The learning curve for the V.A.C. therapy is about two demonstrations without which erosion of wound and tissues adjacent to wound surface may result causing added discomfort to patient.

The clinical results using NPWT provide evidence that the method is of benefit to certain types of wounds. It yields faster healing times and a higher percentage of healed wounds in post-surgical patients (PICO) and in patients with diabetes related ulcers (KCI's V.A.C., HBOT). Although more solid conclusions regarding improvements in clinical outcomes can be obtained from direct comparisons with other advance wound care therapies, it is important to note that the BST technology can perform safely and effectively in a clinical setting from the previously mentioned clinical trial results conducted using standard of care as the control.

Technology: The BST device uses a patented and proprietary electrical stimulation technology in the treatment of hard-to-cure wounds and ulcers, particularly in stages III / IV including pressure ulcers, venous ulcers and diabetic ulcers. The clinical application of the stochastic resonance enables the ease of use, non-invasively and painlessly for wounds that have remained unresponsive to other therapies for an extended period of time. The technology can be beneficial when used as an adjunctive therapy to treat chronic wounds.

Ease of use: Even though NPWT is the most sought after methodology, it is invasive as the negative pressure is applied at the wound site, making it uncomfortable for the patient. With NPWT, the patient is being connected to a pump 24 hours per day. From the patient's perspective, this can limit mobility, particularly if the wound is on a lower limb. There are portable units which can operate on battery power for up to 40 hours, but they still make bathing and normal daily activities more cumbersome. The advantages of the negative pressure dressing are quickly lost if the vacuum is turned off for any significant length of time. The BST device can be powered at an electrical outlet and does not impair the patient's mobility as the therapy needs to be administered at the wound site for only 30 minutes, 3 times per day.

Cost: The growth of advanced wound care devices are currently being hampered by pricing pressure. The mean cost of NPWT treatment for 12 weeks per patient is about $12,000. In order to compete with existing treatments on the cost front, E-QURE projects that their procedure would amount to about $3,000 for 60 days of treatment.

As per the Agency for Healthcare Research and Quality (AHRQ), pressure ulcers cost $9-$12 billion per year in the U.S. A significant complication of hospitalized patients is the occurrence of pressure ulcers that amount to high

[16] Braakenburg A, Obdeijn MC, Feitz R, van Rooij IA, van Griethuysen AJ, Klinkenbijl JH , 2006, The Clinical Efficacy and Cost Effectiveness of the Vacuum-Assisted Closure Technique in the Management of Acute and Chronic Wounds: A Randomized Controlled Trial, Plastic and Reconstructive Surgery 118(2):390-400.

treatment costs ranging from $2,000 to $150,000 per pressure ulcer. Medicare estimated that each pressure ulcer added an additional $43,000 in costs to a patient's stay in a hospital in the year 2007. Further, the human cost of a non-healing wound may be much more severe as compared to the financial cost surrounding treatment. The BST therapy may help reduce expenses related to wound care through a decrease in hospital stays and/or a decrease in attendant's time if treatment is administered at a clinical site. In addition, patients can be transferred quickly to less expensive care settings or even home, as clinical data has shown that healing times are faster with the BST treatment as compared to standard of care.

The BST device is non-invasive and easy to use. This implies fewer disturbances to the wound, decreased discomfort for patients and a reduced risk of wound infection. Since the therapy is easy to administer it causes less pain, and requires fewer dressing changes as the electrodes are not placed directly on the wound, and the use might reduce analgesic requirements. The clinician/therapist costs could be significantly lower as compared to competing therapies such as NPWT or HBOT. By supporting wound healing, use of such innovative devices may decrease hospital visits and also could help reduce the cost of wound management. The clinical benefits of this therapy in chronic wound healing reflect the key features of the device which have been discussed in the prior sections. As the studies have demonstrated, this device could be used to manage patients at home or in hospital care settings, and offer practical and clinical benefits over many other approaches to advanced wound care and could significantly help reduce the cost of chronic wound management.

Trips to the healthcare clinics: An inconvenience associated with other advanced wound care treatments is that dressing changes need to be done in the wound care clinics on the scheduled date instead of at home where it may work better for the patient. Additionally, the need for skilled nursing care is an absolute must to change the dressings. BST's stand-alone device is portable and equipped with mechanisms to insure proper connectivity and has a pre-programmed timer for halting treatment when completed. Therefore, this device can be used in hospitals as well as in in-home care facilities and eliminates the need for trained personnel to administer the therapy.

Global reach: BST has been approved as an electrical therapy for treatment of chronic wounds in the European Union, Canada, Brazil and Israel. We think that the BST technology can compete on price as well as in patient compliance. This provides a convincing thesis that the instrument can be a competitor in the advanced wound care management space.

REGULATORY APPROVAL

The FDA has not approved any electrical stimulation or electromagnetic device specifically for the treatment of chronic wounds. In November 2014 the FDA provided guidance to E-QURE that they would need to follow the Premarket Approval (PMA) regulatory pathway for the BST device in the treatment of non-healing ulcers. This application requires sufficient valid scientific evidence demonstrating the safety and efficacy of the BST device. The FDA committee typically takes about six to twelve months to arrive at a decision. ABIA has been in the business of providing expertise in product development and strategies for obtaining clinical approval of medical products. To accelerate the PMA application process and improve chances of approval, management has signed an alliance with ABIA's Product Innovation and Commercialization Division to spearhead its pre-market clinical trial program.

As per discussions with the FDA, E-QURE's pivotal trial is expected to include a total of 72 patients (36 in control (BST Sham) group and 36 in the BST therapy group) with wound area of at least $3cm^2$ and not more than $8cm^2$ across at least 6 centers in the U.S. to prove the safety and efficacy of the BST technology. In order to improve the robustness of the study, management hopes to recruit 80 patients in order to account for a potential 10% drop-out rate. The trial is designed to be a multi-center, double blinded, placebo controlled and randomized. Treatment is performed with BST device plus standard of care in one group and with the sham device plus standard of care for the control group. Patients from both arms will be treated with the BST device (sham or therapy) will receive 30-minute electrode application, three times per day for 56 days with weekly follow-up exams. Standard of care treatment will be continued alongside for the 56 days. The sham device is designed to not produce any current so that the treatment effect is not felt by most patients. The sham devices and the treatment devices can be identified only if the serial numbers (managed by the CRO) are made available.

The trial duration is set for 8 weeks (approximate duration for an $8cm^2$ wound that could potentially obtain 100% closure). The primary efficacy endpoint is complete wound closure of the treatment group compared to the control group. Secondary endpoints include percent of wound closure in 4 and 8 weeks, average percentage of reduction in wound area, linear progression of the wound edge measured weekly, time to complete wound closure and the percentage of patients achieving complete wound closure. Since wound closure rate is an important criterion for evaluating pressure ulcer treatment, the closure should take into account the ulcer's original size, since the probability of closing a small ulcer is higher than that of a large ulcer (this is an important criteria for determining the BST treatment's effectiveness). The multi-center clinical trials employing the BST device are scheduled to begin in Q3 2015 and are expected to be concluded in 15 months, costing about $800,000.

Currently EQUR is in the process of refiling an investigational device exemption (IDE) which allows the BST device to be used in the clinical studies in order to collect safety and effectiveness data. The results of the multi-center clinical trials are expected before the end of 2016. Additional regulatory challenges might arise to prove the meaningful use of their device. EQUR may have to demonstrate the improved quality and patient outcomes with measurably lower total cost of care while using their device. However, this would broaden the scope of the clinical data and lengthen the time required for FDA approval. If all plans are executed as scheduled, the process to obtain a decision on the approval might take six to twelve months, which we expect sometime during 2017. After receiving FDA approval, we expect EQUR to launch their BST device in the U.S. before the end of 2017.

REIMBURSEMENT

The Centers for Medical and Medicaid Services (CMS) considers the use of off-label electrical stimulation for the treatment of wounds as adjunctive therapies, that are administered when standard wound therapy has been tried for at least 30 days and there are no measurable signs of improved healing. The reimbursement is only covered for chronic Stage III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers. Additionally, electrical stimulation is covered only when performed by a physician, or physical therapist. Wounds must be evaluated monthly by the treating physician and must show measurable signs of improved healing such as decrease in wound size, decrease in amount of exudates, and decrease in amount of necrotic tissue for the treatment to be considered reimbursable.

If the BST device gets FDA approval, then procedures at hospitals, nursing homes and geriatric institutes using the device may be assigned a reimbursement code. Healthcare Common Procedure Coding System (HCPCS) code E0769 is currently applicable for reimbursement towards procedures performed using electrical stimulation devices for wound care. If EQUR were able to obtain this same code for reimbursement towards procedures done using their device, the reimbursement amount to the patient is roughly $2,000 calculated using an average treatment time of 60 days and a reimbursement of $40 per day. This reimbursement estimate is based on our best guesses of the reimbursement amount we expect the company to obtain with the existing code.

CMS reimbursement codes 97605 and 97606 apply to all disposable NPWT, including the VAC (KCI) and PICO (Smith and Nephew) systems that can be reported only once for the total wound surface, regardless of the number of wounds. Billing for the PICO System when used in in-home setting uses A9272 HCPCS code. The NPWT procedure has a reimbursement of $275 per day of treatment. Although the competitor's reimbursement amount is more than that planned to be obtained for the BST treatment, it is important to note that the cost of the NPWT is relatively high. Therefore, we expect EQUR's overall treatment cost to be cheaper as compared to the competitor's even after taking their higher reimbursement into consideration. We believe that failing to obtain reimbursement is not a deal breaker for EQUR. However, we think CMS' (Centers for Medicare and Medicaid Centers) and NPUAP's (National Pressure Ulcers' Advisory Panel) opinion that electrical stimulation therapy has shown to accelerate the process of chronic, recalcitrant ulcers and are superior to standard care of treatment may bode well for EQUR in their quest to obtain reimbursement (provided their clinical trials yield successful results).

Management may plan to drive efforts to establish new/revised HCPCS codes from the Department of Health and Human Services, through CMS. These codes will be the first to provide a payment mechanism for procedures providing different intensity of the electrical stimulation (30 minutes/3 times per day). If this code is able to provide higher reimbursement ($50 per day of treatment) then we expect sales revenues to be quicker. The CPT/HCPAC Advisory

Committee and the CPT Editorial Panel make a decision on providing a dedicated CPT code based on potential clinical efficacy of the procedure, support from peer-reviewed literature and an ongoing clinical trial outlining the efficacy of the procedure, or other evidence of evolving clinical utilization. However, enough clinical evidence needs to be produced to elicit reimbursement by CMS. With a dedicated CPT code, the procedure can be made accessible to more physicians and patients although obtaining this may take longer.

BST Launch/MILESTONES

In June 2014, EQUR entered into an agreement with the Austen BioInnovation Institute in Akron (ABIA), for obtaining regulatory FDA approval for BST Device.

Currently EQUR is preparing to refile the IDE application. If filed before end of 2015, we think the trials could commence in Q1 2016.

Post IDE approval, management plans to complete recruiting patients and begin trials across at least 6 clinical facilities in a double blinded, placebo controlled, double-arm, randomized, multi-center study to assess the safety and efficacy of the BST Device.

If the trials are conducted as per plan then EQUR hopes to submit the clinical trial results for FDA review and approval by end of 2016.

Meanwhile, EQUR will explore strategic alliances with key distributors to penetrate the U.S. market or preferably build its own marketing and sales capabilities.

Pending FDA approval, we expect the product to be launched in the U.S. market sometime in 2017.

Following launch, EQUR will work vigorously towards obtaining a reimbursement CPT code.

The product is currently awaiting marketing approvals in EU, Argentina, and Israel. We expect the sales to be slow at least until receiving FDA approval. FDA approval and supporting data from the upcoming trial should help facilitate uptake in other geographical regions.

PIPELINE

EQUR also hopes to embed a writable electronic component into their electrodes, so that when connected to the stimulation device, a "handshake" with the component is achieved with encrypted information to eliminate counterfeiting of their electrodes. The embedded component will count treatment sessions, hence it will limit the number of treatment sessions to a predefined number, and eliminate usage of the electrode for periods longer than the billed ones.

In the future, management expects BST technology to deliver healing solutions with a broader application across all wound types, such a diabetic foot ulcers, recalcitrant stage II ulcers, recalcitrant surgery ulcers and more.

MARKETING / SALES

EQUR expects to use third-party distributors to market their devices in Europe and South America. Primarily in Germany, most of 2015 will be dedicated for a pilot trial. The renewal of CE Mark is currently being completed. The

BST device launch in Europe is expected to commence in mid-2015. Currently, EQUR is focusing their efforts on obtaining FDA approval by 2017 and then will look to commence direct marketing of the device in the U.S. EQUR expects to expand their device's visibility using medical publications, participation in trade shows and conferences, and advertising in trade magazines.

EQUR expects to employ a business model wherein they lease the BST stimulation device for a minimal fee and sell the electrodes based on days of treatment methodology to each healthcare center. E-QURE's pricing strategy is to lease the BST device at approximately $600 per annum which allows for service, repair or exchange of the device as needed. E-QURE's disposable treatment electrodes will be priced for the customer at $100 per two days (on the average one patient requires one pair every other day of treatment). The electrodes are expected to carry margins in the 88%-90% range. EQUR assumes that about 80% of the days will be sold to hospitals and nursing homes and 20% to wound management clinics. The average treatment period is assumed to be 60 days.

EQUR's revenue model is based on the assumption that the bulk of the revenue is derived from the sale of disposable electrodes that need to be replaced by each patient every other day throughout the treatment period. The revenue model assumes a three year lifespan for their device. A device on average will treat at least 480 days per annum in hospital/long term care, and 240 days in in-home treatment, when borrowed from wound management clinics. The average number of days/device annually is assumed to be 400.

FINANCIAL CONDITION

Cash: As of June 30, 2015 the company had about $1M in cash. We believe that this amount will be sufficient to meet the operating expenses for the near term.

Debt: None

Cash Flow: R&D expenses are expected to be relatively low as the company has acquired a mature product for commercialization. The upcoming clinical trial is expected to use only approximately $800k. As per EQUR's agreement with LifeWave, EQUR would need to pay 10% of net profit in royalty payments for the initial 10 years period. The general and administrative costs are kept minimal as per EQUR's strategy to outsource services and maintain a low operating budget.

Cash burn will likely increase through 2017 as EQUR prepares for FDA approval and marketing expenses related to the BST devices. As bulk of EQUR's revenue is expected to be generated only from the sale of electrodes, cash flow is expected to remain negative until utilization reaches a break-even point. Based on our model we expect EQUR will require at least $2M until product launch in the U.S., which we think could happen sometime in 2017.

VALUATION / RECOMMENDATION

In the advanced wound management segment growth is driven by an aging population, healthcare reforms and technological advances driving shift from traditional products to advanced active therapies. Healthcare providers, third-party payers and patients are now much more focused on lower cost, pay-for-performance products and economically supported treatment pathways. Management believes that the market will continue the trend towards advanced wound products with its ability to accelerate healing rates, reduce hospital stay times and cut the cost of clinician and nursing time as well as aftercare in the home. Effective and low-cost technologies such as offered by EQUR's BST device are crucial for an aging population in whom the growing prevalence of health problems are making wound management much more complex.

In the U.S., expenditure on medical devices is controlled to a large extent by the government, many of which are facing increasingly intense budgetary constraints. Reimbursement rates may be set based on clinical data relating to cost, patient outcomes and comparative effectiveness. The intensifying competition from the large number of key players in this sector has resulted in the downward pressure on product prices. Although there has been growth in biologics and pharmaceutically active products, the market for advanced wound care devices is a developing and successful market.

We believe that there is a moderate potential for EQUR's BST device within this arena as EQUR has optimally priced their product significantly lower than that of competitors'. Additionally, having a global presence in the advanced wound care management business and efforts to capitalize from high growth opportunities in this market would keep EQUR in business. If EQUR gets approval from the FDA via the PMA pathway, although more challenging, may lead to pay or coverage thereby paving way for commercializing their device in the US, after which there is wide scope to increase adoption in other regions of world.

Successfully obtaining FDA approval alone does not guarantee a strong revenue stream. To create a value proposition for the healthcare facilities, EQUR needs extensive clinical data demonstrating the efficacy of the treatment. The efficacy and cost-competitive benefits of the BST device may take some time to bear out after introduction to the clinical market.

Additionally, to gain physician's further support EQUR may need to demonstrate that using their device reduces length of hospital stay as well as treatment time. We expect EQUR to gain visibility slowly as it is a new technology and any new technology can be prone to delayed adoption. Clinicians and nursing professionals may initially prefer to continue with traditional treatments for managing patient's wounds until there is additional evidence of the clinical utility of a novel device. In the U.S. wound care market, many insurers usually adopt coverage criteria similar to Medicare reimbursement policies. Limited reimbursement and the potential reluctance in adoption of novel advanced wound care products by physicians may restrict market growth initially. If they are successful in obtaining a dedicated CPT code that offers a higher reimbursement amount for the therapy, we expect significant increase in the sale of their devices from there on. Reimbursement should then be available from both private and governmental payers. However, it could take at least a year to obtain a dedicated CPT code.

We model sales revenue to grow at a slow rate initially and gain momentum as adoption grows. We estimate $3 million in revenues in year 2019 with the bulk of this amount coming in the latter half of the year and facilitated by an increase in international sales as well as launch of the product in the U.S. Our model assumes that EQUR will obtain a dedicated CPT code one year from the U.S. launch date leading to a steepening in the revenue growth. Even if the company has not achieved widespread reimbursement by 2020, we estimate that the company may turn cash flow positive by this year due to the high margins of the consumables as well as the size of chronic wound management market. EQUR plans to market the device by using third party distributors in Europe, South America and Asia and possibly building its own sales force in the U.S. provided that the company is able to raise enough financial resources. We expect that the general and administrative costs as a percentage of revenue will remain high in the initial years, especially during and immediately following the U.S. launch. We also model expenditures associated with marketing and sales initiatives to remain high in the initial years as EQUR attempts to increase their visibility and drive up sales.

Our revenue estimate of $3.6 million in 2019 with an EPS of $(0.04) is based on our assumption that about 250 units and 70,000 electrodes are placed in wound management clinics and hospitals worldwide. Due to what we view as significant advantages of the BST device provides over the existing devices in the market, we think our revenue estimates could prove conservative. Based on the current market price we feel the shares are undervalued. Using a Discounted Cash Flow (DCF) analysis, we derive the total equity value of approximately $21 million. We reiterate a Buy rating with a target price of $1.00/share.

RISKS

Barrier to entry: In light of the technological progress in the medical device field, research and product development life-cycles can become a lengthy process and product development becomes very expensive. Major biotech companies pose a threat to entry, through combination of acquisition or new product development. New product breakthroughs can change industry dynamics. Despite wound management being an attractive segment to enter due to secular growth and high profit margins, unstable pricing/industry conditions, and regulatory approval can be an impediment.

Pivotal Trial Initiation: While the IDE and IRB approvals remain outstanding, we expect, per management's guidance, that these will be finalized in short order. However, delays in approval of either could push back our timelines related to the pivotal trial commencement, data read-out, and eventual regulatory approval which could affect our financial projections and related valuation.

Regulatory Approval: Medical device products in the U.S. are subject to stringent laws and regulations by the FDA. Unexpected delays in the clinical trials related to the approval will result in a lengthier development and commercialization times. Our revenue estimates are contingent on if and when the BST device obtains regulatory approval. While we expect the FDA approval in a timely fashion, it is possible that it could be delayed due to unforeseeable reasons.

Patent Protection: The BST device is currently patent protected until 2021. Delays in obtaining a timely regulatory approval could reduce the time the BST device enjoys market exclusivity. However, E-QURE presently seeks extension of its patent protection in the U.S. by pursuing a continuing-type application in one of its pending patent applications. This step is expected to extend U.S. market exclusivity of the BST device until 2028. The new patent is intended to cover those electrical operation parameters of the BST device which have been found in clinical studies to be of superior efficacy. In addition, E-QURE has a set of pending patent application for its chronic wound diagnosis technology, which uses electrical sensing and proprietary algorithms for diagnosing wounds and suggesting suitable treatment. These patents are expected to provide protection until 2028.

Lack of diversity: The big players in the wound care management space have diversified their product portfolio, through acquisitions, to address the wider umbrella under wound healing. Although EQUR had made a strategic move by acquiring a mature product, it is their only source of revenue if and when it gets commercialized.

KEY MANAGEMENT PROFILE

Mr. Ron Weissberg, Chairman
Over 20 years of executive experience in the Financial industry in companies specializing in Real Estate, Insurance, Rating & Credit Agencies, and Investment Funds. Extensive experience in the Bio-Med industry around the world. Holds an MBA, New York University and BSc. Industrial Engineering and Management, Cum Laude, Technion, Haifa, Israel.

Mr. Ohad Goren, CEO
Over 20 years of experience in High-Tech and Bio-Tech Management. Former CEO of Pollogen–Medical Device Company , Former CEO of LifeWave–Medical Device Company, Support Sales Manager of Oracle Israel, Deputy Consul - Israeli Foreign Ministry, Israeli Embassy-Washington DC. Holds a B.Sc in Economics and Business Management from the University of Maryland USA.

Mr. ItsikBen Yesha, CTO
Over 30 years of experience in High-tech and Bio-Tech R&D and Management. Former CTO & Executive VP of LifeWave, CFO & Executive VP of Valor, Founder and Partner in Hisense (BabySense), CFO of Innowave (Tadiran Wireless Telecom). Hold a B.Sc in Aeronautical Engineering from Technion Haifa, and MBA, Cum Laude, Tel Aviv University, Israel.

SCIENTIFIC ADVISORY BOARD

Prof. Avi Ohry-MD
Prof. Ohry is an expert in Rehabilitation Medicine, served as a Consultant to the Israeli Ministry of Health, the Israeli Ministry of Defense, the Israeli Ministry of Foreign Affairs, IDF and other national and international agencies and institutions. . From 1985-1999 he served as the director of the Department of Neuro- Rehabilitation ,at Sheba Medical Center, Tel Hashomer, Israel . Since 2000, he is a (full academic) Professor of Rehabilitation Medicine at Tel Aviv University . Since 1999, he is the Chairman of the department of Rehabilitation Medicine at Reuth Medical Center, Tel Aviv. Prof. Ohry served as Member of Biomedical Advisory Board at LifeWave Ltd. In 2005, he was included in the project/book - " Caring Physicians of the World ", On behalf of the World Medical Association , as a representative of Israeli Medical Association.

Dr. Ben Zion Weiner
Dr. Weiner has been with Teva Pharmaceuticals since 1975. In January 2006, Dr. Weiner joined the Office of the CEO and assumed the role of Chief R&D Officer. Dr. Weiner served as Group Vice President -Global Products from April 2002 until January 2006. Previously, he served as Vice President -Research and Development from 1986 to 2002. He received a Ph.D. in chemistry from the Hebrew University, where he also earned B.Sc. and M.Sc. degrees. He conducted his post-doctorate research at Schering-Plough Corporation in the United States. He was granted the Rothschild Prize for Innovation/Export two times, in 1989 for the development of Alpha D3 for dialysis and osteoporosis patients and in 1999 for the development of Copaxone® for multiple sclerosis.

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PROJECTED FINANCIAL STATEMENT

Income Statement

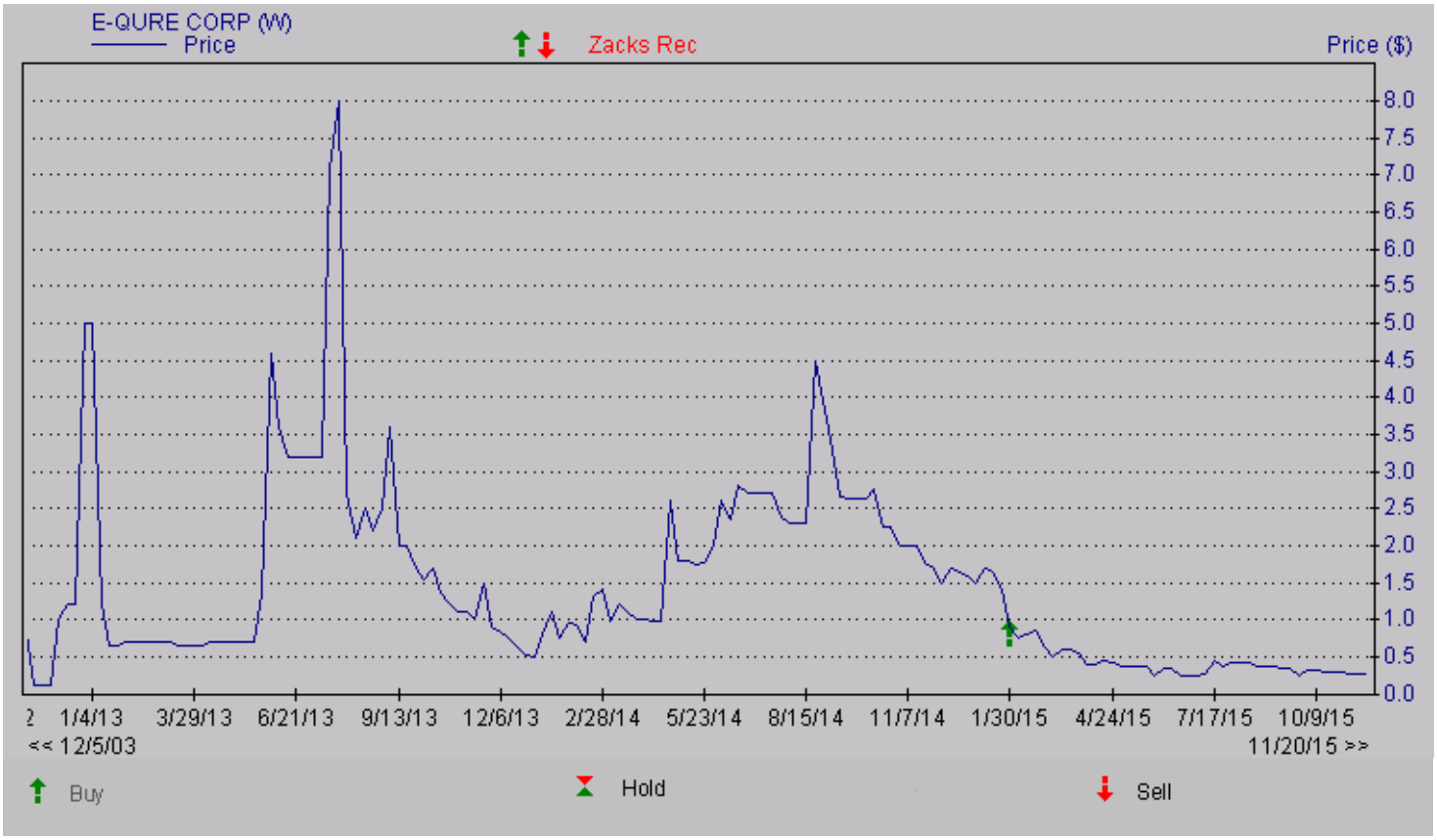
E-QURE Corp.

	2014 A	Q1 A	Q2 A	Q3 A	Q4 E	2015 E	2016 E	2017 E	2018 E	2019 E	2020 E
Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$37.0	$261.0	$1,228.0	$3,650.0	$11,300.0
YOY Growth	*0.0%*					*0.0%*	*0.0%*	*605.4%*	*370.5%*	*197.2%*	*209.6%*
Cost of Goods Sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$12.5	$52.5	$180.0	$475.0	$1,350.0
Gross Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$24.5	$208.5	$1,048.0	$3,175.0	$9,950.0
Gross margin	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*66.2%*	*79.9%*	*85.3%*	*87.0%*	*88.1%*
G&A	$450.7	$136.0	$161.6	$81.7	$85.0	$464.3	$736.0	$1,000.0	$2,000.0	$4,750.0	$6,350.0
%SG&A	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*1989.2%*	*383.1%*	*162.9%*	*130.1%*	*56.2%*
R&D	$561.2	$73.2	$34.2	$54.3	$55.0	$216.8	$800.0	$600.0	$500.0	$500.0	$500.0
R&D Impairment	$250.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
% R&D	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*2162.2%*	*229.9%*	*40.7%*	*13.7%*	*4.4%*
Operating Income	($1,262.0)	($209.3)	($195.8)	($136.0)	($140.0)	($681.1)	($1,511.5)	($1,391.5)	($1,452.0)	($2,075.0)	$3,100.0
Operating Margin										*-56.8%*	*27.4%*
Total Other Expense (Income)	($23,811.9)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($25,073.9)	($209.3)	($195.8)	($136.0)	($140.0)	($681.1)	($1,511.5)	($1,391.5)	($1,452.0)	($2,075.0)	$3,100.0
Taxes (benefit)	$13.9	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1,085.0
Tax Rate	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*
Royalty	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	-$207.5	$201.5
Net Income	($25,087.8)	($209.3)	($195.8)	($136.0)	($140.0)	($681.1)	($1,511.5)	($1,391.5)	($1,452.0)	($1,867.5)	$1,813.5
Net Margin										*-51.2%*	*16.0%*
EPS	($2.41)	($0.01)	($0.01)	($0.01)	($0.01)	($0.03)	($0.05)	($0.04)	($0.04)	($0.04)	$0.05
Diluted Shares O/S	10,408	22,012	22,012	22,012	22,012	22,012	27,610	32,764	38,142	45,058	38,342

Source: Zacks Investment Research Inc. *Anita Dushyanth*

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Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

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