Zacks Equity Research

March 22, 2010
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Oxygen Biotherapeutics, Inc. (OXBT-NASDAQ)

OXBT: Making Progress on Key Initiatives for 2010. Maintain Outperform Rating.

UPDATE

Current Recommendation	**Outperform**
Prior Recommendation	**Neutral**
Date of Last Change	10/26/2009
Current Price (03/22/10)	$4.79
Target Price	**$15.00**

Management is making progress with the two key initiatives for the company right now: 1) Enroll patients in the phase IIb STOP-TBI program taking place and Switzerland and Israel and 2) Ramp sales of Dermacyte online directly to consumers.

We expect enrollment in STOP-TBI to pick-up as we head into 2010 now that certain training and logistical hurdles have been cleared. Safety data from the program should become available from the first patients later in 2010. We remain optimistic on the development of Oxycyte and would use the recent stock pullback as an entry point.

SUMMARY DATA

52-Week High	**$8.01**
52-Week Low	**$3.00**
One-Year Return (%)	**44.01**
Beta	**0.41**
Average Daily Volume (sh)	**18,135**
Shares Outstanding (mil)	**20**
Market Capitalization ($mil)	**$97**
Short Interest Ratio (days)	**3.86**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**N/A**
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 2010 Estimate	**N/A**
P/E using 2011 Estimate	**N/A**
Zacks Rank	**3**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed**
Zacks Rank in Industry	**45 of 99**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Jul)	Q2 (Oct)	Q3 (Jan)	Q4 (Apr)	Year (Apr)
2009	$0 A	$0 A	$0 A	$0 A	$0 A
2010	$0 A	$0 A	$0 A	$0.2 E	$0.2 E
2011					$4.5 E
2012					$8.2 E

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

	Q1 (Jul)	Q2 (Oct)	Q3 (Jan)	Q4 (Apr)	Year (Apr)
2009	-$0.42 A	-$0.37 A	-$0.77 A	-$1.14 A	-$2.90 A
2010	-$0.15 A	-$0.13 A	-$0.13 A	-$0.14 E	-$0.55 E
2011					-$0.36 E
2012					-$0.25 E

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

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WHAT'S NEW

Dermacyte Update…

During the fiscal third quarter (November 2009 – January 2010), Oxycyte produced and sold a limited preproduction batch of Dermacyte (oxygen concentrated gel) from orders taken through the company's website: www.BuyDermacyte.com. Under this initial roll-out phase of 5,000 boxes, Dermacyte was available for $24,99 for a 4-day supply (8 blister pack at 3.2 ml). According to management, the product sold out in the first month after it became available online. Management recorded these revenues as a credit toward the R&D expense line on the income statement for the fiscal third quarter. In the fiscal fourth quarter we expect the company to begin to record revenues as product sales. The BuyDermacyte.com website claims the following benefits to the product:

- Increases the amount of oxygen available to the skin tissue,
- Helps promote the healthy appearance of skin,
- Leaves the skin feeling refreshed and invigorated,
- Helps minimize the appearance of fine lines,
- Brightens and smoothes your complexion,
- Aids in reducing the visibility of blemishes,
- Helps keep skin moist, glowing and healthy looking,
- Works on all skin types.



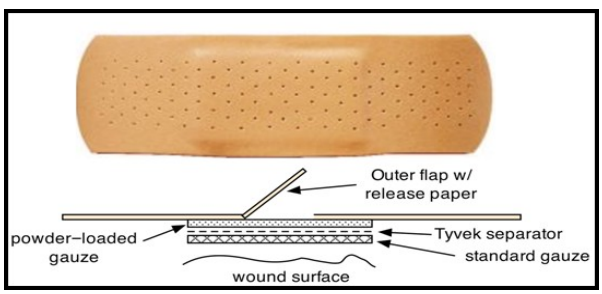
The next phase of the rollout will begin in April 2010 when management will make available additional blister-pack boxes for sale online. This will be followed by distributing Dermacyte in elegant upscale cosmetic 10 ml bottles and vials. These should become available this summer (Oxycyte's fiscal first quarter 2011). Management also plans to launch Dermacyte as an eye cream, which adds fragrances and moisturizers to the formulation, including sunflower oil, avocado essence, vitamin C, and other antioxidants.



Simple skin testing clinical trials are underway looking at the potential reduction in fine lines and wrinkles. We believe that if successful, these 10mL bottles could go for as high as $90 per. Eventually the company will sign distribution partners to help maximize the direct to consumer rollout. With Dermacyte, management has a platform product line that can be expanded to include eye creams, facial creams, moisturizers with SPF, hand and body lotions, toners, lip balms, exfoliators, and regenerating serums. We expect an update on this in the next few months. Peak Dermacyte sales for direct-market cosmetic uses are $20 million in our view.

Next Up, Wundecyte…

Oxygen is critical for the efficient healing by promoting healthy cell growth and recovery in damaged cells. Oxygen is also very important in maintaining an aseptic environment, as many of the more dangerous bacteria of the *Staphylococcus, Streptococcus,* and *Clostridium* class are highly oxygen in-tolerant. This is important in treating wounds, burns, and acne.



Wundecyte is an adhesive bandage that sticks to the skin as a traditional bandage would, except that the center contains a fabric coated with a magnesium peroxide (MgO_2) powder that releases O_2 when mixed with moisture (H_2O). It is a self-contained system that delivers O_2 to the wound for approximately 6 hours. Management refers to Wundecyte as a "mini-hyperbaric chamber" able to provide subcutaneous O_2 in an aseptic and economic package.

In July 2009, management filed a 510K on Wundecyte. The U.S. FDA responded that the bandage will be regulated as a device, and thus management is eligible for an investigation device exemption (IDE). Management plans an animal (pig) feasibility trial in April 2010 to evaluate Wundecyte's effectiveness at wound healing on different kinds of wounds. This study will look at factors such as time to wound closure and reduction in scar tissue formation as compared to a control group. The next step would be to out-license Wundecyte to a larger organization interested in wound-care. If approved, Wundecyte could be used in the emergency room (about 1.5 million incidences per year) and available OTC, where there are 50 million minor acute skin injuries and 1 million minor burns each year. Management is also testing the addition of Oxycyte to the wound or burn with Wundecyte. This would increase the subcutaneous O_2 delivery. However, Oxycyte is regulated as a drug, and thus management needs to file an investigational new drug (IND) application prior to human clinical testing. The most direct competitor in this market would be the product Neosporin, a topical antibiotic with roughly 5% oxygen by volume, or medicated bandages pre-loaded with similar topical medications.

- Adurocyte is the company's oxygen concentration gel specifically for moderate-to-severe burns. Management plans to test these products in combination with a controlled-release hydrogen peroxide for added effect. We expect that management would plan to partner Aduorcyte in sync with Wundecyte when ready.

- Management is conducting pre-IND work on its oxygen concentration gel for the treatment of mild-to-moderate acne vulgaris, an affliction that impacts nearly 20 million Americans each year. Oxygen Bio believes that Acnecyte has potential to reduce acne through a dual mechanism of action: 1) by increasing oxygen to the skin and promoting healthy blood vessel growth to reduce irritation and inflammation and 2) by killing the partially anaerobic bacteria (*P. acnes*) that is linked to causing acne. OTC acne treatments can cost as much as $30 to $60 per month. Prescription treatments can reach up to $200 per month. It is an estimated billion-dollar market for which Oxygen Bio will most likely partner for human clinical trials.

Future potential for the company's topical oxygen concentrated gel includes uses for the treatment of Rosacea with Rosacyte, radiation therapy with Protectocyte, and sexual stimulation with Duracyte. The indication for rosacea will probably be packed into a distribution / deal with Acnecyte. The use in radiation therapy treatment will require human clinical testing, which we do not expect to take place until calendar 2011.

Oxycyte Phase II TBI Program Ongoing…

On December 4, 2009, management announced the first patient had been enrolled studying Oxycyte in the company's phase IIb traumatic brain injury (TBI) program in Switzerland. STOP-TBI (Safety and Tolerability of Oxycyte in Patients with Traumatic Brain Injury) plans to enroll 98 patients presenting to the emergency room with traumatic brain injury. The dose escalation study will focus on finding the lowest dose of Oxycyte that provides clinical benefit in traumatic brain injury while minimizing adverse effects. Dose levels of Oxycyte will start at 1.0 ml/kg body weight and escalate in steps to 2.0 ml/kg, and 3.0 ml/kg for subsequent patient cohorts. Escalation of dose will only occur after a favorable review of safety data by an independent Data Safety Monitoring Board (DSMB). Data will be available after every dose cohort is evaluated. Full data is expected in 12 to 18 months.

In March 2010, management provided a brief update that the program was progressing as planned, with 33% of the first cohort now enrolled, including the first patients in Israel. We remind investors that there are a total of 11 sites for the program, 7 in Switzerland and 4 in Israel. We believe the company is on schedule to complete the first phase of this trial in the calendar second quarter 2010, with data to follow shortly after, perhaps by the middle of the calendar year 2010. An investigator meeting has already been scheduled. The second (45-50 people) and third (35-40 people) cohorts are on track to begin enrolling following the interim analysis of the first cohort.

Management has made the decision to withdraw the orphan drug designation request for Oxycyte in patients with severe, closed-head TBI. Market research yielded that there are too many incidences of this kind of TBI in the U.S. to meet the orphan designation criteria of fewer than 200,000 per year. It's a mixed bag regarding the outcome of this filing. We are disappointed that Oxygen Bio will not benefit from the market protection and tax benefits that come with an orphan designation, but we are early pleased that market research is showing a market size greater than 200,000 cases per year.

INVESTMENT THESIS

Does Oxycyte do what management says it does? (Key Efficacy Question)

In theory, Oxycyte has the potential to be a wonder drug – a sort of WD-40 of medicine. Preclinical data suggests that Oxycyte has astounding potential for the treatment of traumatic brain injury, decompression sickness, carbon monoxide poisoning, sickle cell crisis, organ preservation, and as a neuroprotectant in patients with myocardial infarction or stroke. The effects in TBI were clearly evident in the phase I program conducted by Oxygen Bio in 2006. Initial phase II data from STOP-TBI will become available around the middle of the year. Full data will be available in 2011. However, data from small animal studies show that intravenous injection of Oxycyte following lateral fluid percussion injury acts as a neuroprotectant in preserving neuronal cell counts and improving brain tissue oxygen consumption. Other small animal studies suggest that Oxycyte can improve circulating oxygen levels and cerebral blood flow following an induced ischemic stroke. These results suggest that Oxycyte treatment can greatly improved the cognitive recovery and prevent cell damage in patients with TBI, spinal cord injury, or ischemia due to MI or stroke. The high gas solubility characteristics of Oxycyte suggest significant potential in treating decompression sickness, carbon monoxide poisoning, and surgical iatrogenic air embolism. Our research turned up a significant number of journal articles and abstracts that support the empirical efficacy of PFC's and Oxycyte.

Is it safe? (Key Safety Question)

Oxycyte is biochemically and metabolically inert. It is thermally stable, and produces no immune response or antibody formation. Fluosol's clinical development was held up by concerns the drug initiated an immuno-suppressive effect. To date, Oxycyte has been shown to offer no interaction with the immune system. PFC's are clearly safer than hemoglobin based oxygen carrying solutions (HBOCs) when it comes to risk of vasoconstriction. Oxycyte also offers a significant advantage over donated blood in terms of type matching, stockpiling, and infection. The FDA's concern, which ultimately delayed the initiation of a phase II program in the U.S., was on the risk of thrombocytopenia (low platelet count). Theoretically there should be no reason why a small injection of Oxycyte should cause low platelet count. There were no signs of thrombocytopenia in the preclinical or phase I program.

For the phase II STOP-TBI program, management has established a "platelet and thrombocytopenia" task force to assess data collection along with an independent data safety monitoring board (DSMB). If management can alleviate the FDA's concerns on thrombocytopenia as a result of STOP-TBI, U.S. registration trials shouldn't be too far off. Besides TBI, we could see Oxycyte in clinical programs for decompression sickness (DCS) and spinal cord injury through a collaboration with the U.S. Navy. The U.S. Navy has established a $3.9 million budget through 2012 to determine he safety and effectiveness of PFCs in the treatment of DCS and arterial gas embolism (AGE). Oxygen Bio plans to push forward with this clinical work in calendar 2010.

Does Oxygen Bio have the cash to see this through? (Key Financial Question)

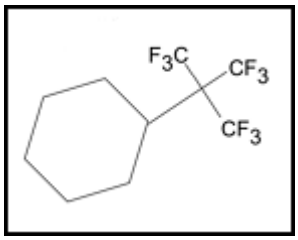
Oxygen Bio exited the fiscal third quarter 2010 (January 31, 2009) with $2.9 million in cash and investments. Burn for the first third quarters was $6.3 million. The current cash level is enough to fund operations into the calendar third quarter of 2010. We believe that management has the opportunity to prolong the current cash level by ramping sales of Dermacyte OTC, achieve the remaining $9 million in milestones from Vatea Fund, and convert a major portion of the $13 million in outstanding warrants. A priority for management in 2010 will be to license or partner Wundecyte for upfront cash to be able to continue the STOP-TBI program with Oxycyte.

OVERVIEW

For additional Details, See Our Initiation Report From October 2009.

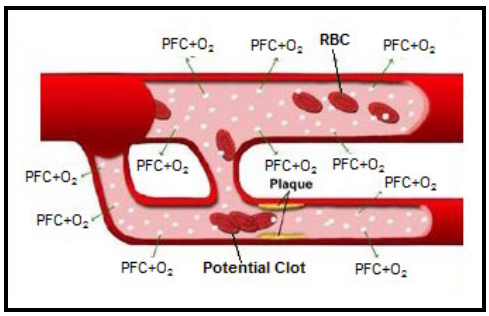
Oxycyte Technology:

Oxycyte (perfluoro-*tert*-butylcyclohexane, $C_{10}F_{20}$) is the company's third generation perfluorocarbon (PFC) therapeutic oxygen carrier. It is designed to enhance oxygen delivery to damaged tissues. When used as an intravenous emulsion, Oxycyte can carry as much as 4x the amount of oxygen as a normal red blood cell (RBC) despite being nearly 1/50th the size. Oxycyte has 50x greater O_2 solubility and diffusibility than RBCs and can move through the circulatory system at rates up to 2x the speed of hemoglobin. Thus, Oxycyte is highly efficient for transporting oxygen to tissues and carrying carbon dioxide (CO_2) to the lungs for disposal. Oxycyte is not a blood substitute because it does not include white blood cells, antibodies, or plasma. There are no supply issues and no disease transmission / typing or cross-matching limitations. It also has a shelf-life far greater than the 42 days for human donated blood. Oxygen Bio expects to market Oxycyte with a 12 to 18 month shelf-life, although in theory the product could last much longer given its chemically and thermally stable structure. And, because Oxycyte is not based on animal hemoglobin, it does not have the safety issues or antibody formation associated with hemoglobin-based products. In fact, Oxycyte is metabolically inert and offers acceptable organ elimination yielding a very favorable risk-benefit profile for its potential indications.



- ✓ Forms stable emulsion – Superior safety profile
- ✓ Metabolically inert – No antibody formation / No disease transmission
- ✓ Acceptable Organ Clearance / Appreciable Residence Time
- ✓ Carries 4x more O_2 than RBCs, 50x smaller than RBCs
- ✓ Offers 50x higher O_2 solubility and diffusibility
- ✓ Moves 2x faster than hemoglobin through blood stream
- ✓ No supply issues / No cross-matching limitations / Stable at room temp

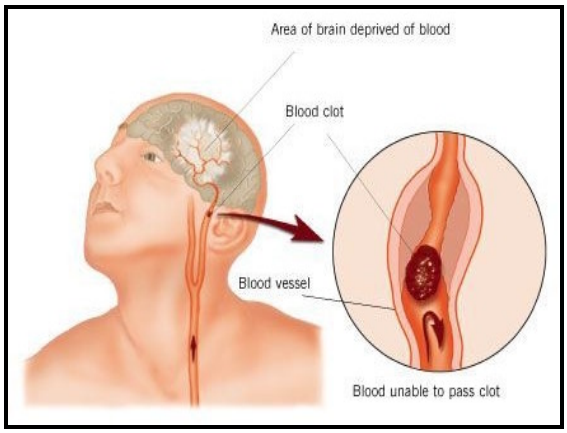
The above characteristics of Oxycyte massively enhance the ability of oxygen to get from the blood stream to the target tissues. Oxycyte acts as a sort of conduit by facilitating transport of oxygen through plasma. Oxycyte improves the solubility and diffusibility of blood plasma, a rather poor O_2 dissolving substance, by filing in the gaps between RBCs and plasma that previously inhibited transport. Size and movement, along with solubility, play a significant role in this process. Since Oxycyte is so small and moves so fast compared to RBCs, the candidate has obvious advantages in patients in low-oxygen stress post myocardial infarction or stroke. Oxycyte has the ability to quickly enter these areas or squeeze by a blockage or clot in the arteries far superior to RBCs. However, Oxycyte also offers potential uses for when damaged tissue requires oxygen for survival, such as in the area of traumatic brain injury, decompression sickness and arterial gas embolism, and severe wound treatment.

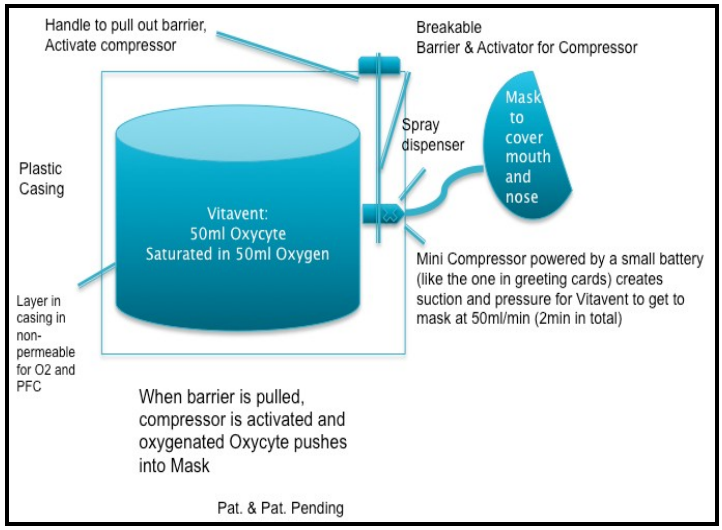


VitaVent For Emergency Ventilation

Traumatic brain injury, decompression sickness, carbon monoxide poisoning, and sickle cell crisis are all excellent potential commercialization avenues for Oxycyte. We are particularly interested in the carbon monoxide indication because it is a non-bleeding focused indication. This eliminates the risk of thrombocytopenia, a potential side effect that the FDA has been concerned with since the phase IIa program in 2006. Carbon monoxide poisoning looks like low-hanging fruit to management. However, the ultimate blockbuster indication for the use of Oxycyte is in cardiovascular disease, more specifically, in the emergency treatment of patients having an acute myocardial infarction or stroke. As noted above, Oxycyte participles are 1/50th the size of RBCs and carry 4x as much oxygen.

Oxycyte travels through the blood stream at rates up to 2x the speed of RBCs. PFC+O_2 have the potential to quickly get to and squeeze by a blocked area, providing oxygen to dying cells. There are an estimated 1.5 million heart attacks and 700k strokes each year. For stroke, only 20-25% of stroke patients arrive at the hospital in less than 3 hours. Over 50% are left with some degree of paralysis or disability as a result. This presents an enormous opportunity to treat patients with ischemia due to a heart attack or blocked artery.





Oxygen Bio is developing VitaVent, a portable inhalation device that is being designed to enhance the delivery of oxygen in the lungs as a pre-hospital "hyperoxygenation" treatment. The initial prototype for VitaVent is a 50ml Oxycyte solution saturated in 50ml pure oxygen, enclosed in a plastic non-permeable casing. VitaVent offers significant advantages over portable oxygen inhalers in that the device has limited mechanical parts, uses no pressure, initiates by no chemical reaction, and has a potential shelf-life of 12 to 18 months. When a patient wants to use the device he/she would simply cover their mouth with a small mask and then break the seal on the container allowing a small battery powered compressor to deliver the solution into the lungs in less than 2 minutes. PFC+O_2 would quickly enter the blood stream potentially saving heart or brain tissue from ischemic death.

The device could be placed in households, cars, public buildings, offices, schools, and restaurants. At risk patients can purchase VitaVent and carry the device around or keep it in their car. The potential target market for VitaVent is enormous. We could see 50 million Americans looking to own VitaVent. Management envisions a target price of $100 per device for VitaVent. The product is still in the early-stage development. Oxygen Bio plans to file a new device application with the FDA prototype when development work has been completed.

Stock Worth A Look…Target is $15…

We currently have an 'Outperform' rating on the shares. Despite what has been a tumultuous past for the company and an abysmal fate for competitors attempting to develop similar products, the potential upside that Oxycyte offers is too significant too ignore. Our 'Outperform' rating should be taken as a message to investors – pay attention to what is going on at Oxygen Bio. We do not recommend piling into the stock or backing up the proverbial "truck" at this point. Risks are still high and the company is still a few years away from sustained profitability. The majority of the indications for Oxycyte injection or the topical gels are still in preclinical trials.

Normally we would not recommend investors acquire shares in a company based on preclinical data alone, but Oxycyte, and PFC's in general, have been well studied over the past decade. The science is easy to understand and the theoretical potential is exciting to extrapolate. Not many biotech companies are sitting with a possible blockbuster drug (a full pipeline platform actually) in waiting if successfully developed.

We have performed a detailed NPV analysis for each potential indication for both injectable and topical Oxycyte using an aggressive 30% discount rate in our calculations, and arrived at a fair market value of $301 million. Based on the current weighted-average shares outstanding, we arrive at a price target of $15 per share.

PROJECTED FINANCIALS

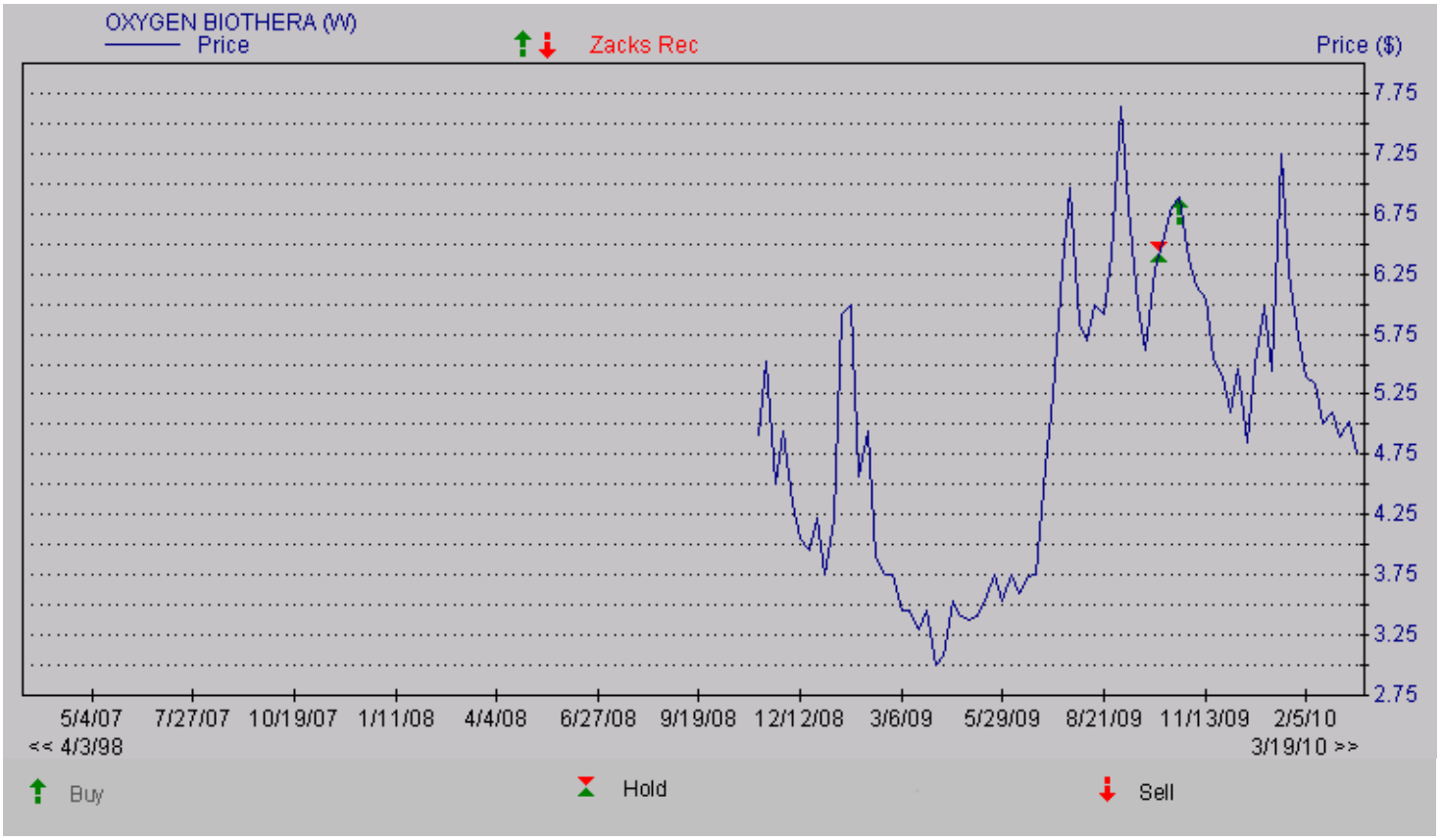
Oxygen Biotherapeutics, Inc. – Income Statement

	Apr-08	Apr-09	Jul-09	Oct-09	Jan-10	Apr-10	Apr-10	Apr-11	Apr-12	Apr-13
Fiscal Year	**2008 A**	**2009 A**	**Q1 A**	**Q2 A**	**Q3 A**	**Q4 E**	**2010 E**	**2011 E**	**2012 E**	**2013 E**
Total Product Sales	**$0**	**$0**	**$0**	**$0**	**$0**	**$0.20**	**$0.20**	**$2.50**	**$6.00**	**$9.50**
YOY Growth	-	-	-	-	-	-	-	*1150.0%*	*140.0%*	*58.3%*
Licensing & Collaborative	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$2.00**	**$2.20**	**$2.50**
YOY Growth	-	-	-	-	-	-	-	-	*10.0%*	*13.6%*
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0.20**	**$0.20**	**$4.50**	**$8.20**	**$12.00**
YOY Growth	-	-	-	-	-	-	-	*2150.0%*	*82.2%*	*46.3%*
Cost of Goods Sold	$0	$0	$0	$0	$0	$0.05	$0.05	$0.63	$1.50	$2.38
Product Gross Margin	-	-	-	-	-	-	-	-	-	-
SG&A	$2.02	$7.00	$1.75	$2.19	$1.75	$1.85	$7.53	$8.00	$8.65	$9.55
% SG&A	-	-	-	-	-	-	-	-	-	-
R&D	$0.94	$1.60	$0.55	$0.41	$1.01	$1.05	$3.01	$3.75	$4.50	$5.50
% R&D	-	-	-	-	-	-	-	-	-	-
Operating Income	($2.96)	($8.60)	($2.29)	($2.59)	($2.76)	($2.75)	($10.40)	($7.88)	($6.45)	($5.43)
Interest & Other Net	($3.61)	($24.86)	($0.11)	$0.00	($0.01)	($0.29)	($0.40)	($1.10)	($0.98)	($0.87)
Pre-Tax Income	($6.58)	($33.46)	($2.40)	($2.59)	($2.78)	($3.04)	($10.80)	($8.98)	($7.43)	($6.30)
Taxes / Other	$0	$0	$0	$0	$0	$0	$0	$0	$0	($0.3)
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*5.0%*
Net Income	($6.58)	($33.46)	($2.40)	($2.59)	($2.78)	($3.04)	($10.80)	($8.98)	($7.43)	($5.98)
YOY Growth	-	-	-	-	-	-	-	-	-	-
Reported EPS (Basic)	**($0.70)**	**($2.90)**	**($0.15)**	**($0.13)**	**($0.13)**	**($0.14)**	**($0.55)**	**($0.36)**	**($0.25)**	**($0.18)**
YOY Growth	-	-	-	-	-	-	-	-	*-31.0%*	*-25.7%*
Wt. Ave. Shares Outstanding	9.4	11.6	16.4	19.6	20.6	22.5	19.8	25.0	30.0	32.5

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

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HISTORICAL ZACKS RECOMMENDATIONS



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