ORTHOLOGIC CORP
Form 10-K/A
September 18, 2009

U.S. SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K/A

x AMENDMENT NO. 1 TO THE ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2008

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission file number: 0-21214

ORTHOLOGIC CORP.
(Exact name of registrant as specified in its charter)

Delaware	86-0585310
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

1275 West Washington Street, Suite 101, Tempe, Arizona 85281
(Address of principal executive offices)
Registrant's telephone number including area code: (602) 286-5520

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

Title of each class	Name of each exchange on which registered
Common Stock, par value $.0005 per share	NASDAQ Global Market
Rights to purchase 1/100 of a share of Series A Preferred Stock	NASDAQ Global Market

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

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

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 x.

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 x 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 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. See the definitions of "large accelerated filer," "accelerated filer" and "small reporting company" in Rule 12b-2 of the Exchange Act. Large accelerated filer ¨ Accelerated filer ¨ Non-accelerated filer ¨ (Do not check if a smaller reporting company)
Smaller Reporting Company x.

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based upon the closing sale price of the registrant's common stock as reported on the NASDAQ Global Market on June 30, 2008 was approximately $40,300,000. Shares of common stock held by each officer and director and by each person who owns 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily conclusive.

Documents incorporated by reference: Portions of the registrant's proxy statement related to its 2009 annual meeting of stockholders to be held on May 8, 2009 are incorporated by reference into Part III of this Form 10-K.

The number of outstanding shares of the registrant's common stock on February 28, 2009 was 40,775,411.

EXPLANATORY NOTE

OrthoLogic Corp. is filing this Amendment No. 1 on Form 10-K/A (this "Form 10-K/A"), which amends its Annual Report on Form 10-K for the year ended December 31, 2008, as originally filed with the Securities and Exchange Commission on March 13, 2009 (the "Original Filing"), for the purpose of correcting the Report of Independent Registered Public Accounting Firm to remove reference to the work of other auditors. The unqualified opinion expressed in the Report of Independent Registered Public Accounting Firm remains unchanged.

Other than the revision described above, the inclusion of an updated Consent of Independent Registered Public Accounting Firm, attached as Exhibit 23.1 hereto, and the updated certifications of our Principal Executive Officer and Principal Financial and Accounting Officer, pursuant to Sections 302 and 906 of the Sarbanes Oxley Act of 2002, attached as Exhibits 31.1, 31.2 and 32.1 hereto, this Form 10-K/A contains no other changes to the Original Filing.

This Form 10-K/A continues to describe conditions as of the date of the Original Filing, and we have not updated the disclosures contained herein, other than as described above, to reflect events that have occurred subsequent to that date. Other events occurring after the date of the Original Filing or other information necessary to reflect subsequent events will be disclosed in reports filed with the SEC subsequent to the Original Filing.

ORTHOLOGIC CORP.
dba Capstone Therapeutics
FORM 10-K/A ANNUAL REPORT
YEAR ENDED DECEMBER 31, 2008

TABLE OF CONTENTS

Table of Contents

PART I

Item 1. Business

Overview of the Business

On October 1, 2008, OrthoLogic Corp. began doing business under the trade name of Capstone Therapeutics.

OrthoLogic Corp., referred to herein as “OrthoLogic”, “Capstone Therapeutics”, “Capstone”, “the Company”, “we”, “us”, or “
a biotechnology company committed to developing a pipeline of novel therapeutic peptides aimed at helping patients with under-served medical conditions. The Company is focused on development and commercialization of two product platforms: AZX100 and Chrysalin® (TP508 or rusalatide acetate).

AZX100

AZX100, a novel 24-amino acid peptide, is believed to relax smooth muscle which modulates blood pressure and the function of blood vessels, airways, sphincters, the gastrointestinal tract and the genitourinary tract. Sustained abnormal contraction of any of these muscles is called a spasm. Any disorders known to be associated with excessive constriction or inadequate dilation of smooth muscle represent potential applications for AZX100.

AZX100 is also believed to inhibit the fibrotic phenotype of fibroblasts and smooth muscle cells in a mechanism similar to that which causes vasorelaxation. Through phenotypic modulation of fibroblasts and smooth muscle cells, AZX100 may inhibit the scarring that results from wound healing and may mitigate fibrotic disease states in the dermis, blood vessels, lungs, liver and other organs.

AZX100 is currently being evaluated for medically and commercially significant applications, such as treatment of pulmonary disease, prevention of hypertrophic and keloid scarring and intimal hyperplasia. We are executing a development plan for this peptide which included filing an IND for dermal scarring in 2007 and commencement of Phase 1 safety studies in this indication in the first quarter of 2008. Our Phase 1a study was completed in May 2008. The study’s Safety Committee reviewing all safety-related aspects of the Phase 1a trial was satisfied with the profile of AZX100. We initiated a second safety study in dermal scarring (Phase 1b), which was completed in the fourth quarter of 2008. The study’s Safety Committee reviewing all safety-related aspects of the Phase 1b trial was satisfied with the profile of AZX100. The Company is preparing to initiate Phase 2 human clinical efficacy studies of AZX100 in dermal scarring in the first quarter of 2009. We expect to continue to perform further pre-clinical studies supporting multiple indications for AZX100 in 2009.

Chrysalin

Chrysalin (TP508), a novel synthetic 23-amino acid peptide, is believed to produce angiogenic and other tissue repair effects in part by 1) activating or upregulating endothelial nitric oxide synthase (eNOS); 2) cytokine modulation resulting in an anti-inflammatory effect; 3) inhibiting apoptosis (programmed cell death); and 4) modulating angiogenic factors. It may have therapeutic value in diseases associated with endothelial dysfunction.

We have conducted clinical trials for two potential Chrysalin applications: acceleration of fracture repair and diabetic foot ulcer healing. We previously conducted a pilot human study for spine fusion, and pre-clinical testing for cartilage defect repair, cardiovascular repair, dental bone repair, and tendon repair. Currently, we are focusing our efforts on pre-clinical studies in vascular applications, such as acute myocardial infarction and chronic myocardial ischemia. If successful, these studies will provide additional support for partnering future development of Chrysalin. We are not currently planning additional pre-clinical or clinical studies in fracture repair, wound healing, spine fusion, cartilage

defect repair, dental bone repair or tendon repair.

Table of Contents

Company History

Prior to November 26, 2003, we developed, manufactured and marketed proprietary, technologically advanced orthopedic products designed to promote the healing of musculoskeletal bone and tissue, with particular emphasis on fracture healing and spine repair. Our product lines included bone growth stimulation and fracture fixation devices including the OL1000 product line, SpinaLogic® and OrthoFrame/Mayo, which we sometimes refer to as our "Bone Device Business."

On November 26, 2003, we sold our Bone Device Business.

On August 5, 2004, we purchased substantially all of the assets and intellectual property of Chrysalis Biotechnology, Inc. ("CBI"), including its exclusive worldwide license for Chrysalin for all medical indications. We became a development stage company commensurate with the acquisition. Subsequently, our efforts were focused on research and development of Chrysalin with the goal of commercializing our product candidates.

On February 27, 2006, we purchased certain assets and assumed certain liabilities of AzERx, Inc. Under the terms of the transaction, OrthoLogic acquired an exclusive license for the core intellectual property relating to AZX100.

Our development activities for Chrysalin and AZX100 represent a single operating segment as they share the same product development path and utilize the same Company resources. As a result, we have determined that it is appropriate to reflect our operations as one reportable segment. Through December 31, 2008, we have incurred $113 million in net losses as a development stage company.

Competition

The biopharmaceutical industry is characterized by intense competition and confidentiality. We may not be aware of the other biotechnology, pharmaceutical companies or public institutions that are developing pharmaceuticals that compete with our potential products. We also may not be aware of all the other competing products our known competitors are pursuing. In addition, these biotechnology companies and public institutions compete with us in recruiting for research personnel and subjects, which may affect our ability to complete our research studies.

Chrysalin

Vascular Endothelial Dysfunction (VED)

Impaired nitric oxide (NO) production reduces the responsiveness of endothelial cells to angiogenic factors and causes loss of endothelial function in ischemic and inflamed blood vessels contributing to a number of chronic diseases. We hypothesize that Chrysalin may produce angiogenic and other tissue repair effects by activating or upregulating nitric oxide synthetase (NOS) in endothelial cells, and if so, that it may have potential therapeutic value in tissues and diseases exhibiting endothelial dysfunction. Currently, we are evaluating multiple VED indications for development potential. While the potential product markets are significant in size, the markets are characterized by intense competition by both large and small companies with a variety of competing technologies.

Table of Contents

Clinical indications associated with VED include the broad areas of coronary artery disease (CAD). Insufficient blood supply to the myocardium can result in myocardial ischemia, injury or infarction, or all three. Atherosclerosis of the larger coronary arteries is the most common anatomic condition that causes diminished coronary blood flow.

Pharmacologic therapies in development for acute myocardial infarction include stem cell-based approaches, selective kinase inhibitors, thrombin-activatable plasminogen and other peptides.

Pharmacologic therapies commonly used in treating myocardial ischemia include 1) aspirin and anticoagulants; 2) ß blockers; 3) nitrates; and 4) calcium channel blockers. Also, the use of angiotensin-converting enzyme (ACE) inhibitors recently has been shown to be beneficial in the treatment of myocardial ischemia. Invasive treatments such as percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass surgery (CABG) may be indicated as well.

We are in the preliminary stages of examining these disease states and the suitability of Chrysalin as a therapeutic agent to treat vascular disorders.

AZX100

Dermal Scarring

Approved

There is no approved pharmacologic treatment for scarless healing. In the setting of keloid or hypertrophic scarring the scars are often excised and treated with steroids with variable results.

In Development

Among potential competing products are recombinant transforming growth factor beta 3 (TGF ß3) and antiTGFß1 antibodies. Renovo is conducting Phase 3 clinical trials in Europe and the U.S. with recombinant TGFß3 (Juvista) for various scar prevention indications, including a recently accepted IND for keloid revisions. While preliminary efficacy has been shown in healing in healthy individuals, like other therapeutics, TGFß3 addresses upstream signaling and only one fibrotic pathway and may have limited effectiveness in scar inhibition. AZX100 inhibits fibrotic responses induced by multiple mediators, suggesting it may be more effective than TGFß3 at scarless healing. Renovo has also begun clinical trials using a TGFß1 antibody, which like TGFß3, blocks part of the signaling cascade resulting in scar formation. AZX100 may be more effective than TGFß1 antibodies through more comprehensive inhibition of multiple scarring cascades.

Asthma

Asthma ranks as the third highest reason for preventable hospitalizations in the U.S. with 470,000 hospitalizations and more than 5,000 deaths each year (American Academy of Allergy Asthma and Immunology Report). Acute asthma accounts for an estimated two-million emergency department visits annually. There are many competitors with asthma products approved or in development. AZX100 has been shown to relax ex vivo airway smooth muscle and may be developed for the treatment of asthmatic attacks. Specific markets include severe acute asthma and asthma that is refractory to current therapies. Severe asthma has been defined as asthma that is refractory to current therapeutic approaches in clinical use (anti-inflammatory agents and bronchodilators). The current approach is to use adrenergic agonists, which activate the cAMP/PKA pathway. AZX100 is a mimetic of the molecule downstream of this pathway and hence may be more sensitive and specific for the treatment of severe asthma. In addition, patients with severe asthma usually are treated in an emergency room; hence efficacy can be closely monitored and outcomes

will be apparent in a short timeframe after treatment. Recent data has demonstrated that one out of every six asthmatics has a mutation in the adrenergic receptor. These patients do not respond to adrenergic agonists and in fact do worse when treated with adrenergic agonists. This patient population would be potentially effectively treated with the AZX100 compound in that it acts downstream of the receptors.

Table of Contents

Intimal Hyperplasia

Intimal hyperplasia is the universal response of a vessel to injury. It is characterized by the thickening of the Tunica intima of a blood vessel as a complication of a reconstruction procedure or endarterectomy, the surgical removal of plaque from an artery that has become narrowed or blocked. Scar tissue forms at the point where a blood vessel is manipulated; as it slowly builds up, significant restenosis may develop. Intimal hyperplasia is an important reason for late bypass graft failure, particularly in vein and synthetic vascular grafts. Patients with end-stage renal disease (approximately 300,000 in the U.S. alone) suffer from intimal hyperplasia due to multiple vein insertions. We are not aware of any existing therapy that effectively modulates this healing response.

Marketing and Sales

Neither Chrysalin nor AZX100 are currently available for sale and we do not expect them to be available for sale for some time into the future. Thus, we currently have no marketing or sales staff. External consultants and members of our staff provide some technical marketing support relating to the development of, and market need for, new potential products and additional therapeutic applications of products already under research.

Research and Development

Our Pre-clinical, Clinical, Chemical Materials and Controls, Regulatory and Quality Assurance departments (research and development) consist of approximately 18 employees who are assisted by consultants from the academic and medical practitioner fields. Our employees have extensive experience in the areas of biomaterials, animal modeling, cellular and molecular biology, clinical trial design and data management. Our Clinical department designs, initiates, monitors and manages our clinical trials. Our staff has been focused on clinical trials to advance AZX100 to NDA status in a dermal indication, pre-clinical studies investigating AZX100's potential for the treatment of pulmonary diseases and intimal hyperplasia, pre-clinical work on Chrysalin in vascular indications and exploring the science behind and potential of AZX100 and Chrysalin. We are executing a development plan for AZX100 which included filing an IND for dermal scarring in 2007 and commencement of Phase 1 safety studies in this indication in the first quarter of 2008. Our Phase 1a study was completed in May 2008. The study's Safety Committee reviewing all safety-related aspects of the Phase 1a trial was satisfied with the profile of AZX100. We initiated a second safety study in dermal scarring (Phase 1b), which was completed in the fourth quarter of 2008. The study's Safety Committee reviewing all safety-related aspects of the Phase 1b trial was satisfied with the profile of AZX100. The Company is preparing to initiate Phase 2 human clinical efficacy studies of AZX100 in dermal scarring in the first quarter of 2009.

We incurred $10.7 million and $9.6 million, in 2008 and 2007, respectively, on research efforts on Chrysalin and AZX100. Given the overlapping nature of our research efforts it is not possible to clearly separate research expenditures between Chrysalin and AZX100; however, the substantial majority of expenditures were AZX100 related in 2008 and 2007.

Table of Contents

Manufacturing

Currently, third parties certified under Good Manufacturing Practices manufacture Chrysalin and AZX100 for us in limited amounts for our clinical and pre-clinical studies. We use a primary manufacturer for the peptides used in our human clinical trials, but secondary manufacturers are available as needed. Our current Chrysalin and AZX100 formulation and manufacturing work is focused on an injectable formulation.

Patents, Licenses and Proprietary Rights

As part of our purchase of CBI on August 5, 2004, the license agreements between CBI and OrthoLogic for the development, use, and marketing of the therapeutic products utilizing Chrysalin were replaced by a direct license agreement between OrthoLogic and the University of Texas. Under this direct license, we expanded our current license for Chrysalin from a license for only orthopedic indications to a license for any and all indications. Subsequently, we entered into an agreement whereby the University of Texas assigned to us certain patents previously exclusively licensed to us. We must pay the University of Texas royalties on future sales of products, sublicense fees and various other fees in connection with filing and maintaining Chrysalin-related patents. This obligation will expire upon the expiration of the subject patents. Chrysalin has been patented in the United States and in some other countries for a number of methods of use, including cardiovascular, chronic wounds, and orthopedic indications. A composition of matter patent covering European countries expired in 2007 and the corresponding United States patent expires in 2011. Our other patents for Chrysalin expire between 2021 and 2026.

As part of the February 27, 2006 AzERx transaction, we acquired a license from AzTE, an affiliate of Arizona State University, for worldwide rights to AZX100 for all indications. Under the license agreement with AzTE, we are required to pay patent filing, maintenance and other related patent fees as well as royalties on future sales of products that contain AZX100. These obligations will end on the expiration of the last patent. The license is supported by patents that expire from 2021 to 2024.

As part of the February 27, 2006 AzERx transaction we also acquired a non-exclusive license from Washington University for transduction domain carrier patents which form part of AZX100. Under the license, we are required to pay license maintenance payments and royalties on future sales of products that contain the licensed technology. These obligations will end on the expiration of the last patent.

Chrysalin, Capstone Therapeutics and OrthoLogic are registered United States domestic trademarks of OrthoLogic Corp.

Insurance

Our business entails the risk of product liability claims. We maintain a product liability and general liability insurance policy and an umbrella excess liability policy. There can be no assurance that liability claims will not exceed the coverage limit of such policies or that such insurance will continue to be available on commercially reasonable terms or at all. Consequently, product liability claims or claims arising from our clinical trials could have a material adverse effect on our business, financial condition and results of operations. We have not experienced any material liability claims to date resulting from our clinical trials.

Employees

As of December 31, 2008, we had twenty-six permanent employees in our operations, including eighteen employees in research and development and eight in administration. As a research and development business, we believe that the success of our business will depend in part on our ability to identify, attract and retain qualified research personnel,

both as employees and as consultants. We face competition from private companies and public institutions for qualified research personnel. None of our employees are represented by a union and we consider our relationship with our employees to be good.

Table of Contents

Additional Information about OrthoLogic

OrthoLogic Corp. was incorporated as a Delaware corporation in July 1987 as IatroMed, Inc. We changed our name to OrthoLogic Corp. in July 1991. Effective October 1, 2008, OrthoLogic Corp. began doing business as Capstone Therapeutics. Our executive offices are located at 1275 West Washington Street, Suite 101, Tempe, Arizona 85281, and our telephone number is (602) 286-5520.

Our website address is www.capstonethx.com. Our annu