Zacks Small-Cap Research

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OxySure Systems, Inc. (OXYS-OTCBB)

OXYS: Rescue Ready – Initiating Coverage With An Outperform Rating.

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	01/14/2013
Current Price (01/14/13)	$0.96
Target Price	**$1.75**

INITIATION

We are initiating coverage of OxySure Systems, Inc. with an Outperform rating and price target of $1.75 per share.

We believe that the company's Model 615 Emergency Oxygen System is a potential breakthrough product for the delivery of medical oxygen in a medical emergency required supplemental oxygen, such as a cardiac arrest or acute asthma attack. We see several distinctive advantages of the Model 615 over portal oxygen cylinders, which are typically not designed for emergency use.

We think that OxySure can turn cash flow positive in 2016, and generate over $10 million in operating cash flow in 2018. We built a 10-year discounted cash flow model that pegs fair-valuation between $1.50 and $2.00 per share. Thus, we are initiating coverage today with a target of $1.75 per share.

SUMMARY DATA

52-Week High	**$1.24**
52-Week Low	**$0.96**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**6,833**
Shares Outstanding (mil)	**21**
Market Capitalization ($mil)	**$21**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**18.0**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2012 Estimate	**N/A**
P/E using 2013 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	0.04 A	0.06 A	0.02 A	0.07 A	0.19 A
2012	0.03 A	0.06 A	0.10 A	0.07 E	0.27 E
2013					0.45 E
2014					1.00 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.02 A	-$0.03 A	-$0.02 A	-$0.02 A	-$0.10 A
2012	-$0.02 A	-$0.01 A	-$0.01 A	-$0.01 E	-$0.04 E
2013					-$0.04 E
2014					-$0.03 E

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COMPANY OVERVIEW

OxySure Systems, Inc. is a medical device company with a potential breakthrough product for the delivery of medical grade oxygen for the treatment of cardiac and respiratory distress situations. The company has developed a unique platform technology, whereby medically pure oxygen is created instantly from two inert dry powders, allowing oxygen to be delivered on demand to patients when needed.

The Product



The Model 615 unit has been cleared by the U.S. Food and Drug Administration (FDA) for over-the-counter (OTC) sale without the need for a prescription (510k/Class-II). The product is also approved in South Africa, Turkey, Brazil, and Israel.

With the Model 615 unit, oxygen is generated on demand from two inert dry powders. There is no storage of oxygen, no compressed tanks, no dials, no valves, no regulatory maintenance, no hydrostatic testing, no batteries, no required training, and none of the hazards associated with traditional oxygen provision systems.

Model 615:

✓ No explosive risk
✓ No storage of oxygen
✓ No heavy tanks
✓ No compressors
✓ No dials
✓ No valves
✓ No maintenance
✓ No batteries
✓ No training required

Saves Lives!

The OxySure Model 615 is safe and simple to use, and provides oxygen instantly with the turn of a knob. It can be used by any lay person, and bridges the gap between the onset of a medical emergency and the time that the first responders arrive on the scene. In the U.S., that gap between calling 911 and emergency medical professionals arriving is 6 to 15 minutes, depending on traffic conditions and other factors. If the medical emergency is of a cardiovascular nature, this gap can be critical, since irreparable damage to brain tissue can occur starting after only three minutes of oxygen deprivation.

COMPARISON OF COMPRESSED OXYGEN AND OXYSURE TECHNOLOGY

COMPRESSED TANK	MODEL 615
Explosion Hazard	No explosion hazard
Heavy Steel Container	Lightweight, Durable Plastic Housing
Maintenance schedule for regulator & volume	No scheduled maintenace; 2 year shelf life; disposable cartridge
Requires training	1-2-3 Operation with no required training
Replacement and/or filling by supplier	Easy to replace disposable cartridge
Stored gas under pressure	Oxygen produced only on demand

Who Needs OxySure?

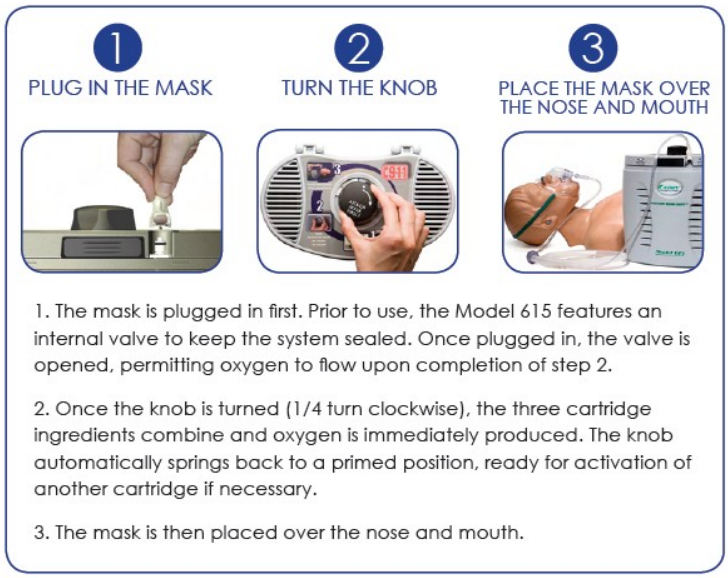
According to the American Heart Association (AHA), an American has a heart attack every 34 seconds. There are an estimated 300,000 occurrences of out-of-hospital sudden cardiac arrest (SCA) in the U.S. each year; over 90% of these occurrences result in fatality. For every minute without cardiopulmonary resuscitation and defibrillation, the chance of survival decreases by roughly 10%. However, in as little as three minutes irreversible brain / tissue damage may begin to occur due to a lack of oxygen. This can occur due to SCA, myocardial infarction (MI), stoke, cluster headaches, asthma attacks, chronic obstructive pulmonary disease (COPD) exacerbations, allergy attacks, altitude sickness, and sports-related injuries. OxySure was designed to allow a lay person / bystander to bridge the gap when supplemental medical oxygen can improve outcomes and save lives.

According to the American National Red Cross, “When serious injury or sudden illness occurs, the body does not function properly and can benefit from supplemental or additional oxygen.” The AHA notes that “Myocardial damage during acute myocardial infarction is minimized by administration of supplemental oxygen.” One of the first things that first responders do in a cardiac emergency is to administer supplemental oxygen.

Portable oxygen tanks are pressurized up to 2,000 psi. This presents both a fire and explosion hazard. The American Lung Associations (ALA) supports the use of small portable oxygen concentrators that allow patients with severe asthma / COPD to leave the home, go to work, and enjoy recreational activities and travel. However, the ALA notes important safety concerns with portable oxygen concentrators, including avoiding open flames, heat, and petroleum, and to take care when handling the cylinders and opening and closing valves and dials on the tanks. The tanks are expensive, prescription only, supplied with medical oversight, and provide low flow rates with low concentrations of oxygen. They are designed for chronic use in patients with lung diseases such as emphysema or chronic bronchitis; they are not feasible for emergency use.

OxySure’s Model 615 is the only OTC device that creates medical oxygen on demand and is suitable for emergency use. It has none of the concerns of portable oxygen concentrators and all of the benefits. The device is safe to store and only creates oxygen once the process is started. There is no compressed oxygen. There is no prescription required. The unit is lightweight (about 11 lbs.) and portable, and can be stored in open access locations at room temperature (usable between 40°F and 160°F). The replaceable cartridge is environmentally friendly and can be disposed of with household trash. And, unlike compressed oxygen sources that require scheduled maintenance to verify the integrity of the regulator and volume of compressed gas present in the cylinder, the Model 615 unit does not require scheduled maintenance. There is no battery to charge or power source necessary for the unit to function.

Plus, the device is extremely simple to operate – designed with the intension that a bystander, with no prior training or experience with the unit, can activate the system and administer oxygen to anyone in a medical emergency with ease. There are three simple steps:

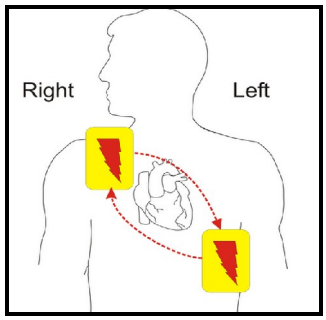


The OxySure Model 615 Emergency Oxygen device is like the oxygen equivalent of a fire extinguisher – it provides a safety net in the event of a medical emergency. It can be placed / pre-positioned in public settings by itself, and / or next to an Automated External Defibrillator (AED). And like an AED or fire extinguisher, it can be placed just about anywhere a medical emergency might occur to help improve medical outcomes – in schools, homes, businesses, churches, corporate and government buildings, sports stadiums, and shopping centers across the US.

The ideal market to benchmark when looking at OxySure’s opportunity with the Model 615 Emergency Oxygen device is the automated external defibrillator (AED) market. Emergency oxygen and external defibrillation go hand-in-hand for resuscitation of a patient following sudden cardiac arrest. The advent of AEDs has allowed those with experience in first aid or basic life support, such as CPR classes, as well as first responders to defibrillate a patient whose heart is experiencing arrhythmia or has stopped.

Similar to the OxySure Model 615, AEDs were designed to bridge the gap between the time it takes an experienced first responder with more sophisticated manual and semi-automatic defibrillators, which can act as pacemakers and perform other functions which require a skilled operator able to read electrocardiograms, to arrive and the need for treatment by laypersons. AEDs are portable electronic devices that automatically diagnose the potentially life threatening cardiac arrhythmias of ventricular fibrillation and tachycardia in patients, and treat through defibrillation to reestablish an effective heart rhythm. AED's offer simple audio and visual commands designed for trained personal and first responders. Layperson use of AEDs presents a bit more of a challenge, but is not impossible.

Unfortunately, AEDs are not as simple to operate as OxySure's Model 615 Emergency Oxygen device. Although AEDs are by no means complicated devices, a basic level of understanding is required for use. For example, bras with metal underwire or torso piercings must be removed prior to use of an AED to avoid arcing.



The electrode pads must be placed in the correct position on the bare chest for the patient for optimal performance. Although the vast majority of AEDs have audio and visual prompts to guide the user through the process of externally defibrillating a patient, apprehension and delay can lead to a lower probability of positive outcome. As noted above, for patients with cardiac arrest, minutes count.

…The AED Market…

AEDs account for around 40% of the total external defibrillator market, with manual external defibrillators accounting for the other 60%. We estimate approximately $220 million, or around 140,000 units at an average price of around $1,600 per unit, were sold in 2012. Frost & Sullivan estimates the size of the AED market to grow to around $300 million by 2016, with 6-7% CAGR. Roughly 60% of AED units are placed in public areas such as airports and bus stations, government and municipal buildings, shopping malls, sports stadiums, schools, casinos, fitness clubs, etc… First responders account for around 25% of all AED use. The remaining 15% of AED use is found inside hospitals and alternative care settings. In the U.S., we estimate there are roughly 2 million AED units placed, with another 1 million units found outside the U.S.

Drivers of the AED market include legislation mandates, an aging population, risk mitigation mechanisms, and out-patient care services. Impediments to use include cost, awareness, and perceived liability.

Drivers of AED Use:	
Legislative Mandates	Legislative mandates are the primary driver of AED placements. The Federal Cardiac Arrest Survival Act (2000) provides AED users and acquirers with liability protection. Additional protection is afforded under U.S. Good Samaritan Laws. The Aviation Medical Assistance Act (1998) requires all passenger commercial aircraft carry AEDs. All 50 U.S. states have specific AED laws and regulations. According to Heartsafe.com, 27 States have laws requiring AEDs in schools, nursing homes, or government offices. Several organizations are lobbying for a federal law.
Aging Population	The average age of a patient with sudden cardiac arrest is 67 years, although approximately 10% of all SCAs occur in subjects under the age of 40. Each year, over 250,000 die of SCA, more than colorectal cancer, breast cancer, prostate cancer, auto accidents, and firearms combined.
Risk Mitigation	AEDs (and emergency oxygen) can lead to improved outcomes for subjects having sudden cardiac arrest or cardiac arrhythmias. SCA is the No. 1 cause of death at work. Given increasing legislation mandating placement and availability of AEDs, impetus exists for schools, shopping malls, airports, etc… stay ahead of the laws to potentially reduce liability of not having an on-site AED.
Impediments to AED Use:	
Cost	Budget constraints and costs of the AED and training are the primary reasons why more units are not placed in the U.S. For schools, shopping malls, airports, hotels, sports stadiums, etc…, the cost of the AED, while not overly prohibitive, is not offset by any gain in revenues.
Liability	Despite state and local mandates, and Good Samaritan Laws, organizations may be concerned with the legal and financial liability of having untrained employees, clients, customers, or patrons administering the AED to a subject experiencing an SCA or cardiac arrhythmia. As noted above, correct placement of the pads or removal of metal around the torso is required for proper use of the device.
Awareness	Lack of awareness is not necessarily an impediment to AED placements, but proper compliance with federal or state and local laws is required for sale into a school or municipal building. Business and organizations may not be aware that AEDs exist, how easy they are to use, or that legislative mandates and favorable liability protection existing to facilitate its purchase.

The AED market is dominated by three players: Philips Healthcare with an estimated 34% market share, Cardiac Science with an estimated 27% market share, and Zoll Medical with an estimated 22% market share. Other players such as Physio-Control with 9% market share, Defibtech with 4% market share, and HeartSince with 3% market share are key players. Products offer unique characteristics, including different sizes, weights, colors, displays, shock levels, battery life, and usability.

The OxySure Model 615

Management launched the Model 615 device into the K-12 education and the commercial markets in the U.S. in 2008. Since that time, the product has been installed in schools and school districts in over 40 states. The Model 615 unit has a manufacturer's suggested retail price (MSRP) of $349.00. Purchase of the Model 615 unit also includes: 1 reusable housing with dust cover, 1 self-contained disposable cartridge (single-use), and 1 mask and tubing system (single-use). The product is ready to use upon arrival (i.e. it is supplied "rescue-ready") and the disposable / replaceable cartridge has a shelf life of two years. Once activated, the unit provides a minimum 15 minutes of medically pure oxygen at a rate of 6 liters per minute or higher. Replacement cartridges and accessories are sold alongside the unit to support continued and expanded use of the base unit. These include:



Replacement Cartridge (MSRP = $149.00)



Adult Replacement Mask (MSRP = $25.00)
Pediatric Replacement Mask (MSRP = $27.50)



Mounted Wall Box (MSRP = $349.00)



Thermal Carry Bag (MSRP = $89.00)



3D Wall Sign (MSRP = $18.95)



CRP Resuscitation Bag (MSRP = $36.00)



Pulse Oximeter (Standard) (MSRP = $99.00)



Pulse Oximeter (Premium) (MSRP = $129.00)

OxySure is looking to piggy-back on the success of the AED market. We see the Model 615 unit and its accessories as a logical adjunct to the purchase of an AED by a school district, airport, municipal building, sports stadium, etc… That being said, statistics show someone is 50 to 100-times more likely to require supplemental oxygen than external defibrillation.

The core drivers that facilitate uptake of AEDs are the same drivers that will help drive purchase and use of the OxySure Model 615 device. One of the main impediments, cost, is less of a barrier, as AED's average around $1,600 per unit and the Model 615 is only $349. The biggest impediment we see to uptake of the Model 615 to date has been lack of awareness.

To combat the lack of awareness issue, OxySure has partnered with a number of distributors, both hardline and online. The company currently has 22 non-exclusive distribution agreements in place in the U.S., covering placement markets such as schools and school districts, colleges, churches, office buildings and manufacturing facilities. The three largest distribution agreements are with Grainger, Global Industrial / Systemax, and AED Professionals, Inc. The largest online distributor is DrugStore.com.

These distribution agreements offer favorable economics back to OxySure with minimal costs. The company currently operates from a purpose built 16,200 square foot facility in Frisco, Texas. Below is a representation of the economics for the Model 615 device and the replacement cartridge:

OxySure P&L Model	Model 615	Cartridge
MSRP	$349.00	$149.00
Wholesale Price	$209.40	$101.32
Wholesaler Profit	$139.60	$47.68
Margin	*~67%*	*~47%*
OxySure CoGS	$85.00	$64.27
OxySure Profit	$124.40	$37.05
Margin	*~59%*	*~37%*

The Model 615 is approved for direct-to-consumer (DTC) advertising. The company has undertaken two initiatives to help drive sales. The first is a traditional campaign designed to create pull through demand at the institutions like schools, airports, shopping malls, etc… Here, both OxySure and its distributor partners spend marketing dollars to create awareness and drive sales. Global Industrial has been very active in this initiative. The second initiative is to drive awareness and sales by the individual end-user – perhaps an "at risk" patient with severe asthma / COPD or a patient with congestive heart failure. Drugstore.com has been very active in this initiative.

We think DTC advertising campaigns creates increased awareness, allowing for greater distributor sales in the "placement market". In the U.S. alone, this is a significant opportunity. Above we noted over two million AEDs placed to-date in the U.S., with roughly 140,000 sold in 2012. In the U.S. alone, there are an estimated:

- ✓ 116,000,000 Residential homes and apartments
- ✓ 20,000,000 OSHA compliant buildings
- ✓ 6,000,000 Residential and commercial swimming pools
- ✓ 925,000 Restaurants
- ✓ 350,000 Manufacturing facilities
- ✓ 325,000 Places of worship
- ✓ 110,000 Shopping centers
- ✓ 100,000 K-12 Schools
- ✓ 25,000 Golf course, Amusement parks, Athletic facilities
- ✓ 4,850 Airports
- ✓ 4,150 Public and private colleges and universities

The next wave of growth following penetration into the placement market is the "at risk" market. This includes patients buying the OxySure Model 615 for personal use. According to Philips management, the biggest player in the AED market, sales of AEDs over the past several quarters has been driven by an emerging trend to purchase and use the device in residential homes and apartment buildings. This is only facilitated by the reduction in AED costs and improved reimbursement. For example, reimbursement codes exist that can be applied to the purchase of an AED by an "at risk" individual. One such code is for cardiopulmonary resuscitation. Each state may have separate codes under Medicare, as well as different negotiation rates with private insurance.

According to Frost & Sullivan, the average AED price peaked in 2007 at $1,750 and has trended down ever since. Frost & Sullivan predicts AED prices will average $1,550 in 2016. However, reimbursement can knock the price of an "at home" AED for a patient with risk down from $1,600 today, to $250-$350 after reimbursement from Medicare or private insurance. This dramatically opens up the market. OxySure's Model 615 device, with an MSRP of $349, is far more affordable and broadly applicable than a $1,600 AED, even without reimbursement. If OxySure can be successful in piggy-backing on these reimbursement codes used for AED devices, the out-of-pack cost for someone with high risk of either a cardiovascular or pulmonary event may be less than $100.

The statistics U.S. show enormous potential upside:

- ✓ 40,000,000 Persons diagnosed with cardiovascular disease
- ✓ 40,000,000 Persons undiagnosed with cardiovascular disease
- ✓ 22,500,000 Persons diagnosed with asthma
- ✓ 16,000,000 Persons diagnosed with COPD
- ✓ 20,000,000 Persons undiagnosed with asthma / COPD
- ✓ 1,650,000 Persons current on long-term supplemental oxygen

In addition to U.S. markets, the company has made significant progress in developing international markets. OxySure is approved and has appointed distributors in Brazil, Turkey, Israel, and South Africa. Other markets are pending. The company plans to pursue European CE Mark, which will facilitate access to all European Union markets. We believe applications will eventually be filed with Health Canada as well. Rollout in each market is supported by public relations campaigns designed to create strong name recognition and pull-through demand. The campaign is accompanied by extensive briefings of medical / safety experts specific to each target market. In addition, a promotional, educational, and news media campaign will accompany direct to consumer availability.

The market opportunity on a global basis is quite astounding:

- ✓ 500,000,000 Persons diagnosed with cardiovascular disease
- ✓ 235,000,000 Persons diagnosed with asthma
- ✓ 64,000,000 Persons diagnosed with COPD

Recent Success

In October 2009, seventeen year old high school senior, Brody Justice, collapsed from a shortness of breath during baseball practice. Wakeland High School in Frisco, Texas had an OxySure Model 615 on hand because Frisco Independent School District ordered 110 units only months before. Wakeland High's athletic trainer, Tysha Beaty, noted that the unit helps asthmatic student athletes when their handheld inhaler is not working. Ms. Beaty also noted that it works to stabilize the student in a true asthmatic emergency before EMS arrives, or can reduce the need to call EMS. The average bill from EMS for sending an ambulance and trained personal is between $400 and $500. The average ambulance fee in the U.S. exceeds $1,000, and that does not include fees from the emergency room (ER) for services performed at the hospital. The cost of the Model 615 replacement cartridge is $149.

In October 2011, twelve year old Kylee Shea collapsed from a previously unknown arrhythmia. Maus Middle School, also in Frisco, Texas, home of OxySure, teachers Kristen Goodgion and Brent Reese performed CPR and used the schools AED to shock Kylee's heart back into rhythm. Kylee was then given supplemental oxygen from the schools OxySure Model 615 unit until EMS arrived. Additional testimonials can be found on the company's website. According to the most recent investor presentation, total lives saved to date are over 300.

In February 2012, the National Athletic Trainers' Association (NATA) published a new position statement and protocols for "Preventing Sudden Death in Sports." The position statement covers ten of the main causes of sudden death in organized sports and physical activity, including asthma and exertional sickling. The new NATA treatment protocols recommend that "supplemental oxygen should be offered to improve the athlete's available oxygenation during asthma attacks." The protocols further stipulate that "for breathing distress, the sports medicine team should provide supplemental oxygen to help maintain blood oxygen saturation above 92%." Similarly, the protocols recommend that athletes with known sickle cell trait (SCT) should "…have supplemental oxygen available for training or competition…" OxySure has teamed up with the School Health Corporation to help promote compliance with the new NATA guidelines by purchasing the OxySure Model 615. As part of this effort, OxySure's Model 615 device was featured by School Health at the College Athletic Trainers Society (CATS) show in Las Vegas, NV in May 2012.

In November 2012, a student at the College of Dental Medicine on the Glendale, Arizona campus of Midwestern University was working with chemicals in a confined area of a laboratory. The student passed out after being overwhelmed with outgassing and fumes. A Dispensary Assistant at the Sim Clinic immediately came to the student's rescue with the OxySure unit. The student was revived and regained consciousness. Staff at the university called 911 but upon arrival of the first responders it was determined that transportation to a hospital was not needed.

We calculate that the Model 615 has an installed base of around 20,000 units around the world, mostly in the U.S. We note that the OxySure Model 615 follows the successful "razor and blade" model pioneered by Gillette. Once the Model 615 base unit has been placed into a school or airport or mall, it becomes an annuity product for the company on the re-orders of cartridges and masks. The unit has a shelf life of two years, although we suspect that the majority of cartridges will be used prior to expiration. The re-ordering of a new cartridge and mask provides around $110 in revenue and $50 in profit to the company.

Future Plans

As noted above, the affordability and accessibility of the Model 615 should facilitate uptake in the next few years now that OxySure and its distribution partners are actively promoting the product and building brand awareness. The ramp to date has been slow, due in part to OxySure launching the product in 2009, during the depths of the recent recession. The company's core market, K-12 public schools, has been hits by budget constraints at both the state and local level. There are, however, signs of improvement in the economy that should leads to looser budgets at these municipal and even state-wide levels.

Growing brand awareness and new reimbursement has the potential to generate a "hockey-stick" like ramp in sales over the next several years. We see potentially multiple reimbursement categories for institutions, depending on the situation. For example, the same CPT code that at "at risk" patient can use under cardiopulmonary resuscitation can be applied to reimbursement for facilities like hospitals, alternate point of care clinics, doctors' offices, etc… Schools for example, may be reimbursed based on legislative mandates, as applicable. For example, Texas has a reimbursement for AEDs that OxySure is look to apply to the Model 615.

We suspect that if the company is not successful gaining reimbursement under existing codes, the company may be able to apply for new device specific codes. Alternatively, the company can seek reimbursement under specific treatment indications, like cardiopulmonary resuscitation or asthma / COPD exacerbations. There are also existing reimbursement codes of oxygen tanks and cylinders for chronic use that may be applicable to the Model 615.

The company plans to launch at least four new products utilizing the OxySure technology over the next 3 to 5 years, covering various vertical markets. These include a line extension called OxySave, a completely disposable low cost unit for mass consumer and "at-risk" markets, a consumable hand-held product for sports & recreation markets, and the OxySure Model SCSR-D, a self-contained self-rescue solution designed for mining, navy, and tunnel safety markets. We see the OxySure pipeline as offering meaningful upside to the existing Model 615 story.

Intellectual Property

The OxySure Model 615 emergency oxygen device was cleared by the U.S. FDA under the 510k / Class II pathway allowing for over-the-counter (OTC) purchase in December 2005. The company holds six U.S. patents comprising three utility patents and three design patents as follows:

(1) #7,407,632 - "Apparatus and delivery of medically pure oxygen" (expires on May 27, 2024)
(2) #7,381,377 - "Method for controlled production of a gas" (expires on June 21, 2025)
(3) #7,465,428 - "Method and apparatus for controlled production of a gas" (expires on June 21, 2025)
(4) #D549,341 - "Breathing device utilizing a catalytic oxygen generation method" (expires on July 30, 2026)
(5) #D549,342 - "Breathing device utilizing a catalytic oxygen generation method"(expires on July 30, 2026)
(6) #D615,186 - "Chemical reaction activation plunger" (expires on June 24, 2022)

The U.S. utility patents (1-3 listed above) cover methods and apparatuses associated with the production (from the chemical process), control, containment and delivery of oxygen (or a gas containing oxygen). The U.S. design patents (4-5 listed above) cover aspects of the design and features of the Model 615 product.

In addition, the company holds one South African patent, #2006/5051 entitled "Method and apparatus for generating oxygen," two Australian patents, number #2007101246 entitled "Method and system for portable breathing devices," and #2007101247 entitled "Method and system for providing breathable air in a closed circuit." South African patent is valid for 20 years from the date of application. The Australian patents are innovation patents and expire as follows: patent #2007101246 expires on January 16, 2015 and patent #2007101247 expires on January 4, 2015. The South African patent covers the process by which oxygen is generated. Australian patent #2007101246 covers certain engineering elements of the system for activation and management of the catalytic oxygen producing system. Australian patent #2007101247 covers certain engineering aspects of a system that combines the catalytic process for generating oxygen, with a scrubbing process that removes at least one element of expired air.

The company has other patents pending. All the company's patents are focused on mechanical designs, methods and systems, and the company has maintained its chemicals and related processes as trade secrets.

The Competition

A quick Google search for portable emergency oxygen units yields a number of potential competitors to OxySure's Model 615 device. We discuss some of these below:

1 – Life O2 SoftPac



Manufactured by Life Corporation, the SoftPac emergency oxygen unit is designed as an AED companion. The device is both lightweight (6 lbs) and portable. It provides 40 minutes of oxygen supply (6 liters per minute) before the onset of fibrillation or CPR, or after successful defibrillation. The 250 liter aluminum cylinder is replaceable, but does contain compressed oxygen and needs to be refilled at a local O_2 gas distributor. The device is simple to use, but does have valves and gauges, and must be checked regularly to make sure the cylinder remains pressurized. Accessories include masks and inhalators for mouth-to-mask CPR.

Cost of device: $275-325 (online)

2 – Life Oxygen-Pac



Manufactured by Life Corporation, the Oxygen-Pac is a larger unit than the SoftPac at 20 inches high and 16 lbs. The device has two flow settings: Low, which provides 90 minutes of oxygen supply at 6 liters per minute, and High, which provides 45 minutes at 12 liters per minute. Oxygen-Pac is designed for use in industrial, office, government, and school medical emergency settings, or by first-responders prior to or after defibrillation or CPR. The company recommends mounting the device on the wall, similar to a fire extinguisher. The 566 liter aluminum cylinder is replaceable or refillable at a local O_2 gas distributor. The device is simple to use, but does have pressurized oxygen with gauges and valves that must be checked regularly.

Cost of device: $525-575 (online)
Cost of replacement tank: $425 (new tank), $200 (local re-fill)

3 – Life-O-Gen



Manufactured by Allied Healthcare Products, Inc., the Life-O-Gen is a one-time use, portable emergency oxygen tank kit. The kit comes with one portable oxygen cylinder with pressurized O_2 gas, an oxygen mask, and a regulator. Kit weights about 8 lbs and the 130 liter tank provides approximately 20 minutes of oxygen at 6 liters per minute. The device is simpler to use than the larger Oxygen-Pac manufactured by Life Corp., but may offer a shorter shelf-life due to the simplicity of its design.

Cost of device: $150-200 (online)
Cost of replacement tank: $75-125 (new tank), $50-75 (local re-fill)

We found a number of larger portable oxygen concentrator units available online for prices ranging from $500 up to as much as $5,000. However, the majority of these stand-alone units are for continuous oxygen therapy when required 24 hours a day, 7 days a week, or prescribed by a physician. We note the three units discussed above, as well as OxySure's Model 615 device, are available without a prescription (OTC) for emergency use. As such, the Model 615 really does not compete with units like the Oxlife Independence 24/7, the Invacare XPO2, the SmartDose LOX, or the Respironics EverGo line of portable oxygen concentrators.

The OxySure Model 615 device is the only portable, emergency oxygen device we found that does not have compressed / pressured oxygen in disposable or reusable tank, with gauges and valves. OxySure has also done among the better jobs we have seen in building an annuity business on every system placement, which we discussed above by the supplying or replacement cartridges and masks, along with upselling the unit with wall mounts, thermal travel bags, and pulse meters.

Recent Financials Show Improving Fundamentals

On November 14, 2012, OxySure Systems, Inc. reported financial results for the third quarter ended September 30, 2012. Total revenues in the quarter were $103K, an increase of 381% over the same period in 2011. Revenues were also up an impressive 63% sequentially from the $63K reported in the second quarter 2012. The surging revenues were a result of increased product sales to customers in both the U.S. and internationally.

We remind investors that in September 2012, OxySure announced they signed a distribution agreement for AED Professionals to market and promote OxySure's Model 615 portable emergency oxygen device, and all related accessories. We are particularly excited about this deal because AED Professionals will offer OxySure as an add-on product to their existing installed base of Automated External Defibrillators (AEDs), and as a companion product for new AED sales. We note that AED Professionals is one of the largest distributors of AEDs in the U.S.

Operating expenses in the quarter totaled $257K, down 29% from the $331K reported in the third quarter 2011. Operating expenses were also down sequentially from the $282K reported in the second quarter 2012. We are pleased to see the company report a significant increase to the top-line while controlling and even lowering expenses. Net loss in the quarter totaled $134K, or $0.01 per share. Loss improved from the $362K reported in the third quarter 2011 and the $218K reported in the second quarter 2012. In fact, net loss has declined for the past five quarters. Although still not yet profitable, OxySure is clearly moving in the right direction.

The company exited the third quarter ended September 30, 2012 with $116K in cash. We note the company also has $210K in inventory on the books as of the end of the third quarter 2012. Year-to-date, OxySure has burned roughly $72K in cash through operating and investing activities, and raised roughly $124K through financing activities. As of September 30, 2012, the company has a differed tax asset of $4.4 million.

…Need For Cash…

On October 10, 2012, OxySure announced it hired C.K. Cooper & Company, Inc. (CKCC) as its financial advisor. We suspect that CKCC will be able to help OxySure secure new funding in the next several months that will allow management to execute on its growth strategy, and pursue the expansion of its sales and distribution capabilities and product offerings in 2013 and beyond. We suspect that the company is in the stages of structuring financing to secure long-term funding to the company beyond the "drip financings" that have funded operations for the past several years. To date, the founder, Chairman and CEO, Julian Ross, has put $2.5 million of his own capital into OxySure. The company has an accumulated deficit of $14.1 million, a differed tax asset of $4.4 million, and cumulative net operating loss carry-forwards of $11.5 million. Securing quality long-term funding will allow the company to build out the sales force, increase marketing activities, and fund distribution partnership efforts in 2013 and beyond.

On January 3, 2013, OxySure announced that affiliates Agave Resources, LLC and JTR Investments, Limited converted a total of $2,018,656 in convertible notes to common stock at an aggregate exercise price of $1.50 per common share. The conversion price of $1.50 per share represents a premium of 52% to the share price at the close of market on January 2, 2013.

…Capital Structure…

For the purpose of our financial model, we are using a fully-diluted share count of 27.1 million.

Basic Shares	
22.310 Million	January 3, 2013
Stock Options	
1.479 Million	@ $0.41 / share
0.053 Million	@ $0.72 / share
Warrants	
1.822 Million	@ $0.67 / share
Convertible Preferred	
1.060 Million	@ $1.00 - $1.50 / share
Convertible Notes	
0.351 Million	@ $1.00 - $1.50 / share

MANAGEMENT

Julian T. Ross, M.B.A., Chairman & CEO
Mr. Ross is the developer of the OxySure technology and the Founder of OxySure Systems, Inc. He has served as CEO of the company since inception in January 2004, and has raised over $13 million for the company to date. He also built the company and all its operations and processes, including the manufacturing operations, spearheaded all regulatory approvals (including FDA approval, ANVISA approval, GSA approval and DOT approval), set up the distribution channels, and took the company public in late 2011. He is a high energy, results-oriented individual, and he brings over 25 years' experience in technology, medical devices and manufacturing, having functioned both in consulting and operational capacities at senior management level. His experience includes at least a decade in corporate finance, including public and private financings, and mergers & acquisitions. He has worked for and with start-ups and established organizations, including Anglo American Corporation, Volt Information Sciences, Tandy Corporation, Merrill Lynch, Ernst & Young, Sun International and Isle of Capri, Inc. Mr. Ross has enjoyed an Academic Scholarship from Shell Petroleum and an Academic Scholarship from the Edwin L. Cox School of Business at Southern Methodist University, where he received an MBA in Finance

Vicki Jones, M.B.A., Board of Directors
Ms. Jones is the Senior Vice President, Mass Market Sales, Service, and Care for AT&T and has more than twenty-nine years experience in P&L management, sales and sales management, marketing, installation, and customer service. Ms. Jones leads an organization of approx. 28,000 employees within AT&T, and has held various positions within AT&T (and SBC Communications, its predecessor company), including President – Business Communications Services, Midwest; Senior Vice President – Product Management and Development; and Vice President – Strategic Marketing. Ms. Jones holds an MBA in E-Commerce Management from Our Lady of the Lake University, San Antonio, Texas.

Don Reed, B.A., B.S., Board of Directors
Don Reed has over 40 years experience in business development, operations, mergers & acquisitions and general management. He currently serves as President of Agave Resources, LLC., a private equity firm focused on investing in early and mid-stage high growth companies. Prior to that Mr. Reed served as CEO and Chairman of Geotrace Technologies, Inc., an international reservoir services company specializing in high technology seismic data processing for oil and gas companies. Geotrace was founded by Mr. Reed under the name Geo-Trace Enterprises in 1979, and was active in it's growth and expansion until the company was sold in 2003. Mr. Reed spent the 17 years prior to founding Geotrace Technologies with Amoco Production Company in various management, technical and exploration positions. He served in the U.S. Infantry as an Intelligence Specialist, and holds a B.A. (Math) and a B.S. (Geology) from the University of Texas.

Thomas D. Fanklin, Jr., Ph.D, Advisory Board
Dr. Franklin is the Executive Vice President for Regulatory Affairs for Organ Transport Systems, Inc., and serves as Sr. Scientific Advisor to North Texas Enterprise Center for Medical Technology in Frisco, Texas. Dr. Franklin is the former President of the Texas Health Research Institute, and he has over 35 years experience in medical research and education.

Mikael Ahlund, M.B.A., Ph.D, Advisory Board
Dr. Ahlund is the Director, RFID Healthcare for Texas Instruments, and has over 30 years global experience in strategic marketing, business management, and product development for complex technologies in the medical, consumer, and industrial fields. His experience includes senior management and Board positions with General Electric, IBAX/HBOC, Delphi, and Marsh Insurance.

James R. Winn, M.D., Advisory Board
Dr. Winn has over 36 years experience in the healthcare industry, having served in a policy role as well as a general practitioner. Dr. Winn served for 11 years as the Executive Director of the Federation of State Medical Boards (FSMB) of the United States. FSMB is a national non-profit organization representing the 70 medical boards of the United States and its territories, and whose mission is to continuously improve the quality, safety and integrity of health care through developing and promoting high standards for physician licensure and practice.

Vincent Mosesso, Jr., M.D., FACEP, Advisory Board
Dr. Mosesso is Medical Director for Pre-hospital Care at the University of Pittsburgh Medical Center (UPMC). He also serves as Associate Professor of Emergency Medicine at the University of Pittsburgh School of Medicine, and Medical Director of the Sudden Cardiac Arrest Association. Dr. Mosesso founded and is the Medical Director of the National Center for Early Defibrillation. Dr. Mosesso is a fellow of the American College of Emergency Physicians and is a member the Society for Academic Emergency Medicine, the American Heart Association and the National Association of Emergency Medical Services Physicians. In 1998, he was named "Physician of the Year" by the Pennsylvania Emergency Health Services Council and he has authored or co-authored more than 40 peer-reviewed scientific manuscripts and textbook chapters related to emergency medicine.

R. Dean White, D.D.S., M.S. , Advisory Board
Dr. White is a past President of the American Board of Oral & Maxillofacial Surgeons, and is one of the foremost Oral & Maxillofacial surgeons in the US, with over 30 years experience in private practice.

Jonathan E. Burke, D.M.D., Advisory Board
Dr. Burke is a private practice Oral and Maxillofacial surgeon in Southern New Jersey. He has served as the team oral and maxillofacial surgeon for the Philadelphia Flyers and Phantoms professional hockey clubs since 1994. He has significant experience in hyperbaric oxygen therapy and received an Attending Hyperbaric Medicine Certificate in 1996.

Craig R. Turner, C.P.A., M.B.A., Advisory Board
Mr. Turner has over 15 years experience in accounting, finance and mergers & acquisitions. He currently serves as Chief Financial Officer of Agave Resources, LLC, a private equity firm focused on investing in early and mid-stage high growth companies. Prior to that Mr. Turner served as CFO for Geotrace Technologies, Inc., a company specializing in high technology seismic data processing for oil companies. He was an integral part of the management team arranging financing, providing strategic planning, and maintaining the Company's focus on revenue growth, profitability and return on investment. His education includes a B.S. Accounting and an MBA from Colorado State University and he is a member of the Colorado Society of CPA's.

George Brody, B.Sc./M.Sc., M.Sc, Advisory Board
George Brody is the Founder & CEO of venture funded GlobeRanger and a former executive of Nortel. Mr. Brody is a much sought out expert and speaker in the area of digital technology for wireless communications systems, sensors as well as RFID systems, and his current professional interests lie in the area of the intersection of wireless technology with medical device applications.

RECOMMENDATION & VALUATION

Initiating Coverage

We are initiating coverage of OxySure Systems, Inc. with an Outperform rating and price target of $1.75 per share. We believe that the company's Model 615 Emergency Oxygen System is a potential breakthrough product for the delivery of medical oxygen in a medical emergency required supplemental oxygen, such as a cardiac arrest or acute asthma attack. We see several distinctive advantages of the Model 615 over portal oxygen cylinders, which are typically not designed for emergency use.

Firstly, with the Model 615 unit, oxygen is generated on demand from two inert dry powders. There is no storage of oxygen, no compressed tanks, no dials, no valves, no regulatory maintenance, no hydrostatic testing, no batteries, no required training, and none of the hazards associated with traditional oxygen provision systems.

Secondly, the OxySure Model 615 is safe and simple to use, and provides oxygen instantly with the turn of a knob. It can be used by any lay person, and bridges the gap between the onset of a medical emergency and the time that the first responders arrive on the scene. In the U.S., that gap between calling 911 and emergency medical professionals arriving is 6 to 15 minutes, depending on traffic conditions and other factors. If the medical emergency is of a cardiovascular nature, this gap can be critical, since irreparable damage to brain tissue can occur starting after only three minutes of oxygen deprivation.

And finally, the OxySure Model 615 is the perfect adjunct product to be placed next to an automated external defibrillator (AED). AED market growth over the past several years has been impressive. In 2012, we estimate that roughly 140,000 units were sold worldwide, generating revenues of $220 million. The market is expected to growth at a CAGR of 6-7% over the next five years (Frost & Sullivan), with uptake being driven by legislative mandates, an aging population, reimbursement, and risk mitigation strategies. OxySure's Model 615 is both more affordable and accessible than AEDs, and data shows a person is up to 100x more likely to require supplemental oxygen in their lifetime than external defibrillation. OxySure is currently looking at piggy-backing on AEF legislation and reimbursement to help facilitate uptake of the Model 615 device. With over 3 million AEDs placed worldwide, acceptance of the Model 615 as a logical supplement to an AED has the potential to create a "hockey-stick" like ramp in revenues.



In October 2012, OxySure announced it had retained C.K. Cooper & Company, Inc. (CKCC) as its financial advisor. We suspect that CKCC will be able to help OxySure secure new funding in the next several months that will allow management to execute on its growth strategy, and pursue the expansion of its sales and distribution capabilities and product offerings in 2013 and beyond. We suspect that the company is in the stages of structuring financing to secure long-term funding to the company beyond the "drip financings" that have funded operations for the past several years. To date, the founder, Chairman and CEO, Julian Ross, has put $2.5 million of his own capital into OxySure. The company has an accumulated deficit of $14.1 million, a differed tax asset of $4.4 million, and cumulative net operating loss carry-forwards of $11.5 million. Securing quality long-term funding will allow the company to build out the sales force, increase marketing activities, and fund distribution partnership efforts in 2013 and beyond.

Below we've built, an admittedly aggressive, financial model based on surging sales of the Model 615 device, facilitated by the signing of additional distribution agreements, expanded marketing and promotional efforts by the company, and growing penetration into both the placement and "at risk" market thanks to improving reimbursement and legislative mandates. We think that OxySure can turn cash flow positive in 2016, and generate over $10 million in operating cash flow in 2018. We built a 10-year discounted cash flow model that pegs fair-valuation between $1.50 and $2.00 per share (assumption to be narrowed once the company secures long-term financing). Thus, we are initiating coverage today with a target of $1.75 per share.

PROJECTED FINANCIALS

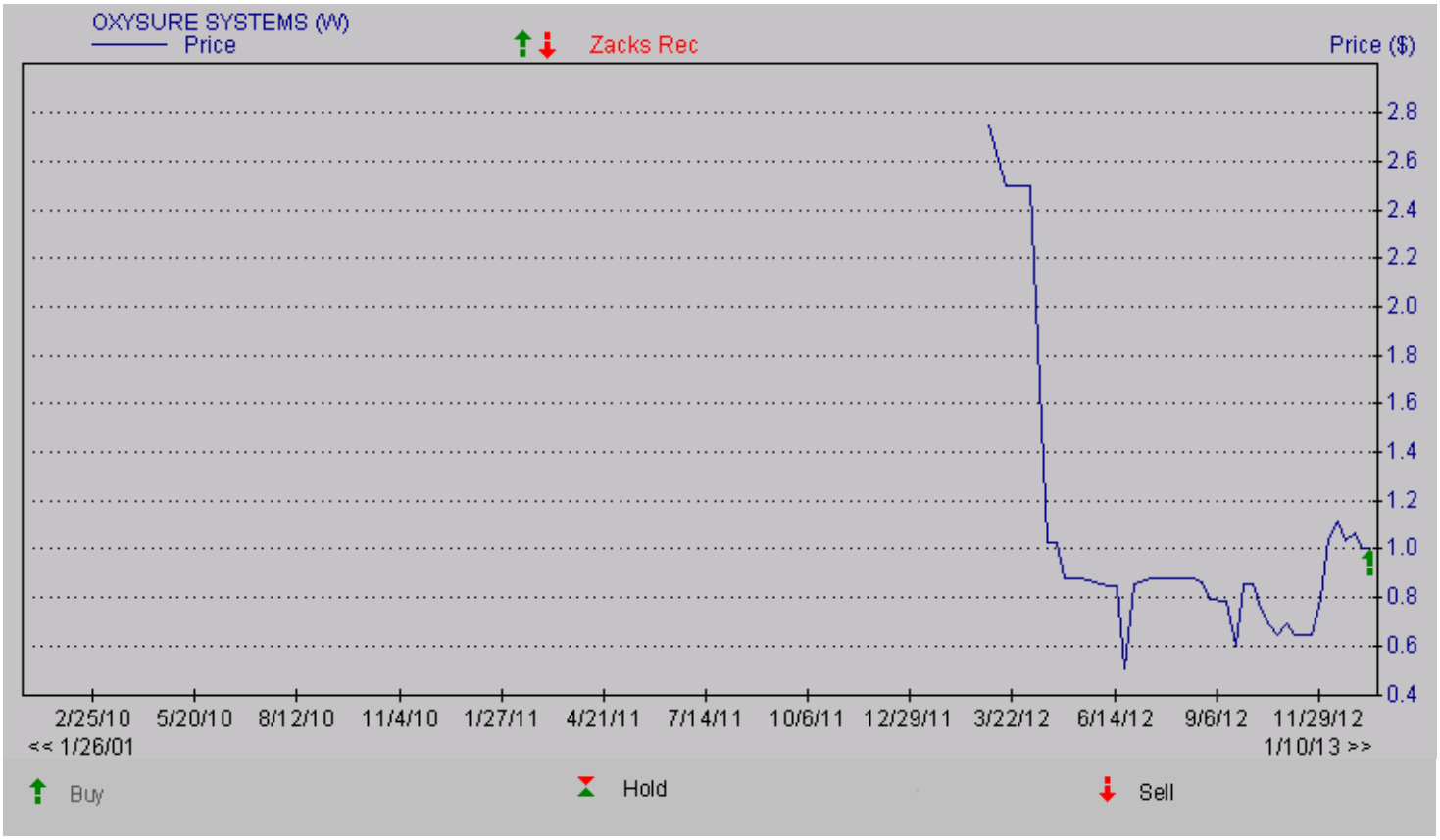
OxySure Systems, Inc.
Income Statement

OxySure Systems, Inc.	2010 A	2011 A	Q1 A	Q2 A	Q3 A	Q4 E	2012 E	2013 E	2014 E	2015 E	2016 E
Product Sales	**$0.131**	**$0.185**	**$0.028**	**$0.063**	**$0.103**	**$0.075**	**$0.269**	**$0.450**	**$1.000**	**$2.500**	**$4.500**
YOY Growth	-	*41.4%*	*-22.6%*	*0.6%*	*380.5%*	*15.1%*	*45.3%*	*67.2%*	*122.2%*	*150.0%*	*80.0%*
Other Revenues	**$0.225**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$0.356**	**$0.185**	**$0.028**	**$0.063**	**$0.103**	**$0.075**	**$0.269**	**$0.450**	**$1.000**	**$2.500**	**$4.500**
YOY Growth	-	*-48.0%*	*-22.6%*	*0.6%*	*380.5%*	*15.1%*	*45.3%*	*67.2%*	*122.2%*	*150.0%*	*80.0%*
Cost of Goods Sold	$0.055	$0.103	$0.013	$0.025	$0.050	$0.03375	$0.122	$0.203	$0.430	$1.000	$1.665
Product Gross Margin	*84.6%*	*44.2%*	*54.4%*	*60.0%*	*51.2%*	*55.0%*	*54.6%*	*55.0%*	*57.0%*	*60.0%*	*63.0%*
Operating Expenses	$1.462	$1.151	$0.283	$0.257	$0.207	$0.215	$0.962	$1.000	$1.100	$1.250	$1.500
% SG&A	*410.8%*	*621.3%*	*1016.7%*	*408.3%*	*200.2%*	*286.7%*	*357.5%*	*222.2%*	*110.0%*	*50.0%*	*33.3%*
Operating Income	($1.161)	($1.069)	($0.268)	($0.219)	($0.154)	($0.174)	($0.815)	($0.753)	($0.530)	$0.250	$1.335
Operating Margin	-	-	-	-	-	-	-	-	-	*10.0%*	*29.7%*
Interest & Other Net	($0.418)	($0.463)	($0.057)	$0.001	$0.0202	$0.025	($0.01)	($0.30)	($0.40)	($0.50)	($0.50)
Pre-Tax Income	($1.579)	($1.532)	($0.325)	($0.218)	($0.134)	($0.149)	($0.826)	($1.053)	($0.930)	($0.250)	$0.835
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	($1.58)	($1.53)	($0.325)	($0.218)	($0.134)	($0.149)	($0.826)	($1.053)	($0.930)	($0.250)	$0.835
YOY Growth	-	*-2.9%*	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	*-10.0%*	*18.6%*
Reported EPS	**($0.10)**	**($0.10)**	**($0.02)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.04)**	**($0.04)**	**($0.03)**	**($0.01)**	**$0.02**
YOY Growth	-	*-4.2%*	-	-	-	-	*-57.0%*	*1.8%*	*-26.4%*	*-77.0%*	*-434.0%*
Shares Outstanding	15.7248	15.930	17.844	19.807	20.762	21.500	20.0	25.0	30.0	35.0	35.0

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

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