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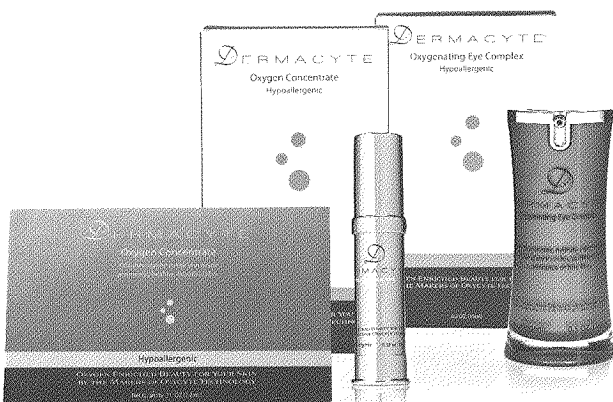
# Oxygen Biotherapeutics®

*Employing O<sub>2</sub>. Preserving Life.*

## A b o u t   t h e   C o m p a n y

Oxygen Biotherapeutics, Inc. is dedicated to commercializing intravenous and topical pharmaceuticals, and personal care products in the field of oxygen therapeutics. The Company has developed a proprietary perfluorocarbon (PFC) therapeutic oxygen carrier and liquid ventilation product called Oxycyte® PFC. This versatile PFC is being tested for use in treating traumatic brain injury, decompression sickness, spinal cord injury and wound healing.

In addition, the Company is also developing and commercializing a line of oxygen-rich personal skin care products for the beauty and cosmetic market. In April 2010, the company launched Dermacyte® Oxygen Concentrate, which is a highly concentrated cream to be used as a "spot" treatment for the skin. In August 2010, we introduced Dermacyte® Oxygenating Eye Complex for reducing dark circles, puffiness and the appearance of fine lines around the contour of your eyes. These creams and gels incorporate the company's oxygen carrier technology to deliver oxygen to the skin.



## T o u r S h a r e h o l d e r s



Chris Stern

### Dear Fellow Shareholders,

Sun Tzu said, "There are not more than five musical notes, yet the combinations of these five give rise to more melodies than can ever be heard." We believe Oxygen Biotherapeutics epitomizes that statement. This fiscal year, we advanced our Oxycyte® perfluorocarbon emulsion (PFCE) into Phase II-B clinical trials; introduced skin care products; conducted wound healing preclinical trials; funded preclinical research for spinal cord injury; entered into binding agreements with the U.S. Navy; secured over \$15 million in funding; executed a 1-for-15 reverse stock split; moved trading in our stock from the Bulletin Board to NASDAQ; and in June listed on the SIX Swiss Exchange.

Until recently, we focused almost entirely on developing Oxycyte for traumatic brain injury (TBI) and as a blood substitute. While interesting, the company moved at

a snail's pace. That has changed. For starters, in 2008 we shelved the blood substitute program. We maintained TBI as a priority, however it is now supplemented by what we believe are nearer-term revenue opportunities. New directors and management now are highly focused on commercializing products in the short-, medium- and long-term. That is a key reason why we dedicated resources to the beauty and topical fields.

Some shareholders thought skin care changed the company's focus. However, we believe it improved our focus. Dermacyte is an immediate opportunity with excellent potential. More importantly, it offers a chance to gain revenue in support of our long-term programs. Currently, Dermacyte is sold to consumers online via [www.buydermacyte.com](http://www.buydermacyte.com) and through spas and medical offices. Furthermore, as a small company we recognize the high hurdles we will need to clear to place our beauty products on department store shelves. Therefore, the second aspect of our Dermacyte commercialization strategy is to partner with a major cosmetic company. We are actively developing relationships with major cosmetic companies. Again, Sun Tzu guides us. "There are not more than five cardinal tastes (sour, acrid, salt, sweet, bitter), yet combinations of them yield more flavors than can ever be tasted."

Topical indications for wound healing and other dermatological applications fill the

medium-term development pipeline. Called Wundecyte™, it is a novel gel that we plan to test alone and with an oxygen-generating bandage. The bandage entered preclinical testing in June 2010.

Acute medical applications of Oxycyte round out our pipeline. We are conducting a Phase II-B double-blind, placebo-controlled dose escalation trial for severe TBI patients in Switzerland and Israel. We are setting up sites in India as well. Because people now wear helmets when at risk, fewer *severe* TBI incidences occur in both civilians and soldiers. We are, therefore, considering *mild* TBI as an extension of this program. Preclinical studies using Oxycyte for spinal cord injury have been performed at the University of Miami. Reports showed that Oxycyte has a marked neuroprotective effect in a rat model of spinal cord injury. Likewise, results from U.S. Navy studies demonstrated decreased mortality in models that were given an intravenous dose of Oxycyte after the onset of decompression sickness. This data was published in the June issue of *Aviation Space and Environmental Medicine*. Such positive results led to the signing of a Cooperative Research and Development Agreement with the Navy in August for decompression sickness. Again, Sun Tzu's timeless wisdom leads us: "There are not more than five primary colors (blue, yellow, red, white, black), yet in combination they produce more hues than can ever been seen."

#### Financial Update

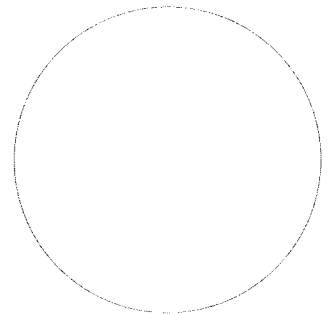
This year we raised approximately \$10.7 million in net proceeds from the Vatea Fund and approximately \$4.4 million in net proceeds from a direct registered offering. In FY2010, we invested approximately \$2.9 million in R&D compared with \$1.6 million in FY2009. We increased total operating expenses from \$8.6 million to \$10.2 million year over year without generating revenues. That fact is not lost on us. We are diligently pursuing sales of our new Dermacyte line and are moderating expenses as much as possible, while still investing in our R&D initiatives. We are actively pursuing additional financing through licensing and collaborative agreements, as well as government grants. Sun Tzu would say, "In financing a company, there are not more than two methods—the direct and the indirect; yet these two in combination give rise to an endless series of maneuvers."

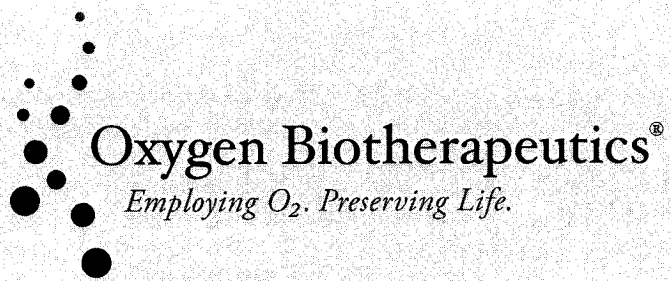
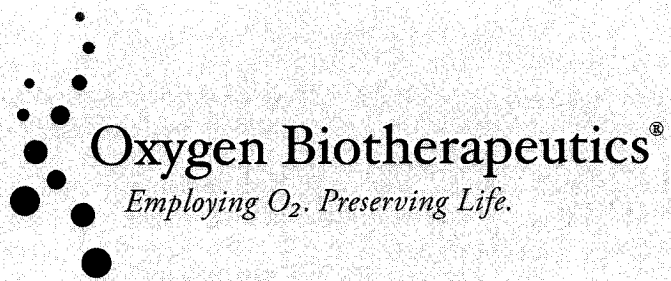
Our goals and strategy are clear, and our motivation is high. We are aggressively working to make this company a profitable and self-sustaining entity. We appreciate your support as we continue along this path. I look forward to updating you on our progress.

Respectfully,



Chris Stern  
Chairman &  
Chief Executive Officer





Oxygen Biotherapeutics®

*Employing O<sub>2</sub>. Preserving Life.*

F o r m I 0 - K

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington D.C., 20549**

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**FORM 10-K**

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**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934**

**For the Fiscal Year Ended April 30, 2010**

**Commission File No. 001-34600**

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**OXYGEN BIOTHERAPEUTICS, INC.**  
(Exact name of registrant as specified in its charter)

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**Delaware**                      **26-2593535**  
(State of Incorporation) (IRS Employer I.D. Number)

**2530 Meridian Parkway, Suite 3078, Durham, North Carolina 27713**  
(Address of Principal Executive Offices) (Zip Code)

**Registrant's Telephone Number and area code: (919) 806-4414**

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**Securities registered pursuant to Section 12(b) of the Act:**

<u>Title of Each Class</u>	<u>Name of Each Exchange on Which Registered</u>
Common Stock, \$0.0001 par value per share	The NASDAQ Stock Market LLC

**Securities registered pursuant to Section 12(g) of the Act: NONE**

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Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to the this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company.

Large Accelerated Filer  Accelerated Filer

Non-Accelerated Filer  Smaller Reporting Company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter: \$115,937,950.

The number of shares outstanding of the registrant's class of \$0.0001 par value common stock as of July 20, 2010 was 23,376,281.

DOCUMENTS INCORPORATED BY REFERENCE:

Proxy Statement for the 2010 Annual Meeting of Stockholders is incorporated by reference in Part III to the extent described therein.

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## TABLE OF CONTENTS

ITEM NUMBER AND CAPTION	Page
<b>Part I</b>	
1. Business	3
1A. Risk Factors	8
1B. Unresolved Staff Comments	18
2. Properties	18
3. Legal Proceedings	18
4. (Removed and Reserved)	18
<b>Part II</b>	
5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	19
6. Selected Financial Data	20
7. Management's Discussion and Analysis of Financial Condition and Results of Operations	20
7A. Quantitative and Qualitative Disclosures About Market Risk	28
8. Financial Statements and Supplementary Data	29
9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	55
9A. Controls and Procedures	55
9A. (T) Controls and Procedures	56
9B. Other Information	56
<b>Part III</b>	
10. Directors, Executive Officers, and Corporate Governance	57
11. Executive Compensation	57
12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	57
13. Certain Relationships and Related Transactions, and Director Independence	57
14. Principal Accountant Fees and Expenses	57
<b>Part IV</b>	
15. Exhibits and Financial Statement Schedules	58



## PART I

### FORWARD-LOOKING STATEMENTS

All statements contained in this report, other than statements of historical fact, which address activities, actions, goals, prospects, or new developments that we expect or anticipate will or may occur in the future, including plans for clinical tests and other such matters pertaining to testing and development products, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "should", "expects", "plans", "anticipates", "believes", "estimates", "predicts", "potential" or "continue" or the negative of such terms or other comparable terminology. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including, but not limited to, progress in our product development and testing activities, obtaining financing for operations, development of new technologies and other competitive pressures, legal and regulatory initiatives affecting our products, conditions in the capital markets, the risks discussed in Item 1A – "Risk Factors," and the risks discussed elsewhere in this report that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activities, performance or achievements expressed or implied by such forward-looking statements.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of such statements. We are under no duty to update any of the forward-looking statements after the date of filing of this report or to conform such statements to actual results.

All references in this Annual Report to "Oxygen Biotherapeutics", "we", "our" and "us" means Oxygen Biotherapeutics, Inc.

### ITEM 1—BUSINESS

#### Overview

Oxygen Biotherapeutics is engaged in the business of developing biotechnology products with a focus on oxygen delivery to tissue. We are currently developing Oxycyte®, a product we believe is a safe and effective oxygen carrier for use acute medical situations. We have developed a family of perfluorocarbon-based oxygen carriers for use in personal care, topical wound healing, and other topical indications. In addition, we also have under development Vitavent™ (formerly called Fluorivent™), an oxygen exchange fluid for facilitating the treatment of lung conditions, and we have out-licensed our rights to a biosensor implant product that uses an enzyme process for measuring the glucose level in subcutaneous fluid. We currently believe that our priority for the foreseeable future will be continuing to develop Oxycyte, Dermacyte and Wundecyte, since we believe the topical products deserve a higher priority due to their greater opportunity for nearer-term commercialization compared to our clinical products.

Oxygen Biotherapeutics was originally formed as a New Jersey corporation in 1967 under the name Rudmer, David & Associates, Inc., and subsequently changed its name to Synthetic Blood International, Inc. Effective June 30, 2008, we changed the domiciliary state of the corporation to Delaware and changed the company name to Oxygen Biotherapeutics, Inc.

#### Oxygen to Tissue Delivery Market

The principal function of human blood is to transport oxygen throughout the body. The lack of an adequate supply of oxygen as a result of blood loss can lead to organ dysfunction or death. The transfusion of human blood is presently the only effective means of immediately restoring diminished oxygen-carrying capacity resulting from blood loss. According to the AABB 2005 Nationwide Blood Collection and Utilization Report, over 14 million units of whole blood and red blood cells were transfused in the United States in 2004. This includes transfusions for trauma, surgery (emergency and elective), unexpected blood loss, chronic anemia, and other general medical applications.

The use of donated blood in transfusion therapy, while effective in restoring an adequate supply of oxygen in the body of the recipient, has several limitations. Although testing procedures exist to detect the presence of certain diseases in blood, these procedures cannot eliminate completely the risk of blood-borne disease. Transfused blood also can be used only in recipients having a blood type compatible with that of the donor. Delays in treatment, resulting from the necessity of blood typing prior to transfusion, together with the limited shelf life of blood and the limited availability of certain blood types, impose constraints on the immediate availability of compatible blood for transfusion. There is no commercially available blood substitute in this country that addresses these problems. The regulatory authorities in the U.S. are very skeptical regarding blood substitutes and Oxygen Biotherapeutics assessed chances of getting a blood substitute approved by the U.S. Food and Drug Administration, or FDA, as very limited. Therefore, Oxygen Biotherapeutics changed its direction away from synthetic blood to oxygen to tissue delivery.

Oxycyte is intended as an oxygen carrier that ordinarily would be applied in cases of trauma, surgery (emergency and elective), and other general medical applications. For trauma and emergency surgical procedures, Oxycyte's immediate availability, universal compatibility, and the absence of risk of blood borne diseases provide significant advantages over transfused blood or other proposed oxygen delivery systems based on biological material.

We believe there exist potential sources of demand for which blood is not currently utilized and for which Oxycyte may be suitable. These include applications in which the required blood type is not immediately available or in which transfusions are desirable but not given for fear of a transfusion reaction due to difficulty in identifying compatible blood. For example, we believe emergenciers and surgicenters both experience events where an oxygen-carrying fluid may be useful. We also believe Oxycyte may be used by emergency medical technicians in ambulances, medical helicopters and other pre-hospital settings. In addition, the military has expressed a high level of interest in oxygen-carrying products for the treatment of battlefield injuries.

Based on these circumstances, we believe there may be a substantial and meaningful market for an effective oxygen carrier, and we believe Oxycyte is a viable candidate for exploiting that market.

Elements of our business strategy are:

- To grow revenue by establishing a partnership with a company that specializes in the global cosmetic and beauty industry. We believe this approach will enable us to commercialize our Dermacyte personal skin care products by providing access to top-line retail consumer point of sales.
- To grow revenue by selling our personal skin care products to medically oriented channels, such as dermatologists, plastic surgeons, and medical spas, via an internal hybrid sales model consisting of internal sales professionals and contract sales representatives. We also intend to grow revenue via on-line sales to consumers.
- To develop and out-license topical formulations, mainly for wound healing, acne and rosacea.
- To provide medical alternatives to our military personnel and others. Currently we are developing and supporting the development of new treatments for Traumatic Brain Injury, or TBI, and decompression sickness, or DCS, respectively. We intend to complete our ongoing phase II-b clinical trial for Oxycyte emulsion in Traumatic Brain Injury, which has become one of the most prolific injuries faced by soldiers today. In addition, we support the U.S. Navy's efforts to investigate using Oxycyte for the treatment of DCS by supplying the U.S. Navy with Oxycyte emulsion for their trials.

#### ***Oxycyte® product***

Our Oxycyte oxygen carrier product is a perfluorocarbon, or PFC, emulsified with water and a surfactant, which is provided to the patient intravenously. The physical properties of PFC enable our product to gather oxygen from the lungs and transport the oxygen through the body releasing it along the way. Over a period of days Oxycyte gradually evaporates in the lungs from where it is exhaled. Oxycyte requires no cross matching, so it is immediately available and compatible with all patients' blood types. Oxycyte has an extended shelf life compared to blood. Oxycyte is provided as a sterile emulsion ready for intravenous administration. Because it contains no biological components, there is no risk of transmission of blood-borne viruses from human blood products. Further, since Oxycyte is based on readily available inert compounds, we believe it can be manufactured on a cost-effective basis in amounts sufficient to meet demand.

We received approval of our Investigational New Drug application, or IND, for severe TBI filed with the U.S. Food and Drug Administration, or FDA, and began Phase I clinical studies in October 2003, which were completed in December 2003. We submitted a report on the results to the FDA along with a Phase II protocol in 2004. Phase II-A clinical studies began in the fourth quarter 2004, and were completed in 2006. A further Phase II study protocol was filed with the FDA in the spring of 2008, but was put on clinical hold by the FDA due to safety concerns raised by the regulatory agency. After receiving this clinical hold, we filed a revised protocol as a dose-escalation study with the regulatory authorities in Switzerland and Israel. The protocol received Ethic Commission approval in Switzerland and Israel. The relevant Swiss regulatory body approved the protocol in August 2009, and the Israel Ministry of Health approved the protocol in September 2009. The new study began in October 2009 and is currently under way both in Switzerland and Israel. In March 2010, we determined that it is feasible to simplify the trial design and also reduce the number of patients to be enrolled. In May 2010, we entered into a relationship with a contract research organization to assist us as we expand our study into India to initiate five to ten new sites for our Phase II-b clinical trial. Study objectives, safety and efficacy endpoints would remain unchanged, and we feel with these optimizations the study could be concluded faster and more economically. We expect to commit a substantial portion of our financial and business resources over the next three years to testing Oxycyte and advancing this product to regulatory approval for use in one or more medical applications.

Should Oxycyte successfully progress in clinical testing and it appears regulatory approval for one or more medical uses is likely, either in the United States or in another country, we will evaluate our options for commercializing the product. These options include licensing Oxycyte to a third party for manufacture and distribution, manufacturing Oxycyte ourselves for distribution through third party distributors, manufacturing and selling the product ourselves, or establishing some other form of strategic relationship for making and distributing Oxycyte with a participant in the pharmaceutical industry. We are currently investigating and evaluating all options.

If approved for one or more medical uses, Oxycyte will compete directly with established therapies for acute blood loss and replacement and may compete with other technologies currently under development. We cannot ensure that Oxycyte will have advantages, which will be significant enough to cause medical professionals to adopt it rather than continue to use established therapies or other new technologies or products. We also cannot ensure that the price of Oxycyte, in light of Oxycyte's potential advantages, will be competitive with the price of established therapies or other new technologies or products.

Several companies have developed, or are in the process of developing, technologies that are, or in the future may be, the basis for products that will compete with Oxycyte. We are aware of five other products at various stages of development that are intended to achieve the same result as Oxycyte. Three of these products are based on hemoglobin derivatives, two from outdated human blood and the third from bovine blood. One product is also based on perfluorocarbon and the other on nanobubble oxygen technology. None of these products is approved for use in the United States. The bovine-source hemoglobin-based oxygen-carrier has been approved for human use in South Africa and a Biologics License Application, or BLA, was submitted to the FDA for its use in the United States, and this was not approved and no clinical trials in the United States are currently underway. All hemoglobin based products were targets of a very critical meta-analysis in the JAMA, the Journal of the American Medical Association, (May 21, 2008, p. 2304ff, www.jama.com) which concluded that "based on the available data, use of HBBs (Hemoglobin-based blood substitutes) is associated with a significantly increased risk of death or MI (myocardial infarction)". Phase III clinical trials on the other perfluorocarbon product in the U.S. were halted in 2001 and have not resumed. That product has now been licensed for development with a drug manufacturer in China.

We believe that important competitive factors in the market for oxygen carrier products will include the relative speed with which competitors can develop their respective products, complete the clinical testing and regulatory approval process, and supply commercial quantities of their products to the market. In addition to these factors, competition is expected to be based on the effectiveness of oxygen carrier products and the scope of the intended uses for which they are approved, the scope and enforceability of patent or other proprietary rights, product price, product supply, and marketing and sales capability. We believe that our competitive position will be significantly influenced by the timing of the clinical testing and regulatory filings for Oxycyte, our ability to maintain and enforce our proprietary rights covering Oxycyte and its manufacturing process, and our ability to develop capabilities for manufacturing and distributing the product ourselves or with others, should we obtain regulatory approval.

#### ***Dermacyte® products***

The Dermacyte line of topical cosmetic products employs our patented PFC technology and other known cosmetic ingredients to promote the appearance of skin health and other desirable cosmetic benefits. Dermacyte is designed to provide a moist and oxygen-rich environment for the skin when it is applied topically, even in small amounts. Dermacyte Concentrate has been formulated as a cosmetic in our lab and Dermacyte Eye Complex was created by a contract formulator, with the patent held by Oxygen Biotherapeutics. Both formulas have passed all safety and toxicity tests, and we have filed a Cosmetic Product Ingredient Statement, or CPIS, with the FDA. The market for oxygen-carrying cosmetics includes anti-aging, anti-wrinkle, skin abrasions and minor skin defects.

In September 2009, we started production of our first commercial product under our topical cosmetic line, Dermacyte Concentrate. We produced and sold a limited pre-production batch in November 2009 as a market acceptance test. The product was sold in packs of 8 doses of 0.4ml. Based on the test market results we identified specific market opportunities for this product and reformulated Dermacyte Concentrate for better product stability. Marketing and shipments of the new Dermacyte Concentrate formulation began in April 2010. We have also developed a 10ml pump package for Dermacyte Concentrate that should be available for market this summer. We worked with a contract formulator in California to develop the Dermacyte Eye Complex which contains PFC technology as well as other ingredients beneficial to the healthy appearance of the skin around the eyes. We anticipate that both formulations should be ready for sale by the second quarter of fiscal 2011.

We market and sell these products through [www.buydermacyte.com](http://www.buydermacyte.com) and to dermatologists and medical spas with a combination of in-house sales and exclusive distributors. We have hired a sales manager based in New York, and we intend to add sales people in other major urban areas like Los Angeles and Miami. We have entered into an agreement with a sales representative for the territories of Arizona and Michigan, and we intend to add more territories with agents or distributors.

Additional potential topical applications of our PFC technology that are under development include:

- Dermacyte Moisturizing Lotion: an evolution of the Dermacyte line that will contain SPF to protect the skin from UV-rays while beautifying.
- Rosacyte: incorporates perfluorocarbon technology to be used as a healing gel against rosacea.
- Acnecyte: incorporates perfluorocarbon technology to be used as a healing gel against acne.

## ***Wundecyte™ products***

Our wound product, Wundecyte, is a novel gel developed under a contract agreement with a lab in Virginia. Wundecyte is designed to be used as a wound-healing gel. In July 2009, we filed a 510K medical device application for Wundecyte with the FDA. Several oxygen-producing and oxygen-carrying devices were cited as predicate devices. The FDA response was that the application likely would be classified as a combination device. The drug component of the combination device will require extensive preclinical and clinical studies to be conducted prior to potential commercialization of the product.

We have also developed an oxygen-generating bandage that can be combined with Wundecyte gel. Wundecyte gel and the oxygen-generating bandage both entered preclinical testing in our first quarter of fiscal 2011. The studies will look at factors such as time to wound closure and reduction in scar tissue formation as compared to a control group. Preliminary results are expected later this year. Our current product development plan is for Wundecyte to emerge into more complex wound-healing indications, also in combination with oxygen-producing technologies based on hydrogen peroxide.

Additionally, we are developing preclinical research protocols for the treatment of burns and other topical indication based on our PFC. We intend to develop additional clinical research protocols for topical indications, including the treatment of acne and rosacea. However, we can provide no assurance that the topical indications we have under development will prove their claims and be successful commercial products.

## **Suppliers**

We are actively pursuing agreements with multiple manufacturers to ensure we are able to consistently obtain our raw materials and topical products timely, within our defined specifications, and at competitive prices.

Our PFC is currently manufactured by a privately held, domestic manufacturing company. We have obtained exclusive manufacturing rights for our PFC, and we strengthened these rights with documentation of the manufacturer's critical formulations and processes. This documentation is being held in escrow and will revert to us in the event the manufacturer undergoes a change-of-control or fails to remain a going concern.

In May 2009 we entered into a supply agreement with Hospira, Inc. to manufacture our Oxycyte emulsion in commercial-sized batches for clinical use. We learned recently that on April 12, 2010, the FDA issued a warning letter to Hospira that the FDA had identified significant violations of Current Good Manufacturing Practice regulations at Hospira's manufacturing facilities in North Carolina. Among other things, the warning letter indicated to Hospira that these violations cause the drug products that it manufactures in these facilities to be adulterated. The Oxycyte used by us currently in our clinical trials was not produced by Hospira but by PrimaPharm; however, PrimaPharm is unable to produce Oxycyte in the quantity required to support long-term clinical trials and commercialization of our product. We currently believe that Oxycyte produced by PrimaPharm will be sufficient to conduct our clinical trials for several months. We are currently in discussions with Hospira regarding its intentions to remedy the CGMP regulation violations in order to meet our future manufacturing needs.

Our cosmetic formulations are manufactured by multiple domestic contract manufacturers.

## **Intellectual Property**

### ***Patents***

Developing and having access to intellectual property is a priority for our Company. We seek to protect our inventions and technology through the use of patents, trade secrets and proprietary know-how. To date, we own or in-license the rights to 8 U.S. and foreign patents. In addition, we have numerous U.S. patent applications pending that are complemented by the appropriate foreign patent applications related to our product candidates and proprietary processes, methods and technologies. Our issued and in-licensed patents, as well as our pending patents, expire between 2014 and 2030. The weighted-average-remaining life of our issued patents and licensed patents is 12.6 years and 18.6 years, respectively.

We have:

- three U.S. patents (5,824,703; 5,840,767; 6,167,887), three Australian patents (690,277; 722,417; 759,557), and two Canadian patents (2,239,170; 2,311,122) pertaining to the use and application of PFCs as gas transport agents in blood substitutes and liquid ventilation;
- exclusive in-licenses to three fundamental gas transport patent applications that represent the core technology used in our products and product candidates; and
- numerous patent applications for treatment of several medical and dermatological conditions such as TBI, acne, burns and wounds.

Our patent and patent applications include claims covering:

- methods to treat certain diseases and conditions and for biological gas exchange;
- therapies for burn and wound victims;
- delivery of oxygenated PFC;
- various formulations containing PFC; and
- methods and compositions for controlled and sustained production and delivery of peroxide and/or oxygen for biological and industrial applications.

### ***Trademarks and Domains***

We have received U.S. trademark registrations for Oxycyte®, Dermacyte®, Defense Medicine® and Oxygen Biotherapeutics®, Employing O<sub>2</sub> Preserving Life®. We have trademark applications pending for the following marks: Acnecyte™, DIFT™, At the Forefront of Defense Medicine™, Wundecyte™, Duracyte™, Vitavent™, Obipet™ and Obivet™.

In addition, we own numerous domain names relevant to our business, such as [www.oxygenbiotherapeutics.com](http://www.oxygenbiotherapeutics.com), [www.buydermacyte.com](http://www.buydermacyte.com), [www.oxybiomed.com](http://www.oxybiomed.com), and others.

### **Government regulation**

The manufacture and distribution of Oxycyte, as well as our other products, and the operation of our manufacturing facilities will require the approval of United States government authorities as well as those of foreign countries. In the United States, the FDA regulates medical products. The Federal Food, Drug and Cosmetic Act and the Public Health Service Act govern the testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of Oxycyte. In addition to FDA regulations, we are also subject to other federal and state regulations, such as the Occupational Safety and Health Act and the Environmental Protection Act. Product development and approval within this regulatory framework requires a number of years and involves the expenditure of substantial funds.

The steps required before a biological product may be sold commercially in the United States include pre clinical testing, the submission to the FDA of an IND, clinical trials in humans to establish the safety and effectiveness of the product, the submission to the FDA of a BLA, relating to the product and the manufacturing facilities to be used to produce the product for commercial sale, and FDA approval of a BLA. After a BLA is submitted there is an initial review by FDA to be sure that all of the required elements are included in the submission. There can be no assurance that the application will be accepted for filing or that the FDA may not issue a refusal to file, or RTF. If a RTF is issued, there is opportunity for dialogue between the sponsor and the FDA in an effort to resolve all concerns. There can be no assurance that such a dialogue will be successful in leading to the filing of the BLA. If the submission is filed, there can be no assurance that the full review will result in product approval.

Pre-clinical tests include evaluation of product chemistry and studies to assess the safety and effectiveness of the product and its formulation. The results of the pre-clinical tests are submitted to the FDA as part of the application. The goal of clinical testing is the demonstration in adequate and well-controlled studies of substantial evidence of the safety and effectiveness of the product in the setting of its intended use. The results of pre clinical and clinical testing are submitted to the FDA from time to time throughout the trial process. In addition, before approval for the commercial sale of a product can be obtained, results of the pre clinical and clinical studies must be submitted to the FDA in the form of a BLA. The testing and approval process requires substantial time and effort and there can be no assurance that any approval will be granted on a timely basis, if at all. The approval process is affected by a number of factors, including the severity of the condition being treated, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. Additional pre-clinical studies or clinical trials may be requested during the FDA review process and may delay product approval. After FDA approval for its initial indications, further clinical trials may be necessary to gain approval for the use of a product for additional indications. The FDA may also require post-marketing testing, which can involve significant expense, to monitor for adverse effects.

Among the conditions for BLA approval is the requirement that the prospective manufacturer's quality controls and manufacturing procedures conform to FDA requirements. In addition, domestic manufacturing facilities are subject to biennial FDA inspections and foreign manufacturing facilities are subject to periodic FDA inspections or inspections by the foreign regulatory authorities with reciprocal inspection agreements with FDA. Outside the United States, we are also subject to foreign regulatory requirements governing clinical trials and marketing approval for medical products. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country.

Our regulatory strategy is to pursue Phase II clinical testing and initial regulatory approval of Oxycyte in Switzerland, and Israel. We then intend to use the results of these tests to pursue FDA approval for Phase III clinical tests and marketing approval of Oxycyte in the United States.

## Research and Development

Our research and development efforts have been, and will continue to be focused on furthering the development and manufacture of Oxycyte for its use in clinical indications, primarily traumatic brain injury, spinal cord injury, and decompression sickness. We will also focus on developing Dermacyte and Wundecyte through further investments in preclinical and clinical studies. During the fiscal years ended April 30, 2010 and 2009, we spent approximately \$2.9 million and \$1.6 million, respectively, on Research and Development.

## Employees

As of April 30, 2010, we had 24 full-time employees, including five officers: Our Chief Executive Officer, President and Chief Operations Officer, Chief Financial Officer, Chief Medical Officer, and our Vice President of Governmental and Military Affairs. Our employees are not represented by a union or any other form of collective bargaining unit.

## ITEM 1A—RISK FACTORS

### Risks Related to Our Financial Position and Need for Additional Capital

***We have a history of net losses. Currently, we have one product available for commercial sale, and to date we have not generated any significant product revenue. As a result, we expect to continue to incur substantial net losses for the foreseeable future.***

We have incurred significant net losses and negative cash flow in each year since our inception, including net losses of approximately \$10.5 million and \$33.2 million for the years ended April 30, 2010 and 2009, respectively. As of April 30, 2010, we had a deficit accumulated during development stage of approximately \$81.5 million. We have devoted most of our financial resources to research and development, including our preclinical development activities and clinical trials. We expect to have substantial expenses as we continue with our Phase II-B clinical program for Oxycyte, our most advanced clinical product candidate, and as we conduct other clinical trials. In addition, if we are required by applicable regulatory authorities, including the FDA, to perform studies in addition to those we currently anticipate, our expenses will increase beyond expectations and the timing of any potential product approval may be delayed. We also expect an increase in our expenses associated with our manufacturing work and the commercialization of our Dermacyte cosmetic line. In addition, we expect to continue to incur costs to support operations as a public company. As a result, we may continue to incur substantial net losses and negative cash flow for the foreseeable future. These losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of substantial expenses or when, or if, we will be able to achieve or maintain profitability. We have financed our operations primarily through the sale of equity securities and debt financings. The size of our future net losses will depend, in part, on the rate of growth of our expenses and the rate of growth of our revenues. If we are unable to develop and commercialize our other product candidates or if sales revenue from Dermacyte is insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability.

***We have a limited operating history, and we expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.***

Our operations, to date, have been primarily limited to organizing and staffing our company, developing our technology and undertaking preclinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our clinical product candidates. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

Specifically, our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following factors, among others:

- our ability to obtain additional funding to develop our product candidates;
- the need to obtain regulatory approval of our most advanced product candidate, Oxycyte, for the potential treatment of traumatic brain injury;
- potential risks related to any collaborations we may enter into for our product candidates, including Oxycyte;
- delays in the commencement, enrollment and completion of clinical testing, as well as the analysis and reporting of results from such clinical testing;
- the success of clinical trials of our Oxycyte product candidate or future product candidates;
- any delays in regulatory review and approval of product candidates in development;

- market acceptance of our cosmetic product candidates;
- our ability to establish an effective sales and marketing infrastructure;
- competition from existing products or new products that may emerge;
- the ability to receive regulatory approval or commercialize our products;
- potential side effects of our product candidates that could delay or prevent commercialization;
- potential product liability claims and adverse events;
- potential liabilities associated with hazardous materials;
- our ability to maintain adequate insurance policies;
- our dependency on third-party manufacturers to supply or manufacture our products;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- our ability, our partners' abilities, and third parties' abilities to protect and assert intellectual property rights;
- costs related to and outcomes of potential intellectual property litigation;
- compliance with obligations under intellectual property licenses with third parties;
- our ability to adequately support future growth; and
- our ability to attract and retain key personnel to manage our business effectively.

Due to the various factors mentioned above, and others, the results of any prior quarterly or annual periods should not be relied upon as indications of our future operating performance.

***We will need substantial additional funding and if we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our product development programs.***

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials and establishing manufacturing capabilities, is expensive. We expect our research and development expenses to increase in connection with our ongoing activities, particularly as we focus on and proceed with our Phase II-B clinical program and begin clinical trials for our other products. In addition, our expenses could increase beyond expectations if applicable regulatory authorities, including the FDA, require that we perform additional studies to those that we currently anticipate, in which case the timing of any potential product approval may be delayed. We believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our projected operating requirements through the third quarter of fiscal 2011. We will need substantial additional capital in the future in order to complete the development and commercialization of Oxycyte and to fund the development and commercialization of future product candidates. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Such funding, if needed, may not be available on favorable terms, if at all. In the event we are unable to obtain additional capital, we may delay or reduce the scope of our current research and development programs and other expenses.

As widely reported, financial markets in the United States, Europe and Asia have been experiencing substantial disruption, including, among other things, high volatility in security prices, diminished liquidity and credit availability, rating downgrades of certain investments and declining valuations of others. Governments have taken actions intended to address market conditions that include restricted credit and declines in real estate values. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases, cease to provide funding to borrowers. Continued turbulence in the United States and international markets and economies may limit our ability to access the capital markets to meet our funding requirements.

If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or to grant licenses on terms that may not be favorable to us. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- the costs and timing of regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the terms and timing of any collaboration, licensing or other arrangements that we may establish;
- the cost and timing of completion of clinical and commercial-scale manufacturing activities; and
- the costs of establishing sales, marketing and distribution capabilities for our cosmetic products and any product candidates for which we may receive regulatory approval.

***We are a development stage company without revenues or profits, which raises doubt about our ability to continue as a going concern.***

We began research and development activities in 1990 and are a development stage company. We have primarily been engaged for the past 20 years in the development and testing of Oxycyte, Wundecyte, Vitavent, and our glucose biosensor. No revenues have been generated to date from commercial sales of any of our products, except for limited revenues from our topical cosmetic product, Dermacyte. At April 30, 2010 our accumulated deficit was approximately \$81.5 million. We will require substantial amounts of outside financing to fund future testing and development of our products. There is no assurance that our clinical testing will be successful, that regulatory approval of Oxycyte or any of our other products will be obtained, that Oxycyte or any of our other products can be manufactured at an acceptable cost and in appropriate quantities or that there will be a viable market for any of our products. The foregoing factors raise substantial doubt about our ability to continue as a going concern.

As a result of the foregoing circumstances our independent registered public accounting firm has included, and is likely in the future to include, an explanatory paragraph in their audit opinions based on uncertainty regarding our ability to continue as a going concern. An audit opinion of this type may interfere with our ability to obtain debt or equity financing in the future.

#### **Risks Related to Commercialization and Product Development**

***We are limited in the number of products we can simultaneously pursue and therefore our survival depends on our success with a small number of product opportunities.***

We have limited financial resources, so at present we are primarily focusing these resources on developing our Oxycyte oxygen carrier product, our Wundecyte topical wound product and our Dermacyte cosmetic products. We have delayed development on Fluorivent, our oxygen-carrying liquid, until we find a licensing partner willing to pursue development or obtain additional financing to pursue development ourselves. We licensed our implantable glucose sensor to a third party for further development, so how that product may progress is, to a large extent, outside of our control. At present we intend to commit most of our resources to advancing Oxycyte to the point it receives regulatory approval for one or more medical uses, and if this effort is unsuccessful we may not have resources to pursue development of our other products and our business would terminate. Furthermore, by delaying development of Fluorivent, this technology may become obsolete by the time we have sufficient capital to resume development and testing, so the funds expended on this product to date would be lost, as well as our opportunity to benefit if the product could be successfully developed.

***The development of Oxycyte is subject to a high level of technological risk.***

We expect to devote a substantial portion of our financial and managerial resources to pursuing Phase II and Phase III clinical trials on Oxycyte over the next three years. The biomedical field has undergone rapid and significant technological changes. Technological developments may result in Oxycyte becoming obsolete or non-competitive before we are able to recover any portion of the research and development and other expenses we have incurred to develop and clinically test Oxycyte. As our opportunity to generate substantial product revenues within the next four to five years is most likely dependent on successful testing and commercialization of Oxycyte for surgical and similar oxygen delivery applications, any such occurrence would have a material adverse effect on our operations and could result in the cessation of our business.



***We are required to conduct additional clinical trials in the future, which are expensive and time consuming, and the outcome of the trials is uncertain.***

We expect to commit a substantial portion of our financial and business resources over the next three years to testing Oxycyte and advancing this product to regulatory approval for use in one or more medical applications. We completed Phase I clinical trials on Oxycyte in December 2003 and completed Phase II-A clinical testing in the fourth quarter of 2004 with filings completed in the second quarter of 2008. A Phase II-B study protocol was filed with the FDA in the spring of 2008, but was put on clinical hold due to safety concerns raised by the FDA. We then filed a revised protocol as a dose-escalation study with the regulatory authorities in Switzerland and Israel. The protocol received Ethic Commission approval in Switzerland and Israel. Swissmedic approved the protocol in August 2009 and the Israel Ministry of Health in September 2009. The new study began in October 2009 and is currently under way both in Switzerland and Israel. If this study is successful (of which there is no assurance) we will need to conduct further trials. All of these clinical trials and testing will be expensive and time consuming and the timing of the regulatory review process is uncertain. The applicable regulatory agencies may suspend clinical trials at any time if they believe that the subjects participating in such trials are being exposed to unacceptable health risks. We cannot ensure that we will be able to complete our clinical trials successfully or obtain FDA or other governmental or regulatory approval of Oxycyte, or that such approval, if obtained, will not include limitations on the indicated uses for which Oxycyte may be marketed. Our business, financial condition and results of operations are critically dependent on obtaining capital to advance our testing program and receiving FDA and other governmental and regulatory approvals of Oxycyte. A significant delay in or failure of our planned clinical trials or a failure to achieve these approvals would have a material adverse effect on us and could result in major setbacks or jeopardize our ability to continue as a going concern.

***The market may not accept our products.***

There is a risk that the efficacy and pricing of Oxycyte, considered in relation to Oxycyte's expected benefits, will not be perceived by health care providers and third-party payers as cost-effective, and that the price of Oxycyte will not be competitive with other new technologies or products. Our results of operations may be adversely affected if the price of Oxycyte is not considered cost-effective or if Oxycyte does not otherwise achieve market acceptance.

***There are significant competitors developing similar products.***

If approved for commercial sale, Oxycyte will compete directly with established therapies for oxygen delivery and acute blood loss and may compete with other technologies currently under development. Oxycyte may not have advantages that will be significant enough to cause medical professionals to adopt it rather than continue to use established therapies or to adopt other new technologies or products. There is also a risk that the cost of Oxycyte will not be competitive with the cost of established therapies or other new technologies or products. Our commercial supply price under our agreement with Hospira Worldwide, Inc., or Hospira, the current manufacturer of Oxycyte, has not yet been determined. This supply price will affect the price we charge our customers for the product. As there is currently no oxygen-delivery product of our kind on the market, competition to develop an efficacious and accepted product is intense. Several companies have developed or are in the process of developing technologies that are, or in the future may be, the basis for products that will compete with Oxycyte. Certain of these companies are pursuing different approaches or means of accomplishing the therapeutic effects sought to be achieved through the use of Oxycyte.

These companies and others may have substantially greater financial resources, larger research and development staffs, more extensive facilities and more experience in testing, manufacturing, marketing and distributing medical products than we do. It is possible that one or more other companies will succeed in developing technologies or products that will become available for commercial use prior to Oxycyte that could be more effective or less costly than Oxycyte or that would render Oxycyte obsolete or non-competitive.

## **Risks Relating to Regulatory Matters**

***Our activities are and will continue to be subject to extensive government regulation, which is expensive and time consuming, and we will not be able to sell our Oxycyte product without regulatory approval.***

Our research, development, testing, manufacturing, marketing and distribution of Oxycyte products are, and will continue to be, subject to extensive regulation, monitoring and approval by the FDA and other regulatory agencies. There are significant risks at each stage of the regulatory scheme.

### *Product approval stage*

During the product approval stage we attempt to prove the safety and efficacy of our product for its indicated uses. There are numerous problems that could arise during this stage, including:

- The data obtained from laboratory testing and clinical trials are susceptible to varying interpretations, which could delay, limit or prevent FDA and other regulatory approvals.
- Adverse events could cause the FDA and other regulatory authorities to halt trials.
- At any time the FDA and other regulatory agencies could change policies and regulations that could result in delay and perhaps rejection of our products.

- Even after extensive testing and clinical trials, there is no assurance that regulatory approval will ever be obtained for any of our products.

#### *Commercialization approval stage*

We will be required to file a Biologics License Application, or BLA, with the FDA in order to obtain regulatory approval for the commercial production and sale of Oxycyte in the United States and similar applications with regulatory authorities in countries where we seek to commercialize Oxycyte. Under FDA guidelines, the FDA may comment upon the acceptability of the applicable application following its submission. After an application is submitted, there is an initial review to be sure that all of the required elements are included in the submission. There can be no assurance that the submission will be accepted for filing or that the FDA may not issue a refusal to file, or RTF. If an RTF is issued, there is opportunity for dialogue between the sponsor and the FDA in an effort to resolve all concerns. There can be no assurance that such a dialogue will be successful in leading to the filing of the BLA. If the submission is filed, there can be no assurance that the full review will result in product approval.

#### *Post-commercialization stage*

Discovery of previously unknown problems with Oxycyte or another product, or unanticipated problems with our manufacturing arrangements, even after FDA and other regulatory approvals of Oxycyte or another product for commercial sale may result in the imposition of significant restrictions, including withdrawal of the product from the market. Our agreement with Hospira is exclusive. As a consequence, a delay in supply by Hospira could cause us to be unable to supply our customers' demand.

Additional laws and regulations may also be enacted that could prevent or delay regulatory approval of Oxycyte or our other products, including laws or regulations relating to the price or cost-effectiveness of medical products. Any delay or failure to achieve regulatory approval of commercial sales of our products is likely to have a material adverse effect on our financial condition, results of operations and cash flows.

The FDA and other regulatory agencies continue to review products even after they receive agency approval. If and when the FDA or another regulatory agency outside the United States approves one of our products, its manufacture and marketing will be subject to ongoing regulation, which could include compliance with current good manufacturing practices, adverse event reporting requirements and general prohibitions against promoting products for unapproved or "off-label" uses. We are also subject to inspection and market surveillance by the FDA for compliance with these and other requirements. Any enforcement action resulting from failure, even by inadvertence, to comply with these requirements could affect the manufacture and marketing of Oxycyte or our other products. In addition, the FDA or other regulatory agencies could withdraw a previously approved product from the market upon receipt of newly discovered information. The FDA or another regulatory agency could also require us to conduct additional, and potentially expensive, studies in areas outside our approved indicated uses.

***We must continually monitor the safety of our products once approved and marketed for signs that their use may elicit serious and unexpected side effects and adverse events, which could jeopardize our ability to continue marketing the products. We may also be required to conduct post-approval clinical studies as a condition to licensing a product.***

As with all pharmaceutical products, the use of our products could sometimes produce undesirable side effects or adverse reactions or events (referred to cumulatively as adverse events). For the most part, we would expect these adverse events to be known and occur at some predicted frequency. When adverse events are reported to us, we will be required to investigate each event and circumstances surrounding it to determine whether it was caused by our product and whether it implies that a previously unrecognized safety issue exists. We will also be required to periodically report summaries of these events to the applicable regulatory authorities.

In addition, the use of our products could be associated with serious and unexpected adverse events, or with less serious reactions at a greater than expected frequency. This may be especially true when our products are used in critically ill or otherwise compromised patient populations. When these unexpected events are reported to us, we will be required to make a thorough investigation to determine causality and implications for product safety. These events must also be specifically reported to the applicable regulatory authorities. If our evaluation concludes, or regulatory authorities perceive, that there is an unreasonable risk associated with the product, we would be obligated to withdraw the impacted lot(s) of that product. Furthermore, an unexpected adverse event of a new product could be recognized only after extensive use of the product, which could expose us to product liability risks, enforcement action by regulatory authorities and damage to our reputation and public image.

A serious adverse finding concerning the risk of Oxycyte by any regulatory authority could adversely affect our reputation, business and financial results.

When a new product is approved, the FDA or other regulatory authorities may require post-approval clinical trials, sometimes called Phase IV clinical trials. If the results of such trials are unfavorable, this could result in the loss of the license to market the product, with a resulting loss of sales.

***After our products are commercialized, we expect to spend considerable time and money complying with federal and state laws and regulations governing their sale, and, if we are unable to fully comply with such laws and regulations, we could face substantial penalties.***

Health care providers, physicians and others will play a primary role in the recommendation and prescription of our clinical products. Our arrangements with third-party payers and customers may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain the business or financial arrangements and relationships through which we will market, sell and distribute our products. Applicable federal and state health care laws and regulations are expected to include, but not be limited to, the following:

- The federal anti-kickback statute is a criminal statute that makes it a felony for individuals or entities knowingly and willfully to offer or pay, or to solicit or receive, direct or indirect remuneration, in order to induce the purchase, order, lease, or recommending of items or services, or the referral of patients for services, that are reimbursed under a federal health care program, including Medicare and Medicaid;
- The federal False Claims Act imposes liability on any person who knowingly submits, or causes another person or entity to submit, a false claim for payment of government funds. Penalties include three times the government's damages plus civil penalties of \$5,500 to \$11,000 per false claim. In addition, the False Claims Act permits a person with knowledge of fraud, referred to as a *qui tam* plaintiff, to file a lawsuit on behalf of the government against the person or business that committed the fraud, and, if the action is successful, the *qui tam* plaintiff is rewarded with a percentage of the recovery;
- Health Insurance Portability and Accountability Act imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- The Social Security Act contains numerous provisions allowing the imposition of a civil money penalty, a monetary assessment, exclusion from the Medicare and Medicaid programs, or some combination of these penalties; and
- Many states have analogous state laws and regulations, such as state anti-kickback and false claims laws. In some cases, these state laws impose more strict requirements than the federal laws. Some state laws also require pharmaceutical companies to comply with certain price reporting and other compliance requirements.

Our failure to comply with any of these federal and state health care laws and regulations, or health care laws in foreign jurisdictions, could have a material adverse effect on our business, financial condition, result of operations and cash flows.

***Health care reform and controls on health care spending may limit the price we can charge for Oxycyte and the amount we can sell.***

As a result of recent legislation signed by President Obama on March 22, 2010, substantial changes are expected to occur in the current system for paying for health care in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage. Approximately 47 million Americans currently lack health insurance of any kind. Extending coverage to such a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services, drugs and devices. Restructuring the coverage of medical care in the United States could impact the reimbursement for prescribed drugs and biopharmaceuticals, including our products. If reimbursement for these products is limited, or rebate obligations associated with them are substantially increased, our financial condition, results of operations and cash flows could be materially impacted.

Extending medical benefits to those who currently lack coverage will likely result in substantial cost to the federal government, which may force significant changes to the United States health care system. Much of the funding for expanded health care coverage may be sought through cost savings. While some of these savings may come from realizing greater efficiencies in delivering care, improving the effectiveness of preventive care and enhancing the overall quality of care, much of the cost savings may come from reducing the cost of care. Cost of care could be reduced by reducing the level of reimbursement for medical services or products (including those biopharmaceuticals that we intend to produce and market), or by restricting coverage (and, thereby, utilization) of medical services or products. In either case, a reduction in the utilization of, or reimbursement for, our products could have a materially adverse impact on our financial performance.

***Uncertainty of third-party reimbursement could affect our future results of operations.***

Sales of medical products largely depend on the reimbursement of patients' medical expenses by governmental health care programs and private health insurers. We will be required to report detailed pricing information, net of included discounts, rebates and other concessions, to CMS for the purpose of calculating national reimbursement levels, certain federal prices, and certain federal rebate obligations. If we report pricing information that is not accurate to the federal government, we could be subject to fines and other sanctions that could adversely affect our business. In addition, the government could change its calculation of reimbursement, federal prices, or federal rebate obligations which could negatively impact us. There is no guarantee that government health care programs or private health insurers will reimburse our sales of Oxycyte, or permit us to sell our product at high enough prices to generate a profit.

***Governments outside the United States tend to impose strict price controls and reimbursement approval policies, which may adversely affect our prospects for generating revenue outside the United States.***

In some countries, particularly European Union countries, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time (6 to 12 months or longer) after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries with respect to any product candidate that achieves regulatory approval, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products upon approval, if at all, is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our prospects for generating revenue, if any, could be adversely affected which would have a material adverse effect on our business and results of operations. Further, if we achieve regulatory approval of any product, we must successfully negotiate product pricing for such product in individual countries. As a result, the pricing of our products, if approved, in different countries may vary widely, thus creating the potential for third-party trade in our products in an attempt to exploit price differences between countries. This third-party trade of our products could undermine our sales in markets with higher prices.

***Commercialization of our wound products will require successful completion of a complex regulatory process.***

In July 2009, we filed a 510K medical device application with the FDA for our Wundecyte wound product. The FDA indicated that the application would likely be classified as a combination drug/device product. Since additional trials will be needed to substantiate our claims, we have decided to divide the regulatory path for Wundecyte into a device application for the self-oxygenating bandage, and a new drug application for the oxygen-carrying gel. We have outlined study designs for preclinical trials to evaluate Wundecyte's effectiveness at wound healing, with and without the bandage. These studies will look at factors such as time to wound closure and reduction in scar tissue formation as compared to a control group. The first such trial began in the first quarter of fiscal year 2011.

A prototype for an oxygenating bandage device has been developed and it is currently undergoing testing. The oxygenating bandage is being evaluated in preclinical studies covering the treatment of different kinds of wounds. We are also developing clinical research protocols for the treatment of burns and other topical indication based on our PFC technology. There is no assurance that the 510K medical device application for the self-oxygenating bandage or the new drug application for the oxygen-carrying gel will be approved, or that the topical indications we have under development will prove their claims and be successful commercial products, any of which could materially affect our financial condition, results of operations and cash flows.

### **Risks Relating to Our Dependence on Third Parties**

***We depend on third parties to manufacture our products.***

We do not own or operate any manufacturing facilities for the commercial-scale production of Oxycyte. Instead, we rely on third party manufacturers. Hospira currently manufactures Oxycyte for us, and Exflur currently produces FtBU for us. In the past we have used PrimaPharm, Inc., or PrimaPharm, for the manufacture of Oxycyte. In order to seek regulatory approval of the sale of Oxycyte produced at the Hospira manufacturing facility and because of the level of inventory produced by PrimaPharm in the past, we may be required to conduct a portion of our clinical trials with product manufactured at the Hospira facility. Accordingly, a delay in achieving scale-up of commercial manufacturing capabilities when needed will have a material adverse effect on sales of our products. Additionally, the manufacture of our products will be subject to extensive government regulation. Among the conditions for marketing approval is that our quality control and manufacturing procedures conform to applicable good manufacturing practice regulations. There is a risk that we will not be able to obtain the necessary regulatory clearances or approvals to manufacture our products on a timely basis or at all.

We learned recently that on April 12, 2010, the FDA issued a warning letter to Hospira that the FDA had identified significant violations of Current Good Manufacturing Practice, or CGMP, regulations at Hospira's manufacturing facilities in North Carolina. Among other things, the warning letter indicated to Hospira that these violations cause the drug products that it manufactures in these facilities to be adulterated. The Oxycyte used by us currently in our clinical trials was not produced by Hospira but by PrimaPharm; however, PrimaPharm is unable to produce Oxycyte in the quantity required to support long-term clinical trials and commercialization of our product. We believe that the Oxycyte provided by PrimaPharm will be sufficient to conduct our clinical trials for several months. We are currently in discussions with Hospira regarding its intentions to remedy the CGMP regulation violations in order to meet our future manufacturing needs.

If Hospira or Exflur are unable to supply Oxycyte or FtBU, respectively, to use in the quantities needed, we may be unable to conclude agreements with a replacement manufacturer on favorable terms, if at all, and may be delayed in identifying and qualifying such replacement. In any event, identifying and qualifying new third-party manufacturers could involve significant costs associated with the transfer of the active pharmaceutical ingredient or finished product manufacturing process. A change in manufacturer likely would require formal approval by the FDA or other regulatory agencies before the new manufacturer could produce commercial supplies of our products. This approval process would likely take at least 12 to 18 months and, during that time, we could face a shortage of supply of our products, which could negatively affect our financial condition, results of operations and cash flows.

***The manufacturing process for Oxycyte is complicated and time consuming, and may experience problems that would limit our ability to manufacture and sell our products.***

Our products require product manufacturing steps that are complicated, time consuming and costly. Minor deviations in the manufacturing processes or other problems could result in unacceptable changes in the products that result in lot failures, increased production scrap, shipment delays, regulatory problems, product recalls or product liability, all of which could negatively affect our financial condition, the results of our operations and cash flows.

***We depend on the services of a limited number of key personnel.***

Our success is highly dependent on the continued services of a limited number of scientists and support personnel. The loss of any of these individuals could have a material adverse effect on us. In addition, our success will depend, among other factors, on the recruitment and retention of additional highly skilled and experienced management and technical personnel. There is a risk that we will not be able to retain existing employees or to attract and retain additional skilled personnel on acceptable terms given the competition for such personnel among numerous large and well-funded pharmaceutical and health care companies, universities, and non-profit research institutions, which could negatively affect our financial condition, results of operations and cash flows.

***We do not have experience in the sale and marketing of medical products.***

We have no experience in the sale or marketing of cosmetics and approved medical products or marketing the licensing of such products before FDA or other regulatory approval. We have not decided upon a commercialization strategy in these areas. We do not know of any third party that is prepared to distribute Oxycyte should it be approved. If we decide to establish our own commercialization capability, we will need to recruit, train and retain a marketing staff and sales force with sufficient technical expertise. We do not know whether we can establish a commercialization program at a cost that is acceptable in relation to revenue or whether we can be successful in commercializing our product. Factors that may inhibit our efforts to commercialize our products directly and without strategic partners include:

- Our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- The inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products;
- The lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- Unforeseen costs and expenses associated with creating and sustaining an independent sales and marketing organization.

Failure to successfully commercialize Dermacyte and Oxycyte or to do so on a cost effective basis would likely result in failure of our business.

***We may enter into distribution arrangements and marketing alliances for certain products and any failure to successfully identify and implement these arrangements on favorable terms, if at all, may impair our ability to commercialize our product candidates.***

We do not anticipate having the resources in the foreseeable future to develop global sales and marketing capabilities for all of the products we develop, if any. We may pursue arrangements regarding the sales and marketing and distribution of one or more of our product candidates and our future revenues may depend, in part, on our ability to enter into and maintain arrangements with other companies having sales, marketing and distribution capabilities and the ability of such companies to successfully market and sell any such products. Any failure to enter into such arrangements and marketing alliances on favorable terms, if at all, could delay or impair our ability to commercialize our product candidates and could increase our costs of commercialization. Any use of distribution arrangements and marketing alliances to commercialize our product candidates will subject us to a number of risks, including the following:

- We may be required to relinquish important rights to our products or product candidates;
- We may not be able to control the amount and timing of resources that our distributors or collaborators may devote to the commercialization of our product candidates;
- Our distributors or collaborators may experience financial difficulties;
- Our distributors or collaborators may not devote sufficient time to the marketing and sales of our products; and
- Business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement.

We may need to enter into additional co-promotion arrangements with third parties where our own sales force is neither well situated nor large enough to achieve maximum penetration in the market. We may not be successful in entering into any co-promotion arrangements, and the terms of any co-promotion arrangements we enter into may not be favorable to us.

## **Risks Relating to Intellectual Property**

### ***Our patents and other proprietary rights may not protect our technology.***

Our ability to compete effectively with other companies will depend, in part, on our ability to protect and maintain the proprietary nature of our technology. We cannot be certain as to the degree of protection offered by our patents or as to the likelihood that additional patents in the United States and certain other countries will be issued based upon pending patent applications. Patent applications in the United States are maintained in secrecy for at least eighteen months after the application is filed. We cannot be certain that we were the first creator of the inventions covered by our patents or pending patent applications or that we were the first to file patent applications for our inventions. The high costs of enforcing patent and other proprietary rights may also limit the degree of protection afforded to us. We also rely on unpatented proprietary technology, and it is possible that others may independently develop the same or similar technology or otherwise obtain access to our proprietary technology. There is a risk that our patents or other proprietary rights will be determined to be invalid or unenforceable if challenged in court or administrative proceedings or that we will become involved in disputes with respect to the patents or proprietary rights of third parties. An adverse outcome from these proceedings could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties, or require us to stop using this technology, any of which would result in a material adverse effect on our results of operations.

### ***We rely on confidentiality agreements that, if breached, may be difficult to enforce and could have a material adverse effect on our business and competitive position.***

Our policy is to enter agreements relating to the non-disclosure and non-use of confidential information with third parties, including our contractors, consultants, advisors and research collaborators, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them. However, these agreements can be difficult and costly to enforce. Moreover, to the extent that our contractors, consultants, advisors and research collaborators apply or independently develop intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to the intellectual property. If a dispute arises, a court may determine that the right belongs to a third party, and enforcement of our rights can be costly and unpredictable. In addition, we rely on trade secrets and proprietary know-how that we seek to protect in part by confidentiality agreements with our employees, contractors, consultants, advisors or others. Despite the protective measures we employ, we still face the risk that:

- These agreements may be breached;
- These agreements may not provide adequate remedies for the applicable type of breach; or
- Our trade secrets or proprietary know-how will otherwise become known.

Any breach of our confidentiality agreements or our failure to effectively enforce such agreements would have a material adverse effect on our business and competitive position.

### ***Our collaborations with outside scientists and consultants may be subject to restriction and change.***

We work with chemists, biologists and other scientists at academic and other institutions, and consultants who assist us in our research, development, regulatory and commercial efforts, including the members of our scientific advisory board. These scientists and consultants have provided, and we expect that they will continue to provide, valuable advice on our programs. These scientists and consultants are not our employees, may have other commitments that would limit their future availability to us and typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, we will be unable to prevent them from establishing competing businesses or developing competing products. For example, if a key scientist acting as a principal investigator in any of our clinical trials identifies a potential product or compound that is more scientifically interesting to his or her professional interests, his or her availability to remain involved in our clinical trials could be restricted or eliminated.

### ***Under current law, we may not be able to enforce all employees' covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees.***

We have entered into non-competition agreements with certain of our employees. These agreements prohibit our employees, if they cease working for us, from competing directly with us or working for our competitors for a limited period. Under current law, we may be unable to enforce these agreements against certain of our employees and it may be difficult for us to restrict our competitors from gaining the expertise our former employees gained while working for us. If we cannot enforce our employees' non-compete agreements, we may be unable to prevent our competitors from benefiting from the expertise of our former employees.

### ***We may infringe or be alleged to infringe intellectual property rights of third parties.***

Our products or product candidates may infringe on, or be accused of infringing on, one or more claims of an issued patent or may fall within the scope of one or more claims in a published patent application that may be subsequently issued and to which we do not hold a license or other rights. Third parties may own or control these patents or patent applications in the United States and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

If we are found to infringe the patent rights of a third party, or in order to avoid potential claims, we or our collaborators may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms.

There have been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the United States Patent and Trademark Office and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products. Our products, after commercial launch, may become subject to Paragraph IV certification under the Hatch-Waxman Act, thus forcing us to initiate infringement proceedings against such third-party filers. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We try to ensure that our employees do not use the proprietary information or know-how of others in their work for us. We may, however, be subject to claims that we or these employees have inadvertently or otherwise used or disclosed intellectual property, trade secrets or other proprietary information of any such employee's former employer. Litigation may be necessary to defend against these claims and, even if we are successful in defending ourselves, could result in substantial costs to us or be distracting to our management. If we fail to defend any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel.

***Product liability lawsuits against us could cause us to incur substantial liabilities, limit sales of our existing products and limit commercialization of any products that we may develop.***

Our business exposes us to the risk of product liability claims that are inherent in the manufacturing, distribution, and sale of biotechnology products. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and an even greater risk when we commercially sell any products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- Decreased demand for our products and any product candidates that we may develop;
- Injury to our reputation;
- Withdrawal of clinical trial participants;
- Costs to defend the related litigation;
- Substantial monetary awards to trial participants or patients;
- Loss of revenue; and
- The inability to commercialize any products that we may develop.

We currently maintain limited product liability insurance coverage for our clinical trials in the total amount of \$3 million. However, our profitability will be adversely affected by a successful product liability claim in excess of our insurance coverage. There can be no assurance that product liability insurance will be available in the future or be available on reasonable terms.

***The commercialization of our cosmetic product line may not be successful.***

In September 2009, we started production of our first commercial product under the topical cosmetic line Dermacyte. We produced and sold a limited preproduction batch on November 16, 2009 for orders taken through our website at buydermacyte.com. We currently have one Dermacyte product available for retail sale, and we anticipate that two more products will be available for retail sale during the second fiscal quarter of 2011. We currently market and sell this product through our website as we seek to identify and retain commercial distributors and/or license partners.

Marketing cosmetic products is a very speculative venture and reaching consumers through web-based marketing is dependent on many factors over which we have no control. There is no guarantee that we will enter into a license or distribution agreement with other parties, or that the consumers will buy our cosmetic products, which could negatively affect our only existing source of revenue.

## **Risks Relating to Employee Matters and Managing Growth**

*We may need to increase the size of our company, and we may experience difficulties in managing growth.*

As of April 30, 2010, we had 24 full-time employees. We may need to expand our managerial, operational, administrative, financial and other resources in order to manage and fund our operations and clinical trials, continue our development activities and commercialize our product candidates. To support this growth, we may hire additional employees within the next 12 months. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we continue to improve our operational, financial and management controls, reporting systems and procedures.

We may not be able to attract or retain qualified management and scientific personnel in the future. If we are unable to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede our achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

In addition, we have scientific and clinical advisors who assist us in our product development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with ours. Because our business depends on certain key personnel and advisors, the loss of such personnel and advisors could weaken our management team and we may experience difficulty in attracting and retaining qualified personnel and advisors.

### **ITEM 1B—UNRESOLVED STAFF COMMENTS**

We have not received any comments from the Securities and Exchange Commission that remain unresolved.

### **ITEM 2—PROPERTIES**

Oxygen Biotherapeutics owns no real property. We lease our principal executive office at 2530 Meridian Parkway, Durham North Carolina 27713 and our principal laboratory facilities at 3189 Airway Avenue, Building C, Costa Mesa, California 92626. The current rent is approximately \$14,400 per month for each facility.

### **ITEM 3—LEGAL PROCEEDINGS**

Oxygen Biotherapeutics is not presently involved in any legal proceedings and was not involved in any such legal proceedings during fiscal year 2010.

### **ITEM 4—(REMOVED AND RESERVED)**



## PART II

### ITEM 5—MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

#### *Market Price and Number of Stockholders*

Since January 15, 2010 our common stock has been listed on the NASDAQ Capital Market under the symbol "OXBT." Prior to that date, our common stock was quoted on the OTCBB under the same symbol.

The following table sets forth, for the past two fiscal years, the range of high and low bid prices in each fiscal quarter for our common stock for the periods our stock was quoted on the OTCBB and the high and low sales prices in each fiscal quarter for our common stock for the periods our stock has been listed on NASDAQ, all as adjusted for the 15-to-1 reverse stock split effected on November 9, 2009. For the periods our stock was quoted on the OTCBB, the prices reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

<u>Year-Ended April 30, 2009</u>	<u>High</u>	<u>Low</u>
First Quarter	\$ 14.01	\$ 8.33
Second Quarter	\$ 11.63	\$ 4.65
Third Quarter	\$ 6.75	\$ 2.25
Fourth Quarter	\$ 5.10	\$ 2.99

<u>Year-Ended April 30, 2010</u>	<u>High</u>	<u>Low</u>
First Quarter	\$ 7.50	\$ 3.00
Second Quarter	\$ 8.25	\$ 4.80
Third Quarter	\$ 7.74	\$ 4.50
Fourth Quarter	\$ 7.50	\$ 4.54

As of July 20, 2010, there were approximately 1,382 holders of record of our common stock. In addition, we believe that a significant number of beneficial owners of our common stock hold their shares in nominee or in "street name" accounts through brokers. On July 20, 2010, the last sale price reported on the NASDAQ Capital Market for our common stock was \$2.60 per share.

#### *Dividend Policy*

Since inception of Oxygen Biotherapeutics, no dividends have been paid on the common stock. Oxygen Biotherapeutics intends to retain any earnings for use in its business activities, so it is not expected that any dividends on the common stock will be declared and paid in the foreseeable future.

#### *Repurchases of Common Stock*

None.

#### *Equity Compensation Plan Information*

<u>Plan category</u>	<u>(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights</u>	<u>(b) Weighted-average exercise price of outstanding options, warrants and rights</u>	<u>(c) Number of securities remaining available for future issuances under equity compensation plans (excluding securities reflected in column (a))</u>
Equity compensation plans approved by security holders	585,172	\$ 4.10	182,424
Equity compensation plans not approved by security holders (2)	396,667(1)	\$ 3.70	0
Total	981,839	\$ 4.28	182,424

(1) This figure includes options issued to nonemployee directors and consultants under individual compensation arrangements.

(2) A description of the compensation agreements pursuant to this item is included in Note G of the financial statements.

### ***Unregistered Sales of Equity Securities***

No unregistered sales of equity securities were made during the period covered by this report that were not previously reported on a Current Report of Form 8-K or a Quarterly Report on Form 10-Q.

### **ITEM 6—SELECTED FINANCIAL DATA**

Not Applicable.

### **ITEM 7—MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*You should read the following discussion and analysis together with the financial statements and the related notes to those statements included in "Item 8 – Financial Statements and Supplementary Data." This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" and elsewhere in this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements.*

#### **Overview**

Oxygen Biotherapeutics is engaged in the business of developing biotechnology products with a focus on oxygen delivery to tissue. We are currently developing Oxycyte; a product we believe is a safe and effective oxygen carrier for use in surgical and similar medical situations. We have developed a family of perfluorocarbon-based oxygen carriers for use in personal care, topical wound healing, and other topical indications. In addition, we also have under development Vitavent (formerly called Fluoravent), an oxygen exchange fluid for facilitating the treatment of lung conditions.

#### ***Oxycyte***

Our Oxycyte oxygen carrier product is a PFC emulsified with water and a surfactant, which is provided to the patient intravenously. The physical properties of PFC enable our product to gather oxygen from the lungs and transport the oxygen through the body releasing it along the way. Over a period of days Oxycyte gradually evaporates in the lungs from where it is exhaled. Oxycyte requires no cross matching, so it is immediately available and compatible with all patients' blood types. Oxycyte has an extended shelf life compared to blood. Oxycyte is provided as a sterile emulsion ready for intravenous administration. Because it contains no biological components, there is no risk of transmission of blood-borne viruses from human blood products. Further, since Oxycyte is based on readily available inert compounds, we believe it can be manufactured on a cost-effective basis in amounts sufficient to meet demand.

We received approval of our IND for severe TBI filed with the FDA and began Phase I clinical studies in October 2003, which were completed in December 2003. We submitted a report on the results to the FDA along with a Phase II protocol in 2004. Phase II-A clinical studies began in the fourth quarter 2004, and were completed in 2006. A further Phase II study protocol was filed with the FDA in the spring of 2008, but was put on clinical hold by the FDA due to safety concerns raised by the regulatory agency. After receiving this clinical hold, we filed a revised protocol as a dose-escalation study with the regulatory authorities in Switzerland and Israel. The protocol received Ethic Commission approval in Switzerland and Israel. The relevant Swiss regulatory body approved the protocol in August 2009, and the Israel Ministry of Health approved the protocol in September 2009. The new study began in October 2009 and is currently under way both in Switzerland and Israel. In March 2010, we determined that it is feasible to simplify the trial design and also reduce the number of patients to be enrolled. In May 2010, we entered into a relationship with a contract research organization to assist us as we expand our study into India to initiate five to ten new sites for our Phase II-b clinical trial. Study objectives, safety and efficacy endpoints would remain unchanged, and we feel with these optimizations the study could be concluded faster and more economically. We expect to commit a substantial portion of our financial and business resources over the next three years to testing Oxycyte and advancing this product to regulatory approval for use in one or more medical applications.

Should Oxycyte successfully progress in clinical testing and it appears regulatory approval for one or more medical uses is likely, either in the United States or in another country, we will evaluate our options for commercializing the product. These options include licensing Oxycyte to a third party for manufacture and distribution, manufacturing Oxycyte ourselves for distribution through third party distributors, manufacturing and selling the product ourselves, or establishing some other form of strategic relationship for making and distributing Oxycyte with a participant in the pharmaceutical industry. We are currently investigating and evaluating all options.

## *Dermacyte*

The Dermacyte line of topical cosmetic products employs our patented PFC technology and other known cosmetic ingredients to promote the appearance of skin health and other desirable cosmetic benefits. Dermacyte is designed to provide a moist and oxygen-rich environment for the skin when it is applied topically, even in small amounts. Dermacyte Concentrate has been formulated as a cosmetic in our lab and Dermacyte Eye Complex was created by a contract formulator, with the patent held by Oxygen Biotherapeutics. Both formulas have passed all safety and toxicity tests, and we have filed a CPIS with the FDA. The market for oxygen-carrying cosmetics includes anti-aging, anti-wrinkle, skin abrasions and minor skin defects.

In September 2009, we started production of our first commercial product under our topical cosmetic line, Dermacyte Concentrate. We produced and sold a limited pre-production batch in November 2009 as a market acceptance test. The product was sold in packs of 8 doses of 0.4ml. Based on the test market results we identified specific market opportunities for this product and reformulated Dermacyte Concentrate for better product stability. Marketing and shipments of the new Dermacyte Concentrate formulation began in April 2010. We have also developed a 10ml pump package for Dermacyte Concentrate that should be available for market this summer. We worked with a contract formulator in California to develop the Dermacyte Eye Complex which contains PFC technology as well as other ingredients beneficial to the healthy appearance of the skin around the eyes. We anticipate that both formulations should be ready for sale by the second quarter of fiscal 2011.

We market and sell these products through [www.buydermacyte.com](http://www.buydermacyte.com) and to dermatologists and medical spas with a combination of in-house sales and exclusive distributors. We have hired a sales manager based in New York, and we intend to add sales people in other major urban areas like Los Angeles and Miami. We have entered into an agreement with a sales representative for the territories of Arizona and Michigan, and we intend to add more territories with agents or distributors.

Additional potential topical applications of our PFC technology that are under development include:

- Dermacyte Moisturizing Lotion: an evolution of the Dermacyte line that will contain SPF to protect the skin from UV-rays while beautifying.
- Rosacyte: incorporates perfluorocarbon technology to be used as a healing gel against rosacea.
- Acnecyte: incorporates perfluorocarbon technology to be used as a healing gel against acne.

## *Wundecyte*

Our wound product, Wundecyte, is a novel gel developed under a contract agreement with a lab in Virginia. Wundecyte is designed to be used as a wound-healing gel. In July 2009, we filed a 510K medical device application for Wundecyte with the FDA. Several oxygen-producing and oxygen-carrying devices were cited as predicate devices. The FDA response was that the application likely would be classified as a combination device. The drug component of the combination device will require extensive preclinical and clinical studies to be conducted prior to potential commercialization of the product.

We have also developed an oxygen-generating bandage that can be combined with Wundecyte gel. Wundecyte gel and the oxygen-generating bandage both entered preclinical testing in our first quarter of fiscal 2011. The studies will look at factors such as time to wound closure and reduction in scar tissue formation as compared to a control group. Preliminary results are expected later this year. Our current product development plan is for Wundecyte to emerge into more complex wound-healing indications, also in combination with oxygen-producing technologies based on hydrogen peroxide.

Additionally, we are developing preclinical research protocols for the treatment of burns and other topical indication based on our PFC. We intend to develop additional clinical research protocols for topical indications, including the treatment of acne and rosacea. However, we can provide no assurance that the topical indications we have under development will prove their claims and be successful commercial products.

## **Results of Operations – Comparison of years ended April 30, 2010 and 2009**

	<u>Year ended April 30,</u>		<u>Increase/</u>	<u>%</u>
	<u>2010</u>	<u>2009</u>	<u>(Decrease)</u>	<u>Increase/</u>
				<u>(Decrease)</u>
Research and development expense	\$ 2,917,688	\$ 1,598,807	\$ 1,318,881	82%
Sales, general and administrative expense	7,235,140	7,002,518	232,622	3%
Interest expense	154,998	24,856,041	(24,701,043)	-99%
Other loss, net	199,550	(238,526)	438,076	-184%

### ***Research and development expenses***

Research and development expenses include, but are not limited to, (i) expenses incurred under agreements with contract research organizations, or CROs, and investigative sites, which conduct our clinical trials and a substantial portion of our pre-clinical studies; (ii) the cost of manufacturing and supplying clinical trial materials; (iii) payments to contract service organizations, as well as consultants; (iv) employee-related expenses, which include salaries and benefits; and (v) facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, depreciation of leasehold improvements and equipment and laboratory and other supplies. All research and development expenses are expensed as incurred.

The increase in research and development expenses for the year ended April 30, 2010 was driven primarily by costs incurred for the development of Dermacyte formulations and the costs associated with the Phase II-b clinical trials for Oxycyte.

- In 2010, we incurred approximately \$240,000 in costs associated with the development and production of Dermacyte. These costs were not incurred during 2009.
- During 2010, we activated multiple clinical sites in Switzerland and Israel. The costs associated with the ongoing Phase II-b clinical trials for Oxycyte increased approximately \$600,000 over 2009. Included in these costs are site set-up fees, CRO costs, and supplying all of the sites with equipment and Oxycyte.
- Also included in the increase in research and development costs for the year ended April 30, 2010 compared to 2009 were increases in preclinical studies and new product development costs of approximately \$200,000 and an increase of approximately \$75,000 in regulatory costs.

Conducting a significant amount of research and development is central to our business model. Product candidates in later-stage clinical development generally have higher development costs than those in earlier stages of development, primarily due to the significantly increased size and duration of clinical trials. We plan to incur substantial research and development expenses for the foreseeable future in order to complete development of our most advanced product candidate, Oxycyte, and to conduct earlier-stage research and development projects.

The process of conducting preclinical studies and clinical trials necessary to obtain FDA approval is costly and time consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among other things, the quality of the product candidate's early clinical data, investment in the program, competition, manufacturing capabilities and commercial viability. As a result of the uncertainties discussed above, uncertainty associated with clinical trial enrollment and risks inherent in the development process, we are unable to determine the duration and completion costs of current or future clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates. Development timelines, probability of success and development costs vary widely. We are currently focused on developing our most advanced product candidate, Oxycyte; however, we will need substantial additional capital in the future in order to complete the development and potential commercialization of Oxycyte and other product candidates.

### ***Sales, general and administrative expenses***

Sales, general and administrative expenses consist primarily of compensation for executive, finance, marketing, legal and administrative personnel, including stock-based compensation. Other sales, general and administrative expenses include facility costs not otherwise included in research and development expenses, legal and accounting services, other professional services, the cost of market research activities, and consulting fees.

Sales, general and administrative expenses for the year ended April 30, 2010 were \$7,235,140 compared to \$7,002,518 for the year ended April 30, 2009.

During the year ended April 30, 2010, we incurred approximately \$179,000 in costs related to direct marketing and market analysis for the cosmetic topical product line Dermacyte that were not incurred in the prior year. In addition, we incurred an increase of approximately \$500,000 in costs over the prior year for services provided for press releases, road show presentations, investment banking fees, market listing fees and legal costs.

Salaries and wages increased approximately \$1,300,000 for the year ended April 30, 2010 over the prior year due to the increase in headcount from 8 to 24 and the increase in goal-based bonus payments. This increase was offset by a reduction of share-based compensation of \$941,415 in 2010 as compared to 2009.

We expanded our Board of Directors from two outside directors in 2009 to seven in 2010, resulting in an increase of approximately \$207,000 in Board related fees. Also, during the year ended April 30, 2010, we incurred an additional \$298,000 in fees paid to a recruiter for the placement of two of the outside directors.

During the year ended April 30, 2010, rent expense increased approximately \$132,000 (including utilities costs) over the prior year due to expansion of the corporate offices in North Carolina.

During the year ended April 30, 2010, travel costs increased approximately \$324,000 over the prior year due to increased international travel to Switzerland and Israel, road shows, and costs related to Board meetings and investor presentations.

For the year ended April 30, 2010, the Company reduced consultant costs by approximately \$1,709,000 from the same period in the previous year by hiring key personnel to manage the development of our products internally.

#### ***Other income and expense***

The increase in other expenses for the year ended April 30, 2010 over the prior year was primarily due to an impairment charge of approximately \$115,000 related to our investment in Glucometrics, Inc. as further described in Item 8., Note C. We also incurred approximately \$98,000 in costs for promotional and legal costs associated with Purple Heart Injury Labs, a not-for-profit organization incorporated to further research and development to benefit wounded veterans. We incurred approximately \$19,000 in foreign currency losses due to currency fluctuations in the Swiss Franc and Israeli New Shekel.

#### ***Interest expense***

Interest expense decreased approximately \$24.7 million, due to the conversion of our notes payable and the related amortization of debt discounts and issue costs during the year ended April 30, 2009.

#### **Liquidity, capital resources and plan of operation**

We have incurred losses since our inception in and as of April 30, 2010 we had an accumulated deficit of \$81.5 million. We will continue to incur losses until we generate sufficient revenue to offset our expenses, and we anticipate that we will continue to incur net losses for at least the next several years. We expect to incur increased research and development and sales, general and administrative expenses related to our development and potential commercialization of Oxycyte and, as a result, we will need to generate significant net product sales, royalty and other revenues to achieve profitability.

#### ***Liquidity***

Oxygen Biotherapeutics has financed its operations since September 1990 through the issuance of debt and equity securities and loans from stockholders. As of April 30, 2010, we had \$2,184,826 of total current assets and working capital of \$785,483. Our practice is to invest excess cash, where available, in short-term money market investment instruments.

We are in the preclinical and clinical trial stages in the development of our products. For example, we are currently conducting Phase II-b clinical trials for the use of Oxycyte in the treatment of severe traumatic brain injury. Even if we are successful with our Phase II-b study, we must then conduct a Phase III clinical study and, if that is successful, file with the FDA and obtain approval of a Biologics License Application to begin commercial distribution, all of which will take more time and funding to complete. Our other products must undergo further development and testing prior to submission to the FDA for approval to initiate clinical trials, which also requires additional funding. Management is actively pursuing private and institutional financing, as well as strategic alliances and/or joint venture agreements to obtain the necessary additional financing and reduce the cost burden related to the development and commercialization of our products though we can give no assurance that any such initiative will be successful. We expect our primary focus will be on funding the continued testing of Oxycyte, since this product is the furthest along in the regulatory review process. Our ability to continue to pursue testing and development of our products beyond 2010 depends on obtaining license income or outside financial resources. There is no assurance that we will obtain any license agreement or outside financing or that we will otherwise succeed in obtaining the necessary resources.

On May 7, 2010 we closed a direct registered offering pursuant to which we sold to certain investors 1,724,138 shares of common stock at \$2.90 per share and warrants to purchase 732,758 shares of common stock with an exercise price of \$5.32 per share. The financing provided approximately \$4.5 million in net proceeds to the Company after deducting the placement agent fee and offering expenses.

Pursuant to our Securities Purchase Agreement, as amended, with JP SPC 1 Vatea, Segregated Portfolio ("Vatea Fund"), we issued shares to, and received payments from, Vatea Fund as follows: (a) 1,333,334 shares on July 10, 2009 for \$5 million, (b) 160,000 shares on October 29, 2009 for \$600,000, (c) 640,000 shares on November 20, 2009 for \$2.4 million, (d) 800,000 shares on December 9, 2009 for \$3 million, (e) 133,334 shares on April 26, 2010 for \$500,000, (b) 133,334 shares on May 27, 2010 for \$500,000.

Based on our working capital at April 30, 2010 and the proceeds from the offering, we believe we have sufficient capital on hand to continue to fund operations through the third quarter of fiscal 2011.

## Cash Flows

The following table shows a summary of our cash flows for the periods indicated:

	Year ended April 30,	
	2010	2009
Net cash used in operating activities	(8,587,272)	(4,057,633)
Net cash used in investing activities	(541,722)	(367,327)
Net cash provided by financing activities	7,205,828	2,276,341

*Net cash used in operating activities.* Net cash used in operating activities was \$8,587,272 million for the year ended April 30, 2010 compared to net cash used in operating activities of \$4,057,633 million for the year ended April 30, 2009. The increase of cash used for operating activities for the year ended April 30, 2010 as compared to the year ended April 30, 2009 was due primarily to:

- the costs of conducting our Phase IIb clinical trials for TBI;
- the costs of manufacturing Oxycyte;
- the development and market research of Dermacyte; and
- increased payroll costs associated with our expansion into North Carolina and the increase in headcount from 8 to 24.

*Net cash used in investing activities.* Net cash used in investing activities was \$541,722 for the year ended April 30, 2010 compared to net cash used in investing activities of \$367,327 for the year ended April 30, 2009. The increase of cash used for investing activities for the year ended April 30, 2010 as compared to the year ended April 30, 2009 was due primarily to the cost of maintaining our portfolio of patents and trademarks.

*Net cash provided by financing activities.* We received \$7,205,828 from financing activities for the year ended April 30, 2010 compared to receiving cash of \$2,276,341 for the year ended April 30, 2009. Net cash provided by financing activities for the year ended April 30, 2010 was due primarily to net proceeds of \$10,030,030 from the securities purchase agreement with the Vatea Fund, less \$2,836,520 used to repurchase and cancel 4,727,564 outstanding warrants. Net cash provided by financing activities for the year ended April 30, 2009 was due to cash of \$2,098,125 received from the exercise of 544,200 outstanding warrant shares.

### Contractual Obligations

In November 2009, we entered into an exclusivity agreement with a contract manufacturer to produce our PFC raw material. Pursuant to the agreement, we are required to pay an exclusivity fee of \$100,000 per year. See "Note H. Commitments and Contingencies" in Part II, Item 8 of this Form 10-K for additional information.

We are bound by a long-term lease for our laboratory in California. The minimum annual lease payments pursuant to the obligation are \$172,130 annually. See "Note H. Commitments and Contingencies" in Part II, Item 8 of this Form 10-K for additional information.

### Operating Capital and Capital Expenditure Requirements

Our future capital requirements will depend on many factors and include, but are not limited to the following:

- the initiation, progress, timing and completion of clinical trials for our product candidates and potential product candidates;
- the outcome, timing and cost of regulatory approvals and the regulatory approval process;
- delays that may be caused by changing regulatory requirements;
- the number of product candidates that we pursue;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- the timing and terms of future in-licensing and out-licensing transactions;
- the cost and timing of establishing sales, marketing, manufacturing and distribution capabilities;
- the cost of procuring clinical and commercial supplies of our product candidates;
- the extent to which we acquire or invest in businesses, products or technologies; and
- the possible costs of litigation.

We believe that our existing cash and cash equivalents will be sufficient to fund our projected operating requirements through the third quarter of fiscal 2011. We will need substantial additional capital in the future in order to complete the development and commercialization of Oxycyte and to fund the development and commercialization of our future product candidates. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Such funding, if needed, may not be available on favorable terms, if at all. In the event we are unable to obtain additional capital, we may delay or reduce the scope of our current research and development programs and other expenses.

As widely reported, financial markets in the United States, Europe and Asia have been experiencing substantial disruption, including, among other things, high volatility in security prices, diminished liquidity and credit availability, rating downgrades of certain investments and declining valuations of others. Governments have taken actions intended to address these market conditions that include restricted credit and declines in real estate values. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases, cease to provide funding to borrowers. Continued turbulence in the U.S. and international markets and economies may limit our ability to access the capital markets to meet our funding requirements. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that may not be favorable to us. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

For a description of additional risks that we face, see Item 1A – "Risk Factors."

#### **Summary of Critical Accounting Policies**

*Development Stage*—We have not commenced our planned principal operations, and have not earned significant revenues; therefore we are considered a "Development Stage Enterprise."

*Use of Estimates*—The preparation of the accompanying consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

*Preclinical Study and Clinical Accruals*—We estimate our preclinical study and clinical trial expenses based on the services received pursuant to contracts with several research institutions and contract research organizations that conduct and manage preclinical and clinical trials on our behalf. The financial terms of the agreements vary from contract to contract and may result in uneven expenses and payment flows. Preclinical study and clinical trial expenses include the following:

- fees paid to CROs in connection with clinical trials,

- fees paid to research institutions in conjunction with preclinical research studies, and
- fees paid to contract manufacturers and service providers in connection with the production and testing of active pharmaceutical ingredients and drug materials for use in preclinical studies and clinical trials.

*Cash and Cash Equivalents*—We consider all highly liquid instruments with a maturity date of three months or less, when acquired, to be cash equivalents.

*Property and Equipment, Net*—Property and equipment are stated at cost, subject to adjustments for impairment, less accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the following estimated useful lives:

Laboratory equipment	3-5 years
Office furniture and fixtures	7 years
Computer equipment and software	3 years
Leasehold improvements	Shorter of useful life or remaining lease term

Maintenance and repairs are charged to expense as incurred, improvements to leased facilities and equipment are capitalized.

*Income Taxes*—Deferred tax assets and liabilities are recorded for differences between the financial statement and tax bases of the assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense is recorded for the amount of income tax payable or refundable for the period increased or decreased by the change in deferred tax assets and liabilities during the period.

*Stock-Based Compensation*—Effective May 1, 2005, we adopted ASC 718 *Compensation — Stock Compensation*, using the prospective transition method, which requires the measurement and recognition of compensation expense for all stock-based payment awards granted, modified and settled to our employees and directors after May 1, 2005. Our financial statements reflect the impact of ASC 718. We chose the "straight-line" attribution method for allocating compensation costs and recognized the fair value of each stock option on a straight-line basis over the requisite service period.

We account for equity instruments issued to non-employees in accordance with ASC 505-50 *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Equity instruments issued to non-employees are recorded at their fair value on the measurement date and are subject to periodic adjustment as the underlying equity instruments vest.

*Loss Per Share*—Basic loss per share, which excludes antidilutive securities, is computed by dividing loss available to common shareholders by the weighted-average number of common shares outstanding for that particular period. In contrast, diluted loss per share considers the potential dilution that could occur from other equity instruments that would increase the total number of outstanding shares of common stock. Such amounts include shares potentially issuable under outstanding options, warrants and convertible debentures. A reconciliation of the numerator and denominator used in the calculation of basic and diluted net loss per share follows.

	<u>Year ended April 30,</u>	
	<u>2010</u>	<u>2009</u>
<b>Historical net loss per share:</b>		
Numerator		
Net loss, as reported	(10,507,376)	(33,218,840)
Less: Effect of amortization of interest expense on convertible notes	—	—
Net loss attributed to common stockholders (diluted)	(10,507,376)	(33,218,840)
Denominator		
Weighted-average common shares outstanding	19,485,065	11,551,356
Effect of dilutive securities	—	—
Denominator for diluted net loss per share	19,485,065	11,551,356
Basic and diluted net loss per share	<u>\$ (0.54)</u>	<u>\$ (2.88)</u>



The following outstanding options, convertible note shares and warrants were excluded from the computation of basic and diluted net loss per share for the periods presented because including them would have had an anti-dilutive effect.

	<u>Year ended April 30,</u>	
	<u>2010</u>	<u>2009</u>
Options to purchase common stock	981,839	858,111
Convertible note shares outstanding	4,292	94,971
Warrants to purchase common stock	3,322,154	8,067,514

*Operating Leases*—We maintain operating leases for our office and laboratory facilities. The lease agreements may include rent escalation clauses and tenant improvement allowances. We recognize scheduled rent increases on a straight-line basis over the lease term beginning with the date we take possession of the leased space. Differences between rental expense and actual rental payments are recorded as deferred rent liabilities and are included in "Other liabilities" on the consolidated balance sheets.

*Fair Value*—On May 1, 2008, we adopted ASC 820 *Fair Value Measurements*, as it relates to financial assets and financial liabilities. Our balance sheet includes the following financial instruments: cash and cash equivalents, short-term notes payable and convertible debentures. We consider the carrying amount of our cash and cash equivalents and short-term notes payable to approximate fair value due to the short-term nature of these instruments. It is not practicable for us to estimate the fair value of its convertible debentures as such estimates cannot be made without incurring excessive costs. The significant terms of our convertible debentures are described in Note D. At April 30, 2010 and 2009 the debentures had a gross carrying value of \$15,903 and \$351,867, respectively, with unamortized discounts totaling \$5,725 and \$124,152, respectively.

In addition to the above financial instruments, we maintain an investment in a start-up technology company, Glucometrics, Inc. The investment is recorded in Other Assets, at cost. This investment totaled \$0 and \$114,193 at April 30, 2010 and 2009, respectively. We review this investment quarterly, including historical and projected financial performance, expected cash needs and recent funding events. We recognize other-than-temporary impairments if the market value of the investment is below its cost basis for an extended period of time or if the issuer has experienced significant financial declines or difficulties in raising capital to continue operations. We recorded an other-than-temporary impairment of \$114,193 in the fourth quarter of 2010. See Note D for additional details.

#### **Recent Accounting Pronouncements**

In September 2009, the Financial Accounting Standards Board, or FASB ratified Revenue Arrangements with Multiple Deliverables issued as Accounting Standards Update, or ASU, 2009-13. ASU 2009-13 updates the existing multiple-element arrangements guidance currently included in ASC 605-25, *Revenue Recognition — Multiple-Element Arrangements*. The revised guidance provides for two significant changes to the existing multiple-element arrangements guidance. The first relates to the determination of when the individual deliverables included in a multiple-element arrangement may be treated as separate units of accounting. This change is significant as it will likely result in the requirement to separate more deliverables within an arrangement, ultimately leading to less revenue deferral. The second change modifies the manner in which the transaction consideration is allocated across the separately identifiable deliverables. These changes are likely to result in earlier recognition of revenue for multiple-element arrangements than under previous guidance. ASU 2009-13 also significantly expands the disclosures required for multiple-element revenue arrangements. The revised multiple-element arrangements guidance will be effective for the first annual reporting period beginning on or after June 15, 2010, and may be applied retrospectively for all periods presented or prospectively to arrangements entered into or modified after the adoption date. Early adoption is permitted provided that the revised guidance is retroactively applied to the beginning of the year of adoption. If the guidance is adopted prospectively, certain transitional disclosures are required for each reporting period in the initial year of adoption. As a result, it is effective for us in the first quarter of fiscal year 2011. We do not believe that the adoption of ASU 2009-13 will have a material impact on our consolidated financial statements.

In January, 2010, the FASB issued ASU 2010-06, *Improving Disclosures about Fair Value Measurements*. The standard amends ASC Topic 820, *Fair Value Measurements and Disclosures* to require additional disclosures related to transfers between levels in the hierarchy of fair value measurement. The standard does not change how fair values are measured. The standard is effective for interim and annual reporting periods beginning after December 15, 2009. As a result, it is effective for us in the first quarter of fiscal year 2011. We do not believe that the adoption of ASU 2010-06 will have a material impact on consolidated our financial statements.

In April 2010, the FASB issued ASU 2010-12, *Accounting for Certain Tax Effects of the 2010 Health Care Reform Acts*. The standard amends ASC Topic 740, *Income Taxes*. The guidance addresses the effect that the different signing dates might have on the accounting for the Health Care and Education Reconciliation Act of 2010 and the Patient Protection and Affordable Care Act. The Company does not anticipate the adoption of the guidance to have a material impact on its results of operations, financial position, or cash flows.

In April 2010, the FASB issued ASU 2010-17, *Milestone Method of Revenue Recognition*. The standard amends ASC Topic 605. The guidance addresses milestone definitions and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. The amendments are effective on a prospective basis for milestones achieved in fiscal years beginning on or after June 15, 2010. The Company does not anticipate the adoption of the guidance to have a material impact on its results of operations, financial position, or cash flows.

**ITEM 7A—QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Management does not believe that we possess any instruments that are sensitive to market risk. Our debt instruments bear interest at fixed interest rates.

**ITEM 8—FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**OXYGEN BIOTHERAPEUTICS, INC.**  
**(a development stage enterprise)**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

	<u>Page</u>
Report of Independent Registered Public Accounting Firm	30
Consolidated Balance Sheets	31
Consolidated Statements of Operations	32
Consolidated Statements of Stockholders' Equity	33
Consolidated Statements of Cash Flows	35
Notes to Consolidated Financial Statements	37



## **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and  
Stockholders of Oxygen Biotherapeutics, Inc.

We have audited the accompanying consolidated balance sheets of Oxygen Biotherapeutics, Inc., formerly, Synthetic Blood International, Inc. (a development-stage enterprise) (the "Company") as of April 30, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the years then ended, and for the period from inception, May 26, 1967, through April 30, 2010. We also have audited the Company's internal control over financial reporting as of April 30, 2010, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, including in Management's Annual Report on Internal Control over Financial Reporting included in Item 9A- Controls and Procedures in the Company's 2010 Annual Report on Form 10K. Our responsibility is to express an opinion on these consolidated financial statements and an opinion on the Company's internal control over financial reporting based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the consolidated financial statements included examination, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Oxygen Biotherapeutics, Inc., formerly Synthetic Blood International, Inc. as of April 30, 2010 and 2009, and the results of its operations and its cash flows for the years then ended, and from the period from inception, May 26, 1967, through April 30, 2010, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of April 30, 2010, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company is a development stage enterprise presently generating no operating revenues, has a significant deficit accumulated during the development stage, and requires substantial additional funds to complete clinical trials and pursue regulatory approvals. In view of these matters, recoverability of a major portion of the recorded asset amounts shown in the accompanying April 30, 2010 consolidated balance sheet is dependent upon continued operations of the Company, which in turn is dependent upon the Company's ability to meet its financing requirements on a continuing basis, to maintain present financing, and to generate cash from future operations. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans concerning these matters are described in Note A. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**CHERRY, BEKAERT & HOLLAND, L.L.P.**

/s/ Cherry, Bekaert & Holland, L.L.P.

Raleigh, North Carolina

July 23, 2010

**OXYGEN BIOTHERAPEUTICS, INC.**  
(a development stage enterprise)

**CONSOLIDATED BALANCE SHEETS**

	April 30,	
	2010	2009
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 632,706	\$ 2,555,872
Accounts receivable	72,055	32,286
Inventory	535,090	—
Prepaid expense	249,780	156,926
Other current assets	695,195	—
Total current assets	2,184,826	2,745,084
PROPERTY AND EQUIPMENT, net	383,959	210,355
DEBT ISSUANCE COSTS, net	—	33,783
INTANGIBLE ASSETS, net	907,710	650,222
OTHER ASSETS, net	52,651	163,393
Total assets	\$ 3,529,146	\$ 3,802,837
 <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 499,044	\$ 195,569
Accrued liabilities	843,903	241,518
Notes payable	56,394	36,666
Total current liabilities	1,399,341	473,753
LONG TERM DEBT, net of current portion	2,767	227,715
Total liabilities	1,402,108	701,468
 <b>STOCKHOLDERS' EQUITY</b>		
Preferred stock, undesignated, authorized 10,000,000 shares; none issued or outstanding		
Common stock, par value \$0.0001 per share; authorized 400,000,000 shares; issued and outstanding 21,457,265 and 15,735,013 respectively	2,146	23,621
Stock subscription receivable	500,000	—
Additional Paid-in capital	83,092,470	74,037,950
Deficit accumulated during the development stage	(81,467,578)	(70,960,202)
Total stockholders' equity	2,127,038	3,101,369
Total liabilities and stockholders' equity	\$ 3,529,146	\$ 3,802,837

The accompanying notes are an integral part of these Consolidated Financial Statements.

**OXYGEN BIOTHERAPEUTICS, INC.**  
(a development stage enterprise)

**CONSOLIDATED STATEMENTS OF OPERATIONS**

	<b>Cumulative Period from May 26, 1967 (inception) to April 30, 2010</b>	<b>Years ended April 30,</b>	
		<b>2010</b>	<b>2009</b>
<b>OPERATING EXPENSES AND LOSSES</b>			
Research and development expense	\$ 16,873,940	\$ 2,917,688	\$ 1,598,807
Sales, general and administrative expense	33,135,174	7,235,140	7,002,518
Loss on impairment of long-lived assets	32,113	—	—
Total operating expenses and losses	50,041,227	10,152,828	8,601,325
INTEREST EXPENSE	32,139,946	154,998	24,856,041
LOSS ON EXTINGUISHMENT OF DEBT	250,097	—	—
OTHER INCOME	(963,692)	199,550	(238,526)
<b>NET LOSS</b>	<b>\$ 81,467,578</b>	<b>\$ 10,507,376</b>	<b>\$ 33,218,840</b>
NET LOSS PER SHARE, basic and diluted		\$ (0.54)	\$ (2.88)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING, basic and diluted		19,485,065	11,551,356

The accompanying notes are an integral part of these Consolidated Financial Statements.

**OXYGEN BIOTHERAPEUTICS, INC.**  
(a development stage enterprise)

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

For the two years ended April 30, 2010 and for the cumulative period from  
May 26, 1967 (date of inception) to April 30, 2008

	Common Stock		Additional paid-in capital	Stock subscription receivable	Deficit accumulated during the development stage	Total stockholders' equity (deficit)
	Number of Shares	Amount				
<b>Balance at April 30, 2008</b>	<b>9,760,374</b>	<b>\$ 1,464,056</b>	<b>\$ 46,029,242</b>	<b>\$ —</b>	<b>\$ (37,741,362)</b>	<b>\$ 9,751,936</b>
Common stock issued for convertible debt	5,372,360	21,699	19,882,906			19,904,605
Issuance of common stock to employees	9,420	428	77,005			77,433
Issuance of common stock for services rendered	27,417	41	296,059			296,100
Compensation on options issued			1,963,578			1,963,578
Issuance of warrants			2,228,432			2,228,432
Exercise of warrants and options	565,442	78,511	2,019,614			2,098,125
Common stock par value change		(1,541,114)	1,541,114			—
Net loss					(33,218,840)	(33,218,840)
<b>Balance at April 30, 2009</b>	<b>15,735,013</b>	<b>\$ 23,621</b>	<b>\$ 74,037,950</b>	<b>\$ —</b>	<b>\$ (70,960,202)</b>	<b>\$ 3,101,369</b>
Common stock sold, net of offering costs	3,146,667	2,406	10,165,095			10,167,501
Common stock issued for convertible debt	90,682	126	335,851			335,977
Common stock subscription receivable				500,000		500,000
Issuance of common stock to employees	21,294	10	109,589			109,599
Issuance of common stock for services rendered	66,667	100				100
Compensation on options issued			853,570			853,570
Issuance of warrants			89,013			89,013
Exchange of warrants	2,363,767	3,544	(2,583,884)			(2,580,340)
Exercise of warrants and options	29,000	20	57,605			57,625
Fractional shares of common stock due to reverse stock split	4,175	(27,681)	27,681			—
Net loss					(10,507,376)	(10,507,376)
<b>Balance at April 30, 2010</b>	<b><u>21,457,265</u></b>	<b><u>\$ 2,146</u></b>	<b><u>\$ 83,092,470</u></b>	<b><u>\$ 500,000</u></b>	<b><u>\$ (81,467,578)</u></b>	<b><u>\$ 2,127,038</u></b>

	<u>Common Stock</u>		Additional paid-in capital	Stock subscription receivable	Deficit accumulated during the development stage	Total stockholders' equity (deficit)
	<u>Number of Shares</u>	<u>Amount</u>				
<b>Balance at May 26, 1967</b>	—	\$ —	\$ —	\$ —	\$ —	\$ —
Common stock sold, net of offering costs	7,040,217	1,056,032	16,683,920			17,739,952
Common stock issued for convertible debt	1,645,126	191,796	3,175,725			3,367,521
Issuance of common stock to employees as compensation	15,520	2,328	1,771,415			1,773,743
Compensation on options issued			6,199,064			6,199,064
Issuance of common stock for services rendered	223,818	33,573	1,032,250			1,065,823
Issuance of common stock to officers to retire shareholder loans	69,630	10,444	177,556			188,000
Common stock issued in conjunction with funding agreements and services rendered	358,425	53,764	883,160			936,924
Contributions of capital by shareholders			581,818			581,818
Contributions of capital for services rendered			65,700			65,700
Beneficial conversion on convertible debt			3,292,648			3,292,648
Warrants issued with debt instruments			8,619,525			8,619,525
Exercise of warrants and options	207,638	86,119	819,386			905,505
Issuance of common stock for promissory notes	200,000	30,000	370,000			400,000
Issuance of warrants for services rendered			2,357,075			2,357,075
Net loss					(37,741,362)	(37,741,362)
<b>Balance at April 30, 2008</b>	<b>9,760,374</b>	<b>\$ 1,464,056</b>	<b>\$ 46,029,242</b>	<b>\$ —</b>	<b>\$ (37,741,362)</b>	<b>\$ 9,751,936</b>

The accompanying notes are an integral part of these Consolidated Financial Statements.



**OXYGEN BIOTHERAPEUTICS, INC.**  
**(a development stage enterprise)**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Period from May 26, 1967 (inception) to April 30, 2010	Year ended April 30,	
		2010	2009
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
Net loss	\$ (81,467,578)	\$ (10,507,376)	\$ (33,218,840)
Adjustments to reconcile net loss to net cash used in operating activities	—		
Depreciation and amortization	1,553,105	110,631	20,475
Amortization of deferred compensation	336,750	—	—
Interest on debt instruments	31,747,074	152,220	24,856,041
Loss (gain) on debt settlement and extinguishment	163,097	—	—
Loss on impairment of long-lived assets	146,306	114,193	—
Loss on disposal and write down of property and equipment and other assets	219,305	—	—
Issuance and vesting of compensatory stock options and warrants	8,098,068	1,198,764	3,838,510
Issuance of common stock below market value	695,248	—	—
Issuance of common stock as compensation	495,592	109,599	373,533
Issuance of common stock for services rendered	1,265,279	—	—
Issuance of note payable for services rendered	120,000	—	—
Contributions of capital through services rendered by stockholders	216,851	—	—
Changes in operating assets and liabilities	—		
Prepaid expenses and other assets	(757,647)	(671,165)	(134,042)
Accounts payable and accrued liabilities	1,549,506	905,862	206,690
Net cash used in operating activities	<u>(35,619,044)</u>	<u>(8,587,272)</u>	<u>(4,057,633)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Purchase of property and equipment	(1,503,267)	(235,727)	(99,691)
Capitalization of patent costs	<u>(1,291,224)</u>	<u>(305,995)</u>	<u>(267,636)</u>
Net cash used in investing activities	<u>(2,794,491)</u>	<u>(541,722)</u>	<u>(367,327)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Proceeds from sale of common stock and exercise of stock options and warrants, net of related expenses	30,964,781	10,030,030	2,098,125
Repayments of amounts due stockholders	(121,517)	—	—
Repurchase of outstanding warrants	(2,836,520)	(2,836,520)	—
Proceeds from stockholder notes payable	977,692	—	—
Proceeds from former officer loans	39,500	—	—
Repayments of former officer loans	(39,500)	—	—
Proceeds from issuance of notes payable, net of issuance costs	2,291,128	96,563	90,145
Proceeds from convertible debentures, net of issuance costs	8,807,285		
Payments on notes - short-term	(745,299)	(84,245)	(88,071)
Payments on notes - long term	<u>(291,309)</u>	<u>—</u>	<u>—</u>
Net cash provided by financing activities	<u>39,046,241</u>	<u>7,205,828</u>	<u>2,100,199</u>
Net change in cash and cash equivalents	632,706	(1,923,166)	(2,324,761)
Cash and cash equivalents, beginning of period	<u>—</u>	<u>2,555,872</u>	<u>4,880,633</u>
Cash and cash equivalents, end of period	<u><u>\$ 632,706</u></u>	<u><u>\$ 632,706</u></u>	<u><u>\$ 2,555,872</u></u>
Cash paid for:			
Interest	\$ 247,403	\$ 2,779	\$ 2,769
Income taxes	\$ 27,528	\$ —	\$ 6,789

The accompanying notes are an integral part of these Consolidated Financial Statements.

**OXYGEN BIOTHERAPEUTICS, INC.**  
**(a development stage enterprise)**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**Non-cash financing activities during the year ended April 30, 2010:**

- (1) The Company made principal payments on its convertible debentures with a gross carrying value of \$335,977 through the issuance of 90,682 shares of common stock. The Company recognized interest expense of \$118,437 for the unamortized discounts and debt issue costs associated with the converted debentures.

**Non-cash financing activities during the year ended April 30, 2009:**

- (1) The Company made principal payments on its convertible debentures with a gross carrying value of \$19,904,605 through the issuance of 5,372,362 shares of common stock. The Company recognized interest expense of \$21,775,567 for the unamortized discounts and debt issue costs associated with the converted debentures.

The accompanying notes are an integral part of these Consolidated Financial Statements.

**OXYGEN BIOTHERAPEUTICS, INC.**  
**(a development stage enterprise)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**As of April 30, 2010 and 2009, and for the years then ended.**

**NOTE A—DESCRIPTION OF BUSINESS AND GOING CONCERN**

*Description of Business*—Oxygen Biotherapeutics (the "Company") was originally formed as a New Jersey corporation in 1967 under the name Rudmer, David & Associates, Inc., and subsequently changed its name to Synthetic Blood International, Inc. On June 17, 2008, the stockholders of Synthetic Blood International approved the Agreement and Plan of Merger dated April 28, 2008, between Synthetic Blood International and Oxygen Biotherapeutics, Inc., a Delaware corporation. Oxygen Biotherapeutics was formed on April 17, 2008, by Synthetic Blood International to participate in the merger for the purpose of changing the state of domicile of Synthetic Blood International from New Jersey to Delaware. Certificates of Merger were filed with the states of New Jersey and Delaware, and the merger was effective June 30, 2008. Under the Plan of Merger, Oxygen Biotherapeutics is the surviving corporation and each share of Synthetic Blood International common stock outstanding on June 30, 2008 was converted to one share of Oxygen Biotherapeutics common stock.

The Company was inactive through September 1990, when it began conducting operations for the purpose of developing a synthetic blood emulsion to act as a human blood substitute, and a method of using a PFC compound to facilitate oxygen exchange for individuals with respiratory distress syndrome. The Company submitted an Investigational New Drug Application ("IND") for Oxycyte, the Company's alternative to transfused blood for use in surgical and similar medical situations, to the Food and Drug Administration ("FDA") in 2003 and successfully conducted a Phase I safety clinical study in the fourth quarter of 2003. The results of the Phase I study were consistent with the results of preclinical animal safety studies, and showed a good safety profile for Oxycyte. The Company started Phase II clinical trials of Oxycyte in surgical patients in the fourth quarter of 2004. The protocol was successfully completed in 2006 and filed in April 2008. This protocol was put on clinical hold due to safety concerns raised by the regulatory agency. In April 2009, the Company filed an application with the FDA to obtain orphan drug designation for Oxycyte for the treatment of patients with severe, closed-head Traumatic Brain Injury ("TBI"). The Company filed a Cosmetic Product Ingredient Statement ("CPIS") with the FDA for Dermacyte Gel, its new Oxycyte-based cosmetic product. The gel is an oxygen-rich formulation of Oxycyte which OBI believes will promote skin health and other desirable cosmetic benefits when applied to the skin. A CPIS is a voluntary registration with the FDA recommended for a cosmetic product's proposed commercial introduction. The Company is currently evaluating the market opportunities for this product has entered into agreements for the manufacture of a Dermacyte concentrate pump and a Dermacyte eye cream, which we anticipate will be available for retail sale in early second quarter. Vitavent (previously Fluoravent), an oxygen exchange device, for facilitating the treatment of lung conditions is at the preclinical development stage and is currently inactive. The Company has not generated significant revenues since inception.

The accompanying consolidated financial statements include the accounts and transactions of Oxygen Biotherapeutics, Inc. and Synthetic Blood International, Inc. All material intercompany transactions and balances have been eliminated in consolidation.

*Reverse Stock Split*—The Company initiated a 1-for-15 reverse stock split effective November 19, 2009. All shares and per share amounts in these consolidated financial statements and notes thereto have been retroactively adjusted to give effect to the reverse stock split.

*Going Concern*—Management believes the accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern. The Company has an accumulated deficit during the development stage of \$81,467,578 and \$70,960,202 at April 30, 2010 and 2009, respectively, and used cash in operations of \$8,587,272 and \$4,057,633 during the years ended April 30, 2010 and 2009, respectively. The Company requires substantial additional funds to complete clinical trials and pursue regulatory approvals. Management is actively seeking additional sources of equity and/or debt financing; however, there is no assurance that any additional funding will be available.

In view of the matters described above, recoverability of a major portion of the recorded asset amounts shown in the accompanying April 30, 2010 balance sheet is dependent upon continued operations of the Company, which in turn is dependent upon the Company's ability to meet its financing requirements on a continuing basis, to maintain present financing, and to generate cash from future operations. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

**NOTE B—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Development Stage*—The Company has not commenced its planned principal operations, and has not earned significant revenues; therefore it is considered a "Development Stage Enterprise."

*Use of Estimates*—The preparation of the accompanying consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

*Principles of Consolidation*—The accompanying consolidated financial statements include the accounts and transactions of Oxygen Biotherapeutics, Inc. and Synthetic Blood International, Inc. All material intercompany transactions and balances have been eliminated in consolidation.

*Preclinical Study and Clinical Accruals*—The Company estimates our preclinical study and clinical trial expenses based on the services received pursuant to contracts with several research institutions and contract research organizations ("CROs") that conduct and manage preclinical and clinical trials on our behalf. The financial terms of the agreements vary from contract to contract and may result in uneven expenses and payment flows. Preclinical study and clinical trial expenses include the following:

- fees paid to contract research organizations in connection with clinical trials,
- fees paid to research institutions in conjunction with preclinical research studies, and
- fees paid to contract manufacturers and service providers in connection with the production and testing of active pharmaceutical ingredients and drug materials for use in preclinical studies and clinical trials.

*Cash and Cash Equivalents*—The Company considers all highly liquid instruments with a maturity date of three months or less, when acquired, to be cash equivalents.

*Cash Concentration Risk and Other Risks and Uncertainties*—During 2008, the Federal Deposit Insurance Corporation, or FDIC, temporarily increased the coverage on substantially all depository accounts to \$250,000 and for certain qualifying and participating non-interest bearing transaction accounts the coverage is unlimited. The increase in coverage is scheduled to expire on December 13, 2013, at which time the amounts insured by the FDIC will return to \$100,000. At April 30, 2010, the Company's cash and cash equivalents included balances uninsured by the FDIC of \$449,684.

*Property and Equipment, Net*—Property and equipment are stated at cost, subject to adjustments for impairment, less accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the following estimated useful lives:

Laboratory equipment	3-5 years
Office furniture and fixtures	7 years
Computer equipment and software	3 years

Leasehold improvements                      Shorter of useful life or remaining lease term

Maintenance and repairs are charged to expense as incurred, improvements to leased facilities and equipment are capitalized.

*Impairment of Long-Lived Assets*—The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

*Research and Development Costs*—Research and development costs include, but are not limited to, (i) expenses incurred under agreements with contract research organizations and investigative sites, which conduct our clinical trials and a substantial portion of our preclinical studies; (ii) the cost of manufacturing and supplying clinical trial materials; (iii) payments to contract service organizations, as well as consultants; (iv) employee-related expenses, which include salaries and benefits; (v) facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, depreciation of leasehold improvements and equipment and laboratory and other supplies; and (vi) stock-based compensation expense. All research and development expenses are expensed as incurred.

*Income Taxes*—Deferred tax assets and liabilities are recorded for differences between the financial statement and tax bases of the assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense is recorded for the amount of income tax payable or refundable for the period increased or decreased by the change in deferred tax assets and liabilities during the period.

*Stock-Based Compensation*—We account for stock based compensation in accordance with ASC 718 *Compensation — Stock Compensation*, using the prospective transition method, which requires the measurement and recognition of compensation expense for all stock-based payment awards granted, modified and settled to our employees and directors after May 1, 2005. Our financial statements reflect the impact of ASC 718. We chose the "straight-line" attribution method for allocating compensation costs and recognized the fair value of each stock option on a straight-line basis over the requisite service period.

We account for equity instruments issued to non-employees in accordance with ASC 505-50 *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Equity instruments issued to non-employees are recorded at their fair value on the measurement date and are subject to periodic adjustment as the underlying equity instruments vest.

*Loss Per Share*—Basic loss per share, which excludes antidilutive securities, is computed by dividing loss available to common shareholders by the weighted-average number of common shares outstanding for that particular period. In contrast, diluted loss per share considers the potential dilution that could occur from other equity instruments that would increase the total number of outstanding shares of common stock. Such amounts include shares potentially issuable under outstanding options, warrants and convertible debentures. A reconciliation of the numerator and denominator used in the calculation of basic and diluted net loss per share follows.

	<u>Year ended April 30,</u>	
	<u>2010</u>	<u>2009</u>
<b>Historical net loss per share:</b>		
Numerator		
Net loss, as reported	(10,507,376)	(33,218,840)
Less: Effect of amortization of interest expense on convertible notes	<u>—</u>	<u>—</u>
Net loss attributed to common stockholders (diluted)	(10,507,376)	(33,218,840)
Denominator		
Weighted-average common shares outstanding	19,485,065	11,551,356
Effect of dilutive securities	<u>—</u>	<u>—</u>
Denominator for diluted net loss per share	<u>19,485,065</u>	<u>11,551,356</u>
Basic and diluted net loss per share	<u>\$ (0.54)</u>	<u>\$ (2.88)</u>

The following outstanding options, convertible note shares and warrants were excluded from the computation of basic and diluted net loss per share for the periods presented because including them would have had an anti-dilutive effect.

	<u>Year ended April 30,</u>	
	<u>2010</u>	<u>2009</u>
Options to purchase common stock	981,839	858,111
Convertible note shares outstanding	4,292	94,971
Warrants to purchase common stock	3,322,154	8,067,514

*Operating Leases*—The Company maintains operating leases for its office and laboratory facilities. The lease agreements may include rent escalation clauses and tenant improvement allowances. We recognize scheduled rent increases on a straight-line basis over the lease term beginning with the date we take possession of the leased space. Differences between rental expense and actual rental payments are recorded as deferred rent liabilities and are included in "Other liabilities" on the consolidated balance sheets.

*Fair Value*—On May 1, 2008, we adopted ASC 820 *Fair Value Measurements*, as it relates to financial assets and financial liabilities. The Company's balance sheet includes the following financial instruments: cash and cash equivalents, short-term notes payable and convertible debentures. The Company considers the carrying amount of its cash and cash equivalents and short-term notes payable to approximate fair value due to the short-term nature of these instruments. It is not practicable for the Company to estimate the fair value of its convertible debentures as such estimates cannot be made without incurring excessive costs, but management believes the difference between fair value and carrying value to not be material. The significant terms of the Company's convertible debentures are described in Note D. At April 30, 2010 and 2009 the debentures had a gross carrying value of \$15,903 and \$351,867, respectively, with unamortized discounts totaling \$5,725 and \$124,152, respectively.

In addition to the above financial instruments, the Company maintains an investment in a start-up technology company, Glucometrics, Inc. The investment was recorded in Other Assets at cost at April 30, 2009. We review this investment quarterly, including historical and projected financial performance, expected cash needs and recent funding events. We recognize other-than-temporary impairments

if the market value of the investment is below its cost basis for an extended period of time or if the issuer has experienced significant financial declines or difficulties in raising capital to continue operations. We recorded an other-than-temporary impairment of \$114,193 in the fourth quarter of 2010. See Note C for additional details. This investment totaled \$0 and \$114,193 at April 30, 2010 and 2009, respectively.

#### *Recent Accounting Pronouncements*

In September 2009, the Financial Accounting Standards Board, or FASB ratified Revenue Arrangements with Multiple Deliverables issued as Accounting Standards Update, or ASU, 2009-13. ASU 2009-13 updates the existing multiple-element arrangements guidance currently included in ASC 605-25, *Revenue Recognition — Multiple-Element Arrangements*. The revised guidance provides for two significant changes to the existing multiple-element arrangements guidance. The first relates to the determination of when the individual deliverables included in a multiple-element arrangement may be treated as separate units of accounting. This change is significant as it will likely result in the requirement to separate more deliverables within an arrangement, ultimately leading to less revenue deferral. The second change modifies the manner in which the transaction consideration is allocated across the separately identifiable deliverables. These changes are likely to result in earlier recognition of revenue for multiple-element arrangements than under previous guidance. ASU 2009-13 also significantly expands the disclosures required for multiple-element revenue arrangements. The revised multiple-element arrangements guidance will be effective for the first annual reporting period beginning on or after June 15, 2010, and may be applied retrospectively for all periods presented or prospectively to arrangements entered into or modified after the adoption date. Early adoption is permitted provided that the revised guidance is retroactively applied to the beginning of the year of adoption. If the guidance is adopted prospectively, certain transitional disclosures are required for each reporting period in the initial year of adoption. As a result, it is effective for us in the first quarter of fiscal year 2011. The Company does not believe that the adoption of ASU 2009-13 will have a material impact on our consolidated financial statements.

In January, 2010, the FASB issued ASU 2010-06, *Improving Disclosures about Fair Value Measurements*. The standard amends ASC Topic 820, *Fair Value Measurements and Disclosures* to require additional disclosures related to transfers between levels in the hierarchy of fair value measurement. The standard does not change how fair values are measured. The standard is effective for interim and annual reporting periods beginning after December 15, 2009. As a result, it is effective for us in the first quarter of fiscal year 2011. The Company does not believe that the adoption of ASU 2010-06 will have a material impact on its consolidated financial statements.

In April 2010, the FASB issued ASU 2010-12, *Accounting for Certain Tax Effects of the 2010 Health Care Reform Acts*. The standard amends ASC Topic 740, *Income Taxes*. The guidance addresses the effect that the different signing dates might have on the accounting for the Health Care and Education Reconciliation Act of 2010 and the Patient Protection and Affordable Care Act. The Company does not anticipate the adoption of the guidance to have a material impact on its results of operations, financial position, or cash flows.

In April 2010, the FASB issued ASU 2010-17, *Milestone Method of Revenue Recognition*. The standard amends ASC Topic 605. The guidance addresses milestone definitions and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. The amendments are effective on a prospective basis for milestones achieved in fiscal years beginning on or after June 15, 2010. The Company does not anticipate the adoption of the guidance to have a material impact on its results of operations, financial position, or cash flows.

#### **NOTE C—BALANCE SHEET COMPONENTS**

##### *Inventory*

In late April 2010, the Company completed production of its cosmetic product Dermacyte. The Dermacyte blister packs were available for retail sale and distribution through the Company's website beginning April 27, 2010.

The Company operates in an industry characterized by rapid improvements and changes to its technology and products. The introduction of new products by the Company or its competitors can result in its inventory being rendered obsolete or requiring it to sell items at a discount. The Company estimates the recoverability of its inventory by reference to its internal estimates of future demands and product life cycles. If the Company incorrectly forecasts demand for its products or inadequately manages the introduction of new product lines, the Company could materially impact its consolidated financial statements by having excess inventory on hand. The Company's future estimates are subjective and could be incorrect. As of April 30, 2010, management evaluated the Company's inventory and determined that the quantities were not excessive and the carrying value was not subject to reserve.

Inventories are recorded at cost using the First-In-First-Out ("FIFO") method. Ending inventories are comprised of raw materials and direct costs of manufacturing and valued at the lower of cost or market. Inventories consisted of the following as of April 30, 2010 and 2009:

	April 30,	
	2010	2009
Raw materials	\$ 310,315	\$ —
Work in process	—	—
Finished goods	224,775	—
	<u>\$ 535,090</u>	<u>\$ —</u>

*Property and equipment, net*—Property and equipment consist of the following:

	April 30,	
	2010	2009
Laboratory equipment	\$ 980,025	\$ 812,597
Office furniture and fixtures	32,900	29,184
Computer equipment and software	53,921	30,152
Leasehold improvements	4,810	4,810
	1,071,656	876,743
Less: Accumulated depreciation and amortization	(687,697)	(666,388)
	<u>\$ 383,959</u>	<u>\$ 210,355</u>

Depreciation and amortization expense was approximately \$107,667 and \$66,941 for the years ended April 30, 2010 and 2009, respectively.

*Other assets*—Other assets consist of the following:

	April 30,	
	2010	2009
Investment in Glucometrics	\$ —	\$ 114,193
Prepaid royalty fee	50,000	—
Other	2,651	49,200
	<u>\$ 52,651</u>	<u>\$ 163,393</u>

*Investment in Glucometrics*—In September 2008, the Company assigned all of its patent rights related to glucose monitoring technology to Glucometrics, Inc. ("Glucometrics"). Pursuant to the terms of the agreement, Glucometrics has exclusive rights to this technology for the remaining life of the patents. In exchange for these rights, we received a ten percent interest in Glucometrics and acquired the right to receive royalty payments on revenues generated by any product developed by Glucometrics that uses the glucose monitoring technology. In addition, Glucometrics is required to reimburse us for all of the costs associated with prosecuting and maintaining the assigned patents. As of April 30, 2010, we have recorded a receivable of \$65,895 from Glucometrics for reimbursable patent costs incurred on their behalf.

The Company recognizes an impairment charge when the decline in the estimated fair value of an asset below the amortized cost is determined to be other-than-temporary. We consider various factors in determining whether to recognize an impairment charge, including the duration of time and the severity to which the fair value has been less than our amortized cost and any adverse changes in the investees' financial condition. Management reviewed the financial condition of Glucometrics as of April 30, 2010 and evaluated the company's business plan for the next fiscal year and determined the decline in the estimated fair value of our investment in

Glucometrics is impaired and the impairment is not temporary. Due to the tightening of the credit markets and Glucometrics' inability to raise sufficient cash for operations in the capital markets, we concluded the company's ability to continue as a going concern is at significant risk. In the fourth quarter of 2010, we recorded an impairment charge of \$114,193 as a non-operating *Other Loss*.

*Accrued liabilities*—Accrued liabilities consist of the following:

	April 30,	
	2010	2009
Clinical trial related	\$ 135,276	\$ —
Employee related	254,485	49,402
Professional services	391,210	102,520
Other	62,932	89,596
	<u>\$ 843,903</u>	<u>\$ 241,518</u>



#### NOTE D—NOTES PAYABLE

In November 2009, we financed our annual commercial, product liability, and Director and Officer insurance policy through the issuance of a short-term note payable. The note was in the amount of \$96,563 with a ten-month term and 6.99% interest. As of April 30, 2010, we had \$47,580 of the outstanding principal and recorded \$2,261 in interest expense.

In 2008 we issued \$20,282,532 five-year convertible debentures. These notes were issued at a 55% discount and were convertible into common shares at \$3.705 per share. As part of the financing agreement, the Company also issued five-year warrants with an exercise price of \$3.705. In accordance with ASC815-40-05, the Company valued the embedded conversion feature and warrants utilizing the Black-Scholes valuation model.

The Company incurred \$5,510,562 additional costs associated with the convertible note financing. These costs were capitalized and amortized as interest expense over the term of the notes.

During the year ended April 30, 2010 and 2009, we issued 90,682 and 5,372,362 shares of common stock as settlement of \$335,977 and \$19,904,605 of the principal outstanding, respectively. Interest charges associated with the notes payable, including amortization of the original issue discount, common stock purchase warrant value, beneficial conversion feature, and debt issue costs aggregated \$152,220 and \$24,856,041 for the years ended April 30, 2010 and 2009, respectively.

As of April 30, 2010 and 2009, the outstanding notes had a principal balance of \$15,903 and \$351,866 and unamortized discounts of \$5,725 and \$124,151, respectively.

In November 2008, we financed our annual commercial, product liability, and Director and Officer insurance policy through the issuance of a short-term note payable. The note was in the amount of \$90,145 with a ten-month term and 6.75% interest. During the year ended April 30, 2010 and 2009 we repaid \$36,666 and \$53,479 of the outstanding principal and recorded \$517 and \$2,295 in interest expense, respectively.

The following table summarizes our outstanding notes payable as of April 30:

	<u>April 30,</u>	
	<u>2010</u>	<u>2009</u>
Note payable	\$ 48,983	\$ 36,666
Convertible debentures	<u>15,903</u>	<u>351,866</u>
	64,886	388,532
Less: Unamortized discount	<u>(5,725)</u>	<u>(124,151)</u>
	<u><u>\$ 59,161</u></u>	<u><u>\$ 264,381</u></u>

The following table summarizes our unamortized debt issuance costs as of April 30:

	<u>April 30,</u>	
	<u>2010</u>	<u>2009</u>
Unamortized debt issuance costs	—	—
	<u>\$</u>	<u>\$ 33,783</u>

The Company's long-term debt at April 30, 2010 matures as follows:

<u>Year ending April 30,</u>	<u>Amount</u>
2011	\$ 7,410
2012	4,638
2013	<u>3,855</u>
Total scheduled maturities	15,903
Less: Unamortized discount at April 30, 2010	<u>(5,725)</u>
	<u>\$ 10,178</u>

#### NOTE E—INTANGIBLE ASSETS

The following table summarizes our intangible assets as of April 30, 2010:

<u>Asset Category</u>	<u>Value Assigned</u>	<u>Weighted Average Amortization Period (in Years)</u>	<u>Impairments</u>	<u>Accumulated Amortization</u>	<u>Carrying Value (Net of Impairments and Accumulated Amortization)</u>
Patents	\$ 434,612	12.6	—	\$ (111,363)	\$ 323,249
License Rights	519,353	18.6	—	(38,042)	481,311
Trademarks	<u>103,150</u>	N/A	—	—	<u>103,150</u>
Total	<u>\$ 1,057,115</u>		<u>—</u>	<u>\$ (149,405)</u>	<u>\$ 907,710</u>

The following table summarizes our intangible assets as of April 30, 2009:

<u>Asset Category</u>	<u>Value Assigned</u>	<u>Weighted Average Amortization Period (in Years)</u>	<u>Impairments</u>	<u>Accumulated Amortization</u>	<u>Carrying Value (Net of Impairments and Accumulated Amortization)</u>
Patents	\$ 241,290	9.6	—	\$ (88,425)	\$ 152,865
License Rights	496,408	19.6	—	(12,473)	483,935
Trademarks	<u>13,422</u>	N/A	—	—	<u>13,422</u>
Total	<u>\$ 751,120</u>		<u>—</u>	<u>\$ (100,898)</u>	<u>\$ 650,222</u>

For the years ended April 30, 2010 and 2009, the aggregate amortization expense on the above intangibles was approximately \$48,265 and \$19,763, respectively. The following table summarizes the aggregate amortization expense over the remaining life of the patents and license rights as of April 30, 2010:

<u>Year ending April 30,</u>	<u>Aggregate amortization expense</u>
2011	\$ 54,852
2012	54,852
2013	54,852
2014	53,050
2015	49,834
Thereafter	<u>537,119</u>
	 <u><u>\$ 804,559</u></u>

*Agreement with Virginia Commonwealth University*—In May 2008 the Company entered into a license agreement with Virginia Commonwealth University ("Licensor", "VCU") whereby it obtained a worldwide, exclusive license to valid claims under three of the Licensor's patent applications that relate to methods for non-pulmonary delivery of oxygen to tissue and the products based on those valid claims used or useful for therapeutic and diagnostic applications in humans and animals. The license includes the right to sub-license to third parties. The term of the agreement is the life of the patents covered by the patent applications unless we elect to terminate the agreement prior to patent expiration. Under the agreement the Company has an obligation to diligently pursue product development and pursue, at our own expense, prosecution of the patent applications covered by the agreement. As part of the agreement, the Company is required to pay to VCU nonrefundable payments upon achieving development and regulatory milestones. The following table summarizes the milestones and associated payments under the agreement:

<u>Clinical Indication</u>	<u>Medical Device</u>
\$25,000 upon filing of IND	\$25,000 upon filing of FDA 510K or PMA
\$100,000 upon completion of Phase I clinical trial	\$250,000 upon receipt of FDA or foreign equivalent marketing approval
\$200,000 upon completion of Phase II human clinical trial	
\$300,000 upon completion of Phase III human clinical trial	
\$500,000 upon receipt of FDA or foreign equivalent marketing approval	

As of April 30, 2010, the Company has not met any of the milestones described above.

The Company has capitalized \$519,353 and \$496,408 in costs as of April 30, 2010 and 2009, respectively, to acquire the license rights and legal fees to maintain the licensed patents. These costs are being amortized over the life of the agreement.

The agreement with VCU also requires the Company to pay royalties to VCU at specified rates based on annual net sales derived from the licensed technology. The following table summarizes the royalty payment rates based on annual net sales:

<u>Net Sales</u>	<u>Royalty fee</u>
Up to \$10 million	25%
Over \$10 million to \$49 million	15%
Over \$49 million	10%
Dermacyte sales	4%

Pursuant to the agreement, we must make minimum annual royalty payments to VCU totaling \$70,000 as long as the agreement is in force. These payments are fully creditable against royalty payments due for sales and sublicense revenue earned during the fiscal year as described above. We have paid \$70,000 and \$0 in royalty fees for the years ended April 30, 2010 and 2009 respectively.

*Patents*—The Company currently holds, or has filed for, US and worldwide patents covering 13 various methods and uses of our PFC technology. We capitalize amounts paid to third parties for legal fees, application fees and other direct costs incurred in the filing and prosecution of our patent applications. These capitalized costs are amortized on a straight-line method over their useful life or legal life, whichever is shorter.

*Trademarks*—The Company currently holds, or has filed for, trademarks to protect the use of names and descriptions of our products and technology. We capitalize amounts paid to third parties for legal fees, application fees and other direct costs incurred in the filing and prosecution of our trademark applications. These trademarks are evaluated annually in accordance with ASC 350, *Intangibles – Goodwill and other*. We evaluate (i) our expected use of the underlying asset, (ii) any laws, regulations, or contracts that may limit the useful life, (iii) the effects of obsolescence, demand, competition, and stability of the industry, and (iv) the level of costs to be incurred to commercialize the underlying asset. As of April 30, 2010, we have concluded that none of our trademarks are impaired.

## **NOTE F—STOCKHOLDERS' EQUITY**

### ***Preferred Stock***

Our Certificate of Incorporation authorizes us to issue 400,000,000 shares of \$0.0001 par value common stock and 10,000,000 shares of undesignated par value preferred stock. As of April 30, 2010 and 2009 and 2008, there were no shares of preferred stock issued or outstanding.

### ***Common Stock***

During the years ended April 30, 2010 and 2009, we recorded \$102,843 and \$9,330, respectively, as compensation expense for the fair value of 19,858 and 1,953 shares of restricted common stock, respectively, issued to the CEO in accordance with his employment agreement.

*Securities Purchase Agreement*—On June 8, 2009, the Company entered into a securities purchase agreement with JP SPC 1 Vatea, Segregated Portfolio, ("Vatea Fund"), an investment fund formed under the laws of the Cayman Islands (the "Agreement"). The agreement establishes milestones for the achievement of product development and regulatory targets and other objectives, after which Vatea Fund is required to purchase up to 4 million additional shares of common stock at a price of \$3.75 per share. If a milestone is not achieved by its corresponding target date, then the date is automatically extended for three months. Thereafter, if a milestone is not achieved by its extended target date, the Company and Vatea Fund shall negotiate in good faith agreement on a new target date for the milestone, but if no agreement is reached within 30 days Vatea Fund has no obligation to purchase any shares with respect to that milestone should it subsequently be achieved. The obligation of Vatea Fund to purchase any additional shares upon achieving milestones ends for any milestones not achieved by September 30, 2011. Including the initial investment in July 2009, and assuming all milestones are achieved in a timely manner, the securities purchase agreement provides for a maximum of 5,333,334 shares being sold for \$20 million. The number of shares issued is subject to adjustment for stock dividends, stock splits, reverse stock splits, and similar transactions.

Under the terms of the agreement, Vatea Fund purchased on July 10, 2009, 1,333,334 shares of the Company's restricted common stock at a price of \$3.75 per share, or a total of \$5 million.

In connection with the closing, the Company paid a consulting fee to Melixia SA for services provided as facilitating agent, which consisted of \$500,000 in cash and 66,667 shares of restricted common stock valued at \$350,002. The Company also paid \$75,000 in fees to another consultant who assisted with the Agreement.

On September 2, 2009, the Company and the Vatea Fund amended the Agreement providing an alternative milestone schedule.

In August 2009, the Company received formal approval from Swissmedic to begin Phase II clinical trials of Oxycyte in Switzerland. The Swissmedic approval triggered the first milestone payment in the amended milestone schedule of the. In accordance with the Agreement, Vatea Fund was required to purchase an additional 1,600,000 shares of common stock at \$3.75 per share, or \$6,000,000, on or before December 10, 2009.

- The initial partial closing occurred on October 29, 2009, pursuant to which 160,000 shares were delivered to Vatea Fund against payment to the Company of \$600,000.
- The second partial closing occurred on November 20, 2009, pursuant to which 640,000 shares were delivered to Vatea Fund against payment to the Company of \$2.4 million.
- The final closing occurred on December 9, 2009, pursuant to which 800,000 shares were delivered to Vatea Fund against payment to the Company of \$3 million.

In connection with the three closings, the Company paid a consulting fee to Melixia SA for services provided as facilitating agent, which consisted of \$600,000 in cash and 80,000 shares of restricted common stock valued at \$412,000. The Company also paid \$90,000 in fees to another consultant who assisted with the Agreement.

On April 23, 2010, the Company and Vatea Fund entered into a second amendment to the Agreement. Under the second amendment, the parties agreed to modify two provisions of the Agreement. The first modification was a change to the form of fees paid to the facilitating agent, Melixia SA. For all closings under the Agreement occurring on or after April 23, 2010, cash fees will no longer be paid. Fees will be paid in the form of restricted shares of common stock, issued in an amount equal to 20% of the shares issued at each closing. The second modification changes the schedule of milestones. The new schedule includes a closing of \$500,000 on or before April 30, 2010, another closing in the same amount on or before May 30, 2010, and a closing in the amount of \$3,500,000 on the earlier of (1) closing of a license or sales agreement with an aggregate value in excess of \$500,000 or (2) December 31, 2011. The remaining balance of \$4,500,000 under the Agreement shall be paid upon achievement of the amended product development and regulatory milestones.

- On April 26, 2010, in accordance with the second amendment of the agreement, the Company received \$500,000 and issued 133,334 shares to the Vatea Fund.
- On May 27, 2010, in accordance with the second amendment of the agreement, the Company received \$500,000 and issued 133,334 shares to the Vatea Fund.

In connection with the two closings, the Company issued 53,334 shares of restricted common stock valued at \$160,002 to Melixia for their services provided as facilitating agent. The Company also paid \$67,500 in fees to another consultant who assisted with the Agreement.

### ***Warrants***

In May 2008, the Company issued warrants to purchase 92,334 shares of common stock to FIONA International as compensation for consulting fees for development of Oxycyte. The warrants were granted with a strike price of \$3.705 with a term of 2 years. The Company recorded compensation expense of \$786,265 for the computed fair value of the warrants at the grant date.

In May 2008, the Company issued warrants to purchase 33,334 shares of common stock to VCU Intellectual Property Foundation as partial consideration for the license agreement for exclusive rights to develop their patented technology. The warrants were granted with a strike price of \$6.30 and term of 5 years. The Company capitalized expense of \$353,500 for the computed fair value of the warrants at the grant date.

In July 2008, the Company issued warrants to purchase 109,800 shares of common stock to FIONA International as compensation for consulting fees for development of Oxycyte. The warrants were granted with a strike price of \$3.705 with a term of 2 years. The Company recorded compensation expense of \$1,088,667 for the computed fair value of the warrants at the grant date.

In May 2009, as part of a consulting agreement with an unrelated third party to provide services in connection with the Company's Share Purchase Agreement, we agreed to extend the term of 151,111 outstanding warrants that were set to expire on May 31, 2009. The term for these warrants was extended through January 31, 2011. We recorded \$256,181 in compensation expense for the difference in the computed fair values of the modified warrants and the original warrants at the modification date.

In July 2009, the holders of 6,085,280 outstanding warrants accepted an exchange agreement (the "Agreement") whereby the holders of the warrants agreed to cancel their outstanding warrant shares in exchange for a cash payment equal to \$0.60 per warrant share and 1/2 share of restricted Common Stock for each warrant share cancelled. In accordance with the Agreement, we had, at our sole discretion, the option to exchange all, a portion of, or none of the holders' warrants. On July 20, 2009, we cancelled 4,727,564 of the outstanding warrants in exchange for \$2,836,520 in cash and 2,363,767 shares of restricted common stock. The cancelled warrants had strike prices ranging from \$3.675 - \$3.705; a 5-year term; and were issued between April 2006 and October 2008.

On November 2, 2009, as part of a consulting agreement with an unrelated third party to provide services in connection with the placement of a Director of the Board, we issued 7,408 warrants to Blaise Group International. The warrants were issued with an exercise price of \$6.75 and a seven year term. We recorded \$37,339 in compensation expense for the computed fair value of the warrants. On February 11, 2010, we issued an additional 8,130 warrants to Blaise Group International for their services in placing a second member on our Board of Directors.

On February 17, 2010, we issued warrants to purchase 22,000 shares of restricted common stock to a consultant for advisory services. The warrants we issued with an exercise price of \$3.705 and expire on January 31, 2011. These warrants were valued at \$18,319.

During the year ended April 30, 2009, we issued 544,200 shares and received a total of \$2,225,624 for exercised warrants. The following table summarizes our warrant activity for the years ended April 30, 2010 and 2009:

	<u>Warrants</u>	<u>Weighted Average Exercise Price</u>
<b>Outstanding at April 30, 2008</b>	<b>8,376,580</b>	<b>\$ 3.75</b>
Granted	235,467	4.05
Exercised	(544,200)	4.05
Forfeited	<u>(333)</u>	<u>1.50</u>
<b>Outstanding at April 30, 2009</b>	<b>8,067,514</b>	<b>\$ 3.75</b>
Granted	57,539	5.72
Exercised	—	—
Cancelled	(4,727,564)	3.70
Forfeited	<u>(75,335)</u>	<u>6.02</u>
<b>Outstanding at April 30, 2010</b>	<b><u>3,322,154</u></b>	<b><u>\$ 3.89</u></b>

See Note K—"Subsequent Events" for a discussion of warrants issued after the end of fiscal 2010.

### ***Stock Options***

#### *1999 Amended Stock Plan*

In October 2000, we adopted the 1999 Stock Plan (the "Plan"), as amended and restated on June 17, 2008. Under the Plan, with the approval of the Compensation Committee of the Board of Directors, we may grant stock options, restricted stock, stock appreciation rights and new shares of common stock upon exercise of stock options. Stock options granted under the Plan may be either incentive stock options ("ISOs"), or nonqualified stock options ("NSOs"). ISOs may be granted only to employees. NSOs may be granted to employees, consultants and directors. Stock options under the Plan may be granted with a term of up to ten years and at prices no less than fair market value for ISOs and no less than 85% of the fair market value for NSOs. To date, stock options granted generally vest over one to three years and vest at a rate of 34% upon the first anniversary of the vesting commencement date and 33% on each anniversary thereafter. As of April 30, 2010 we had 182,424 shares of common stock available for grant under the Plan.

Option activity under the Plan is as follows:

	<u>Outstanding Options</u>			
	<u>Shares Available for Grant</u>	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Aggregate Intrinsic Value</u>
Shares reserved at inception	266,667			
Options granted	(447,007)	447,007	\$ 3.25	
Options exercised		(3,667)	\$ 2.22	\$ 23,607 (1)
Options cancelled	<u>97,055</u>	<u>(87,671)</u>	\$ 2.48	
<b>Balances, at April 30, 2008</b>	(83,285)	355,669		
Additional shares reserved	533,333			
Options granted	(104,000)	104,000	\$ 5.30	
Options exercised	—	(9,121)	\$ 1.80	\$ 33,174 (1)
Options cancelled	<u>5,212</u>	<u>(5,212)</u>	\$ 1.80	
<b>Balances, at April 30, 2009</b>	351,260	445,336		
Options granted	(252,170)	252,170	\$ 5.61	
Options exercised	—	(29,000)	\$ 1.99	\$ 115,393 (1)
Options cancelled	<u>83,334</u>	<u>(83,334)</u>	\$ 3.35	
<b>Balances, at April 30, 2010</b>	182,424	585,172	\$ 4.10	\$ 1,104,483 (2)

(1) Amounts represent the difference between the exercise price and fair value of Oxygen Biotherapeutics' stock at the time of exercise.

(2) Amount represents the difference between the exercise price and \$5.00, the closing price of Oxygen Biotherapeutics' stock on April 30, 2010, as reported on The NASDAQ Capital Market, for all in-the-money options outstanding.

Option activity under the Plan is as follows:

	Shares Available for Grant	Outstanding Options		
		Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
Shares reserved at inception	266,667			
Options granted	(447,007)	447,007	\$ 3.25	
Options exercised		(3,667)	\$ 2.22	\$ 23,607 (1)
Options cancelled	97,055	(87,671)	\$ 2.48	
<b>Balances, at April 30, 2008</b>	(83,285)	355,669		
Additional shares reserved	533,333			
Options granted	(104,000)	104,000	\$ 5.30	
Options exercised	—	(9,121)	\$ 1.80	\$ 33,174 (1)
Options cancelled	5,212	(5,212)	\$ 1.80	
<b>Balances, at April 30, 2009</b>	351,260	445,336		
Options granted	(252,170)	252,170	\$ 5.61	
Options exercised	—	(29,000)	\$ 1.99	\$ 115,393 (1)
Options cancelled	83,334	(83,334)	\$ 3.35	
<b>Balances, at April 30, 2010</b>	182,424	585,172	\$ 4.10	\$ 1,104,483 (2)

(1) Amounts represent the difference between the exercise price and fair value of Oxygen Biotherapeutics' stock at the time of exercise.

(2) Amount represents the difference between the exercise price and \$5.00, the closing price of Oxygen Biotherapeutics' stock on April 30, 2010, as reported on The NASDAQ Capital Market, for all in-the-money options outstanding.

#### Other Stock Options

In September 2008, the Company recognized expense of \$2,236,149 for the computed fair value of 326,667 stock options issued in conjunction with the Glucometrics, Inc. licensing agreement. These options were granted to outside consultants and directors and had exercise prices ranging between \$3.68 and \$4.50 with 3 to 10 year terms. As of April 30, 2010 and 2009, the Company had 396,667 non-qualified options outstanding.

The following table summarizes all options outstanding at April 30, 2010:

Exercise Price	Options Outstanding at April 30, 2010		Options Exercisable and Vested at April 30, 2010	
	Number of Options	Weighted Average Remaining Contractual Life (Years)	Number of Options	Weighted Average Exercise Price
\$1.35 to \$2.40	108,000	1.6	108,000	\$ 2.01
\$2.55 to \$3.90	485,669	6.6	480,114	\$ 3.57
\$4.20 to \$4.73	159,666	2.0	154,221	\$ 4.47
\$5.00 to \$6.60	119,503	4.5	81,669	\$ 5.56
\$6.90 to \$13.20	109,001	2.7	107,111	\$ 7.85
	981,839	4.69	931,115	\$ 4.20



The following table summarizes options outstanding that have vested and are expected to vest based on options outstanding as of April 30, 2010:

	<u>Number of Option Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Aggregate Intrinsic Value (1)</u>	<u>Weighted Average Remaining Contractual Life (Years)</u>
Vested	931,115	\$ 4.20	\$ 352,171.00	4.6
Vested and expected to vest (2)	831,618	\$ 4.28	\$ 397,862.00	4.7

(1) Amount represents the difference between the exercise price and \$5.00, the closing price of Oxygen Biotherapeutics' stock on April 30, 2010, as reported on The NASDAQ Capital Market, for all in-the-money options outstanding.

(2) Options outstanding that have vested and expected to vest are net of estimated future option forfeitures in accordance with the provisions of ASC 718.

The weighted-average grant-date fair value of options granted was \$3.67 in 2010 and \$4.81 in 2009.

The total fair value of options that vested during the years ended April 30, 2010 and 2009 was approximately \$913,000 and \$2,245,000, respectively.

As of April 30, 2010, there were unrecognized compensation costs of approximately \$66,000 related to non-vested stock option awards granted after May 1, 2004 that will be recognized on a straight-line basis over the weighted average remaining vesting period of 1.5 years.

#### *Other Information Related to Stock Options and Warrants*

We received \$57,625 and \$0 in cash from sales of shares through our equity plan for the years ended April 30, 2010 and 2009, respectively.

#### **NOTE G—STOCK-BASED COMPENSATION FOR EMPLOYEES**

The following table summarizes the stock-based compensation expense for stock options and our employee stock purchase plan that we recorded in the condensed statements of operations in accordance with ASC 718 for the years ended April 30, 2010 and 2009, respectively:

	<u>Years Ended April 30,</u>	
	<u>2010</u>	<u>2009</u>
General and administrative	\$ 812,996	\$ 2,328,634
Research and development	40,574	23,473
	<u>\$ 853,570</u>	<u>\$ 2,352,107</u>

We used the following assumptions to estimate the fair value of options granted under our stock option plans for the years ended December 31, 2009, 2008 and 2007:

	<u>Years Ended April 30,</u>	
	<u>2010</u>	<u>2009</u>
Risk-free interest rate (weighted average)	1.71%	2.90%
Expected volatility (weighted average)	98.11%	92.00%
Expected term (in years)	3-7.14	3-10
Expected dividend yield	0.00%	0.00%

*Risk-Free Interest Rate* The risk-free interest rate assumption was based on U.S. Treasury instruments with a term that is consistent with the expected term of our stock options.

<i>Expected Volatility</i>	The expected stock price volatility for our common stock was determined by examining the historical volatility and trading history for our common stock over a term consistent with the expected term of our options.
<i>Expected Term</i>	The expected term of stock options represents the weighted average period the stock options are expected to remain outstanding. It was calculated based on the historical experience that we have had with our stock option grants.
<i>Expected Dividend Yield</i>	The expected dividend yield of 0% is based on our history and expectation of dividend payouts. We have not paid and do not anticipate paying any dividends in the near future.
<i>Forfeitures</i>	As stock-based compensation expense recognized in the condensed consolidated statement of operations for the years ended 2010 and 2009 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on our historical experience.

#### **NOTE H—COMMITMENTS AND CONTINGENCIES**

*Operating Leases*—The Company leases its laboratory space under an operating lease that includes fixed annual increases and expires in July 2015. The Company leases its office space under a short-term operating lease that is renewable for three, six, or twelve month terms. Total rent expense for the two leases was \$249,240 and \$223,975 for the periods ended April 30, 2010 and 2009, respectively.

The future minimum payments for the long-term, non-cancelable lease are as follows:

<u>Year ending April 30,</u>	
2011	\$ 172,130
2012	172,130
2013	172,130
2014	172,130
2015	172,130
Thereafter	<u>43,033</u>
	<u><u>\$ 903,685</u></u>

The Company has sublet a portion of its lab facility in California to an unrelated third party. The sublease is for a 12 month term with an annual option to renew. At each renewal period, the monthly rental fee escalates 5%. For the years ended April 30, 2010 and 2009, the Company recorded \$77,435 and \$76,444, respectively, as other income for the rents received under the sublease agreement.

*Exflur Manufacturing Agreement*—The Company entered into a Supply Agreement with Exflur for the manufacturing and supply of FtBu. Under the terms of the Agreement, Exflur is to supply FtBu exclusively to the Company, and no other party. The fee for this exclusivity a non-refundable, non-creditable fee of \$25,000 each quarter for the term of the Agreement. The term of the Agreement is three years, beginning from January 1, 2010. The process of manufacturing FtBu is a trade secret owned by Exflur. Therefore, the Agreement also contains a provision requirement Exflur to maintain documentation of the entire manufacturing process in an Escrow Account, to be released to the Company only upon the occurrence of a triggering event, which includes dissolution, acquisition by another company who is not a successor, bankruptcy or creditors take action to secure rights against the manufacturing technology to satisfy a financial obligation.

*Litigation*—The Company is subject to litigation in the normal course of business, none of which management believes will have a material adverse effect on the Company's financial statements. At April 30, 2010 the Company is not a party to any litigation matters.

*Registration Requirement*—As further described in Notes D and F, warrants and convertible notes issued during the year ended April 30, 2008 are subject to a requirement that the Company file a registration statement with the SEC to register the underlying

shares, and that it be declared effective on or before January 9, 2009. In the event that the Company does not have an effective registration statement as of that date, or if at some future date the registration ceases to be effective, then the Company is obligated to pay liquidated damages to each holder in the amount of 1% of the aggregate market value of the stock, as measured on January 9, 2009 or at the date the registration statement ceases to be effective. As an additional remedy for non-registration of the shares, the holders would also receive the option of a cashless exercise of their warrant or conversion shares. As of April 30, 2010, approximately 44,669 of these warrants are subject to the registration requirement. EITF 00-19 provides guidance to proper recognition, measurement, and classification of certain freestanding financial instruments that are indexed to, and potentially settled in, any entity's own stock. If an issuer does not control the form of settlement, an instrument is classified as an asset or liability. An issuer is deemed to "control the settlement" if it has both the contractual right to settle in equity shares and the ability to deliver equity shares. EITF 00-19 states that the existence of a contractual requirement for the issuer to deliver registered shares is one of the conditions that is considered outside the control of the issuer. However, the Financial Accounting Standards Board issued a FASB Staff Position on EITF 00-19-2, *Accounting for Registration Payment Arrangements* ("FSP EITF 00-19-2") in December 2006. The FSP specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with ASC 450, *Accounting for Contingencies*.

Pursuant to the guidance in EITF 00-19 and FSP EITF 00-19-2, the Company has accounted for the warrants as equity instruments in the accompanying financial statements. The Company does not believe the registration payments are probable, and as such, has not recorded any amounts with respect to the separately measured registration rights agreement.

#### NOTE I—401(k) BENEFIT PLAN

The Company sponsors a 401(k) Retirement Savings Plan (the Plan) for all eligible employees. Full-time employees over the age of 18 are eligible to participate in the Plan after 90 days of continuous employment. Participants may elect to defer earnings into the Plan up to the annual IRS limits and the Company provides a matching contribution up to 5% of the participants' annual salary in accordance with the Plan documents. The Plan is managed by a third-party trustee. For the period ended April 30, 2010 and 2009, the Company recorded \$32,471 and \$9,869, respectively, for matching contributions expense.

#### NOTE J—INCOME TAXES

The Company has not recorded any income tax expense for the periods ended April 30, 2010 and 2009 due to our history of operating losses.

The reconciliation of income tax expenses (benefit) at the statutory federal income tax rate of 34% to net income tax expenses (benefit) for the years ended April 30, 2010 and 2009 is as follows:

	April 30,	
	2010	2009
U.S. federal taxes (benefit) at statutory rate	\$ (3,572,505)	\$ (11,294,405)
Interest expense	(1,077,865)	7,251,656
Stock compensation expense	290,214	668,858
Others	189,213	(31,758)
Net operating loss not used	4,170,943	3,405,649
	<u>\$ —</u>	<u>\$ —</u>

The tax effects of temporary differences and carry forwards that give rise to significant portions of the deferred tax assets are as follows:

	April 30,	
	2010	2009
Deferred tax assets		
Net operating loss carryforwards	\$ 19,401,438	\$ 15,510,482
Interest	6,173,791	7,251,656
Accruals and others	223,841	(10,149)
Depreciation and amortization	(23,599)	22,795
Total deferred tax assets	25,775,471	22,774,784
Less: Valuation allowance	(25,775,471)	(22,774,784)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

At April 30, 2010 and 2009 we had net operating loss carry forwards of approximately \$75.8 million and \$44.8 million available to reduce future taxable income, if any, for Federal and California state income tax purposes, respectively. The net operating loss carry forwards expire between 2010 and 2030, and valuation allowances have been provided.

Utilization of the net operating loss carry forward may be subject to an annual limitation due to the ownership percentage change limitations provided by the Internal Revenue Code of 1986 and similar state provisions. The annual limitations may result in the expiration of the net operating loss before utilization.

The Company adopted ASC 740-10 on May 1, 2007. As of April 30, 2010, we had no unrecognized tax benefits and do not expect any material change during the next year. As of April 30, 2010, we have not recorded any interest or penalties under this pronouncement.

The Company files U.S. and state income tax returns with varying statutes of limitations. The tax years 1995 forward remain open to examination due to the carryover of unused net operating losses or tax credits.

#### **NOTE K—SUBSEQUENT EVENTS**

On May 4, 2010, the Company entered into a placement agency agreement (the "Placement Agency Agreement") with Roth Capital Partners, LLC (the "Placement Agent") relating to the sale by the Company of 1,724,138 units to certain institutional investors pursuant to a registered direct offering (the "Offering"), at a purchase price of \$2.90 per unit (each, a "Unit" and collectively, the "Units"). Each Unit consisted of one share of the Company's common stock and a warrant to purchase 0.425 shares of common stock. The warrants have a five-year term from the date of issuance, are exercisable on or after the date of issuance, and are exercisable at an exercise price of \$5.32 per share of Common Stock.

The sale of the Units was made pursuant to subscription agreements, dated May 4, 2010 (the "Subscription Agreements"), with each of the investors. The Offering was completed on May 7, 2010.

The aggregate net proceeds to the Company, after deducting placement agent fees and other estimated offering expenses payable by the Company, were approximately \$4.4 million. The Placement Agent received a placement fee equal to 6.5% of the gross proceedings of the Offering. The Company also reimbursed the Placement Agent \$75,000 for expenses incurred in connection with the Offering. The Placement Agency Agreement contained customary representations, warranties, and covenants by the Company. It also provided for customary indemnification by the Company and the Placement Agent for losses or damages arising out of or in connection with the sale of the securities offered.

On May 27, 2010, in accordance with the second amendment of the agreement, the Company received \$500,000 and issued 133,334 shares to the Vatea Fund. In connection with the closings, the Company issued 53,334 shares of restricted common stock valued at \$160,002 to Melixia for their services provided as facilitating agent. The Company also paid \$67,500 in fees to another consultant who assisted with the Agreement. See Note F for additional details.

## **ITEM 9—CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

Not applicable.

## **ITEM 9A—CONTROLS AND PROCEDURES**

### **Disclosure Controls and Procedures**

Our disclosure controls and procedures, as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, are designed to ensure that information required to be disclosed in reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in rules and forms adopted by the SEC, and that such information is accumulated and communicated to management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures.

Management, with the participation of the Chief Executive Officer and the Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Form 10-K. Based on such evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that, as of April 30, 2010, our disclosure controls and procedures were effective at the reasonable assurance level.

### **Changes in Internal Controls over Financial Reporting**

From time to time, we may review and make changes to our internal control over financial reporting that are intended to enhance the effectiveness of our internal control over financial reporting and which do not have a material effect on our overall internal control over financial reporting. During the three months ended April 30, 2010, we made no changes to our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, that we believe materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **Management's Annual Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting, as defined in rules promulgated under the Exchange Act, is a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer and affected by our Board of Directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. Internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and our Board of Directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process, and it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Our management assessed the effectiveness of our internal control over financial reporting as of April 30, 2010. In making its assessment, management used the criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO. Based on its assessment, management has concluded that our internal control over financial reporting was effective as of April 30, 2010.

Cherry, Bekaert & Holland, L.L.P., our independent registered public accounting firm, who audited our consolidated financial statements included in this Annual Report on Form 10-K, has also audited the effectiveness of our internal control over financial reporting. Such report is included in Item 8 on page 30.

**ITEM 9A(T)—CONTROLS AND PROCEDURES**

Not applicable.

**ITEM 9B—OTHER INFORMATION**

There is no information to report under this item for the quarter ended April 30, 2010.

## **PART III**

### **ITEM 10—DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE**

The information required by this item is incorporated by reference to our Proxy Statement for its 2010 Annual Meeting of Stockholders.

### **ITEM 11—EXECUTIVE COMPENSATION**

The information required by this item is incorporated by reference to our Proxy Statement for its 2010 Annual Meeting of Stockholders.

### **ITEM 12—SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information required by this item is incorporated by reference to our Proxy Statement for its 2010 Annual Meeting of Stockholders.

### **ITEM 13—CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by this item is incorporated by reference to our Proxy Statement for its 2010 Annual Meeting of Stockholders.

### **ITEM 14—PRINCIPAL ACCOUNTANT FEES AND EXPENSES**

The information required by this item is incorporated by reference to our Proxy Statement for its 2010 Annual Meeting of Stockholders.

## PART IV

### ITEM 15—EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(A)(1) The financial statements and information listed below are included in this report in Part II, Item 8.

- Reports of Independent Registered Public Accounting Firm.
- Balance Sheets as of April 30, 2010 and 2009.
- Statements of Operations for each of the two years ended April 30, 2010 and April 30, 2009 and for the period May 26, 1967 (Date of Inception) to April 30, 2010.
- Statements of Stockholders' Equity (Deficit) for each of the two years ended April 30, 2010 and April 30, 2009 and for the period May 26, 1967 (Date of Inception) to April 30, 2008.
- Statements of Cash Flows for each of the two years ended April 30, 2010 and April 30, 2009 and for the period May 26, 1967 (Date of Inception) to April 30, 2010.
- Notes to the Financial Statements.

(A)(2) No schedules have been included because they are not applicable or the required information is shown in our consolidated financial statements or our notes thereto.

(A)(3) The exhibits required by Item 601 of Regulation S-K are listed in the Exhibit Index immediately following the signature pages to this report.



SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: July 23, 2010 **OXYGEN BIOTHERAPEUTICS, INC.**

By: /s/ Chris J. Stern

Chris J. Stern  
Chairman and Chief Executive Officer

## POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS that each individual whose signature appears below constitutes and appoints Chris J. Stern and Michael B. Jebsen and each of them, his true and lawful attorneys-in-fact and agents with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Chris J. Stern</u> Chris J. Stern	Chairman and Chief Executive Officer (Principal Executive Officer)	July 23, 2010
<u>/s/ Michael B. Jebsen</u> Michael B. Jebsen	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	July 23, 2010
<u>/s/ J. Melville Engle</u> J. Melville Engle	Director	July 23, 2010
<u>/s/ Gregory Pepin</u> Gregory Pepin	Director	July 23, 2010
<u>/s/ Rene A. Eckert</u> Rene A. Eckert	Director	July 23, 2010
<u>/s/ William A. Chatfield</u> William A. Chatfield	Director	July 23, 2010
<u>/s/ Ronald R. Blanck</u> Ronald R. Blanck, DO	Director	July 23, 2010

## EXHIBIT INDEX

<b>Exhibit No.</b>	<b>Exhibits Required by Item 601 of Regulation S-K</b>
2.1	Agreement and Plan of Merger dated April 28, 2008 (1)
3.1	Certificate of Incorporation (1)
3.2	Certificate of Amendment of the Certificate of Incorporation (14)
3.3	Bylaws (1)
4.1	Specimen Stock Certificate *
10.1	Agreement with Leland C. Clark, Jr., Ph.D. dated November 20, 1992 with amendments, Assignment of Intellectual Property/ Employment (2)
10.2	Agreement between the Registrant and Keith R. Watson, Ph.D. Assignment of Invention (2)
10.3	Children's Hospital Research Foundation License Agreement dated February 28, 2001 (2)
10.4	Form of Option issued to Executive Officers and Directors (2)
10.5	Form of Option issued to Employees (2)
10.6	Form of Warrant issued to Unsecured Note Holders 2006-2007 (3)
10.7	Form of Convertible Note – 2008 (4)
10.8	Form of Warrant issued to Convertible Note Holders (4)
10.9	Form of Purchase Agreement – US Purchase (without exhibits, which are included as exhibits 10.7 and 10.8, above) (4)
10.10	Form of Purchase Agreement – Non-US Purchase (without exhibits, which are included as exhibits 10.7 and 10.8, above) (4)
10.11	Form of Purchase Agreement – US Note Exchange (without exhibits, which are included as exhibits 10.7 and 10.8, above) (4)
10.12	Form of Purchase Agreement – Non-US Note Exchange (without exhibits, which are included as exhibits 10.7 and 10.8, above) (4)
10.13	Form of Warrant issued to Financing Consultants (5)
10.14	1999 Amended Stock Plan (amended 2008) (5)
10.15	Employment Agreement with Chris J. Stern dated February 1, 2009 (12)
10.16	Business Consultant Agreement with Institute for Efficient Management, Inc., as amended March 26, 2008 (5)
10.17	Engagement and Consulting Agreement with Bruce Spiess (5)
10.18	Engagement and Consulting Agreement with Gerald L. Klein (5)

- 10.19 Business Consultant Agreement with Edward Sitnik (8)
- 10.20 Agreement with Hospira to manufacture Oxycyte (8)
- 10.21 Business Consultant Agreement with J. Melville Engle (8)
- 10.22 Employment Agreement with Kirk Harrington (8)
- 10.23 Employment Agreement with Charles H. Seeman, CPA (8)
- 10.24 Employment Agreement with Richard Kiral, restated February 1, 2009 (8)
- 10.25 Description of Non-Employee Director Compensation \*
- 10.26 Securities Purchase Agreement (including exhibits) between OBI and Vatea Fund, Segregated Portfolio dated June 8, 2009 (6)
- 10.27 Amendment no. 1 to the Securities Purchase Agreement between OBI and Vatea Fund, Segregated Portfolio (11)
- 10.28 Amendment no. 2 to the Securities Purchase Agreement between OBI and Vatea Fund, Segregated Portfolio (12)
- 10.29 Form of Exchange Agreement dated July 20, 2009 (7)
- 10.30 Exclusive License Agreement with Virginia Commonwealth University dated May 22, 2008 (9)
- 10.31 Exclusive Supply Agreement with Exflor dated November 12, 2009 (10)
- 10.32 Amendment no. 1 to the Exclusive License Agreement with Virginia Commonwealth University Intellectual Property Foundation (10)
- 10.33 Amendment no. 2 to the Exclusive License Agreement with Virginia Commonwealth University Intellectual Property Foundation (10)
- 10.34 Waiver—convertible note (10)
- 10.35 Amendment—Common Stock Purchase Warrant (10)
- 10.36 Form of Warrant for May 2010 Offering (13)
- 10.37 Form of Subscription Agreement for May 2010 Offering (13)
- 10.38 Standard Industrial Lease relating to OBI's California facility (12)
- 10.39 Warrant issued to Blaise Group International, Inc. (14)
- 23.1 Consent of Independent Registered Accounting Firm \*
- 31.1 Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350
- 32.2 Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350

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(1) These documents were filed as exhibits to the current report on Form 8-K filed by Oxygen Biotherapeutics with the SEC on June 30, 2008, and are incorporated herein by this reference.

- (2) These documents were filed as exhibits to the annual report on Form 10-K filed by Oxygen Biotherapeutics with the SEC on August 13, 2004, and are incorporated herein by this reference.
- (3) These documents were filed as exhibits to the current report on Form 8-K filed by Oxygen Biotherapeutics with the SEC on September 6, 2006, and are incorporated herein by this reference.
- (4) These documents were filed as exhibits to the quarterly report on Form 10-Q filed by Oxygen Biotherapeutics with the SEC on March 21, 2008, and are incorporated herein by this reference.
- (5) These documents were filed as exhibits to the annual report on Form 10-K filed by Oxygen Biotherapeutics with the SEC on August 13, 2008, and are incorporated herein by this reference.
- (6) This document was filed as an exhibit to the current report on Form 8-K filed by Oxygen Biotherapeutics with the SEC on June 8, 2009, and is incorporated herein by this reference.
- (7) This document was filed as an exhibit to the current report on Form 8-K filed by Oxygen Biotherapeutics with the SEC on July 21, 2009, and is incorporated herein by this reference.
- (8) These documents were filed as exhibits to the annual report on Form 10-K filed by Oxygen Biotherapeutics with the SEC on August 12, 2009, and are incorporated herein by this reference.
- (9) This document was filed as an exhibit to the quarterly report on Form 10-Q filed by Oxygen Biotherapeutics with the SEC on September 22, 2008, and is incorporated herein by this reference.
- (10) These documents were filed as exhibits to the quarterly report on Form 10-Q filed by Oxygen Biotherapeutics with the SEC on March 19, 2010, and are incorporated herein by this reference.
- (11) This document was filed as an exhibit to the current report on Form 8-K filed by Oxygen Biotherapeutics with the SEC on September 2, 2009, and is incorporated herein by this reference.
- (12) These documents were filed as exhibits to the current report on Form 8-K filed by Oxygen Biotherapeutics with the SEC on April 28, 2010, and are incorporated herein by this reference.
- (13) These documents were filed as exhibits to the current report on Form 8-K filed by Oxygen Biotherapeutics with the SEC on May 4, 2010, and are incorporated herein by this reference.
- (14) These documents were filed as exhibits to the current report on Form 8-K filed by Oxygen Biotherapeutics with the SEC on November 13, 2009, and are incorporated herein by reference.

\* Filed herewith.

## CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Chris J. Stern, certify that:

1. I have reviewed this Annual Report on Form 10-K of Oxygen Biotherapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 23, 2010      **OXYGEN BIOTHERAPEUTICS, INC.**

By:                    /s/ Chris J. Stern  
Chris J. Stern  
Chief Executive Officer

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER**

I, Michael B. Jebsen, certify that:

1. I have reviewed this Annual Report on Form 10-K of Oxygen Biotherapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 23, 2010 **OXYGEN BIOTHERAPEUTICS, INC.**

By:           /s/ Michael B. Jebsen            
Michael B. Jebsen  
Chief Financial Officer

**Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Annual Report of Oxygen Biotherapeutics, Inc. (the "Company") on Form 10-K for the period ended April 30, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Chris J. Stern, Chief Executive Officer of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: July 23, 2010 By: /s/ Chris J. Stern  
Chris J. Stern  
Chief Executive Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.



**Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Annual Report of Oxygen Biotherapeutics, Inc. (the "Company") on Form 10-K for the period ended April 30, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael B. Jebsen, Chief Financial Officer of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: July 23, 2010 By: /s/ Michael B. Jebsen

Michael B. Jebsen

Chief Financial Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

# C o r p o r a t e I n f o r m a t i o n

## OXYGEN BIOTHERAPEUTICS, INC.

### Executive Officers

Chris J. Stern, DBA  
Chairman, Chief Executive Officer

Richard Kiral, PhD  
President, Chief Operations Officer

Michael B. Jebsen, CPA  
Secretary, Chief Financial Officer

Gerald L. Klein, MD<sup>4</sup>  
Chief Medical Officer

Kirk Harrington  
Chief of Staff

### Board of Directors

Chris J. Stern, DBA<sup>1</sup>  
Chairman & Chief Executive Officer  
Oxygen Biotherapeutics, Inc.

Lt. Gen. Ronald R. Blanck, DO,  
U.S. Army (Ret.)<sup>1,2,4</sup>  
Chairman  
Martin, Blanck & Associates

The Honorable William A. Chatfield<sup>3</sup>  
Former Director  
U.S. Selective Service System

Rene A. Eckert<sup>1,2,3</sup>  
Former Chairman & Chief Executive Officer  
Boehme Filatex Inc.

J. Melville Engle<sup>1,2</sup>  
Former President & Chief Executive Officer  
Dey LP

Richard Kiral, PhD<sup>4</sup>  
President & Chief Operations Officer  
Oxygen Biotherapeutics, Inc.

Gregory Pepin<sup>4</sup>  
Senior Vice President  
Melixia SA

<sup>1</sup> Audit Committee Member

<sup>2</sup> Compensation Committee Member

<sup>3</sup> Corporate Governance &  
Nominating Committee Member

<sup>4</sup> Development Committee Member (note: this  
committee also includes members of management)

### Corporate Headquarters

Oxygen Biotherapeutics, Inc.  
2530 Meridian Parkway  
Suite 3078  
Durham, NC 27713  
T (919) 806-4530  
F (919) 806-4417  
www.oxybiomed.com

### Securities Information

U.S.: NASDAQ Global Market<sup>SM</sup>  
Switzerland: SIX Swiss Exchange  
Symbol: OXBT

### Annual Meeting

Oxygen Biotherapeutics' General Annual Meeting of  
Shareholders will be held on Friday, September 24, 2010  
at 8:00 AM EDT at  
Doubletree Guest Suites  
2515 Meridian Parkway  
Durham, NC 27713  
(919) 361-4660

### Stockholder Information

Copies of the Company's Form 10-K, Form 10-Q, press  
releases or other information may be obtained through our  
corporate web site, www.oxybiomed.com, a written request to  
Oxygen Biotherapeutics, Inc.  
Attn: Investor Relations  
2530 Meridian Parkway  
Suite 3078  
Durham, NC 27713  
or by calling Investor Relations at (919) 806-4405.

### Transfer Agent

Interwest Transfer Company  
1981 E. 48 South, Suite 100  
P.O. Box 17136  
Salt Lake City, UT 84117  
T (801) 272-9294  
F (801) 277-3147

### Independent Registered Public Accounting Firm

Cherry, Bekaert & Holland, L.L.P.  
2626 Glenwood Avenue  
Suite 200  
Raleigh, NC 27608

### Corporate Counsel

Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P.  
2500 Wachovia Capitol Center  
P.O. Box 2611  
Raleigh, NC 27602

### Trademarks

The following are registered trademarks of  
Oxygen Biotherapeutics, Inc.:  
Dermacyte<sup>®</sup>  
Oxycyte<sup>®</sup>  
Oxygen Biotherapeutics Employing O<sub>2</sub>  
Preserving Life<sup>®</sup>

### Forward-Looking Statements

This document contains forward-looking statements  
that present our expectations and plans regarding future  
performance, and these statements are subject to significant  
risks and uncertainties that could affect our future perfor-  
mance, including those relating to product development and  
commercialization. Actual results could differ materially from  
those described herein. Information on various factors that  
could affect our results is detailed in Item 1A entitled "Risk  
Factors" of our Form 10-K filed with the U.S. Securities and  
Exchange Commission.

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Oxygen Biotherapeutics, Inc.

2530 Meridian Parkway

Suite 3078

Durham, NC 27713

(919) 806-4530

[www.oxybiomed.com](http://www.oxybiomed.com)

[www.buydermacyte.com](http://www.buydermacyte.com)