CHAMPIONS ONCOLOGY, INC.

Form 10-K/A March 13, 2012

## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K/A

(Amendment No. 1)

(Mark One)

þANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the fiscal year ended April 30, 2011

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF  $^{\rm o}$  1934

For the transition period from

to

#### Commission file number 0-17263

#### CHAMPIONS ONCOLOGY, INC.

(Exact name of registrant as defined in its charter)

Delaware 52-1401755 State or other jurisdiction of (I.R.S. Employer incorporation or organization Identification No.)

One University Plaza, Suite 307 07601 Hackensack, New Jersey (Zip Code)

(Address of principal executive offices)

# Registrant's telephone number, including area code:

(201) 808-8400

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

Title of Each Class

Name of Each Exchange on Which Registered
Common Stock, par value \$0.001 per share

Over-the-Counter Bulletin Board (OTCBB)

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

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 o No b

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 b No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, 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 file such reports). Yes b No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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 "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer o Non-accelerated filer o Smaller reporting company b (Do not check if a smaller reporting company)

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

The approximate aggregate market value of the voting stock held by non-affiliates of the Registrant as of October 31, 2010 was \$16,179,907 based on the closing price of the Registrant's Common Shares as quoted on the OTCBB as of that date.

The number of Common Shares of the Registrant outstanding as of July 15, 2011 was 46,253,436.

## **DOCUMENTS INCORPORATED BY REFERENCE - None**

#### **EXPLANATORY NOTE**

The purpose of this amendment to the Annual Report on Form 10-K for the fiscal year ended April 30, 2011 of Champions Oncology, Inc. (the "Company") filed on July 15, 2011 (the "Original Filing") is to:

- (i) Revise Item 1 (Business) to include a discussion of the Company's previously disclosed agreement with Cephalon, Inc.
- (ii) Revise Item 15(a)(3) (Exhibits) to include the Agreement dated March 16, 2011 between the Registrant and Cephalon, Inc..

Except as described above, no other amendments are being made to the Company's Annual Report on Form 10-K for the fiscal year ended April 30, 2011. This Form 10-K/A does not modify or update the disclosures contained in the Annual Report in any way other than as described above.

As used in this Annual Report on Form 10-K, "Champions Oncology, Inc.," "Champions," the "Company,", "we," "ours," and refer to Champions Oncology, Inc. and its subsidiaries, except where the context otherwise requires or as otherwise indicated.

#### DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This document contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 ("Securities Act") and Section 21E of the Securities Exchange Act of 1934 ("Exchanges Act") that inherently involve risk and uncertainties. Forward-looking statements may be identified by the words "project," "believe," "anticipate," "plan," "expect," "estimate," "intend," "should," "would," "could," "will," "may,"," "likely" or similar expressions. Forward-looking this Annual Report include statements about our business strategies and product and services development activities, including the anticipated benefits and risks associated with those strategies as well as statements about the sufficiency of our capital resources. One should not place undue reliance on these forward-looking statements. We cannot guarantee that we will achieve the plans, intentions or expectations expressed or implied in our forward-looking statement. There are a number of important factors that could cause actual results, levels of activity, performance or events to differ materially from those expressed or implied in the forward-looking statements we make. These important factors are described under "Risk Factors" set forth below. In addition, any forward-looking statements we make in this document speak only as of the date of this document, and we do not intend to update any such forward-looking statements to reflect events or circumstances that occur after that date, except as required by law. As a result of these and other factors, our stock price may fluctuate dramatically.

#### **PART I**

Item 1. Business

#### Overview

Champions Oncology, Inc. is engaged in the development of advanced technology solutions to personalize the development and use of oncology drugs. The Company's Tumorgraft Technology Platform is a novel approach to personalizing cancer care based upon the implantation of human tumors in immune deficient mice. The Company uses this technology in conjunction with related services to offer solutions for two customer groups:

Our Personalized Oncology Solutions ("POS) business which provides services to physicians and patients looking for information to help guide the development of a personalized treatment plans.

Our Translational Oncology Solutions ("TOS) business, which provides services to pharmaceutical and biotech companies seeking personalized approaches to drug development that will lower the cost and increase the speed of developing new drugs and increasing the adoption of existing drugs.

Tumorgraft Technology Platform

Our technology platform consists of processes, physical tumors and information that we use to personalize the development and use of oncology drugs. Our process technology involves the:

implantation of human tumor fragments in immune compromised mice; expansion of the original human tumor into a larger colony of mice through the passage of the tumor to subsequent generations of mice;

treatment of the implanted mice with oncology drugs; measurement of tumor growth inhibition in treated mice relative to a control group of mice to determine the response of the tumor to the drug.

Our process is used for our POS business to test numerous drugs or drug combinations against a single patient's tumor to determine which therapy results in the most efficacious response from the tumor.

The second component of our technology platform is a bank of tumors that we have collected, processed, validated and stored for use in our TOS business. We implant these tumors in mice to provide pharmaceutical and biotechnology companies the opportunity to test oncology compounds on multiple tumors to test efficacy.

The third component of our technology platform is an extensive database of information about each tumor in our tumorbank. This includes information about the patient (e.g. age, gender), the response of each tumor to different oncology drugs or drug combinations, mutational status of key oncogenes and other genetic and epigenetic data about each tumor. We use this database to provide our pharmaceutical and biotechnology customers with bioinformatic studies to assist them with the drug development process.

Personalized Oncology Solutions ("POS") Business

Our POS business offers physicians and patients information to help guide the development of a personalized treatment plans. Our core offering utilizes our technology platform to empirically test the response of a patient's tumor to multiple oncology drugs or drug combinations. The process begins by implanting a fresh fragment of the customer/patient's tumor, typically received within four to twenty-four hours of surgery or biopsy, in a small colony of immune compromised mice. This colony is then expanded until a sufficient number of mice are available for testing. At that point, the colony is allocated to different groups, and each mouse in a group is dosed with a different drug or drug combination. The response of the tumor in each mouse is tracked over time and analyzed to determine which drug or drug combination is providing the highest level of tumor growth inhibition. Our data demonstrates that there is high correlation between the response of the tumor in mice to drugs with the response of the tumor in the customer/patient from whom the tumor was originated.

In addition to our core product, we also offer related personalized oncology services to our customers including personalized tumor panels. Personalized tumor panels are designed to offer our customers/patients access to world renowned oncologists with expertise in particular tumor types of interest. The physicians on the panel receive an overview of the patient's history of treatment and current status, typically from the treating physician and advanced molecular and sensitivity testing (which might include our Tumorgraft testing), and offer insight into possible treatments based on their expertise and the cutting edge information available to them from their academic institutions and colleagues. These panels can be done in person or over the phone and can include from 3 to more than 15 physicians.

We rely on the internet, word of mouth and a small sales force to market these products to patients and physicians.

For the year ended April 30, 2011, our revenues from POS totaled \$3,382,000, a 5% increase from the previous year.

Translational Oncology Solutions ("TOS") Business

Our TOS business utilizes our technology platform to assist pharmaceutical companies and biotechnology with the drug development process. We provide studies that predict the efficacy of experimental oncology drugs or approved drugs as stand-alone therapies or in combination with other drugs. These studies include in vivo studies that rely on implanting multiple tumors from our tumorbank in mice and testing the therapy of interest on these tumors. Studies may also include bioinformatics analysis that reveal the differences in the genetic signatures of the tumors that responded to a therapy as compared to the tumors that did not respond. Our studies can be used to determine which types of cancer, if any, are inhibited by a drug. The studies can also be used to identify specific sub-populations, often characterized by particular genetic mutations, that are differentially sensitive or resistant to a drug or drug combination. These studies, used in pre-clinical testing or during phase 1 of a clinical trial, can help guide the clinical development path of new compounds and find new indications or combinations for compounds that are already approved by the FDA. The results can lead to lower costs and shorter timeframes for drug development.

On March 16, 2011, the Company entered into an agreement with Cephalon, Inc., ("Cephalon"), pursuant to which the Company will conduct Tumorgraft studies on proprietary chemical compounds provided by Cephalon to determine the activity or response of a compound in potential clinical indications. In April 2011, Cephalon paid an initiation fee of \$1,390,000 to the Company. We anticipate that the studies will be initiated and completed within 12 months. Cephalon will, under certain conditions, also pay the Company various amounts upon achieving certain milestones. Potential milestone payments under the Agreement total \$27 million. In addition, under certain conditions, Cephalon will pay the Company royalties on any commercialized products developed under the Agreement. These royalties, if any, will be at rates of under 10% of aggregate net sales over a period of 15 years or the life of the applicable patent (whichever is less). We are not able to estimate the amount, if any, of milestone and royalty payments we may receive under this agreement. Cephalon has the option to pay Champions a one-time payment in lieu of future milestone and royalty payments with respect to one or more of the chemical compounds provided by Cephalon to Champions. The amount of any such one-time payment is agreed to in advance, and for the two compounds currently under study, such payments are \$460,000 and \$880,000, respectively. The agreement will terminate when all payment obligations to the Company have been satisfied, and may be terminated sooner upon a breach or bankruptcy.

Our sales and marketing efforts are dependent on a dedicated sales force that sells directly to pharmaceutical and biotechnology companies.

For the year ended April 30, 2011, our revenues from TOS services totaled \$3,500,000, an increase of 107% over 2010.

#### **Operations**

Until recently, we have relied solely on a single clinical research organization for substantially all of our in vivo studies and tumorbank development. During the fourth quarter of 2011, we started the process of developing in-house capabilities to supplement the activities of the clinical research organization.

#### In-licensed Compounds

Historically, our strategy was to use our technology platform to identify promising compounds that could be in-licensed during the preclinical phase. The strategy was to invest in the clinical development of these compounds and then seek a partner that would bring them to market in exchange for some combination of upfront payments, milestone payments and royalties on sales. Since 2007, the company pursued this strategy with four compounds. All four of these compounds were subjected to Tumorgraft testing, and the results of one of the compounds warranted further investment.

During 2011, we changed our strategy and no longer intend to in-license additional compounds. We have refocused the Company on developing advanced technologies to personalize the development and use of oncology drugs. We intend to continue the development of the compound which warranted further investment and we are seeking a partner to finance the future development of the product.

#### Competition

Our Tumorgraft Technology Platform is proprietary and requires significant know-how to both initiate and operate, but is not patented. It is, therefore, possible for competitors to develop other implantation procedures or to discover the same procedures utilized by the Company that could compete with the Company in its market. Competition our industry is intense and based significantly on scientific, technological and market forces. These factors include the

availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain government approval for testing, manufacturing and marketing. The Company faces significant competition from other healthcare companies in the United States and abroad. The majority of these competitors are and will be substantially larger than the Company, and have substantially greater resources and operating histories. There can be no assurance that developments by other companies will not render our products or technologies obsolete or noncompetitive or that we will be able to keep pace with the technological or product developments of our competitors. These companies, as well as academic institutions, governmental agencies and private research organizations also compete with us in recruiting and retaining highly qualified scientific, technical and professional personnel and consultants.

#### Patent Applications

It is our intention to protect our proprietary property through the filing of United States and international patent applications, both broad and specific, where necessary and reasonable. In February 2007, we acquired the patent rights to two BPU sulfur analog compounds that have shown promising potent activity against in vitro and in vivo models of prostate and pancreatic cancer. The acquired rights include pending United States Patent Application no. 11/673,519 and corresponding international patent application (PCT/US2006/014449) filed under the Patent Cooperation Treaty ("PCT"), both entitled Design and Synthesis of Novel Tubulin. We are no longer pursuing the development of this compound or the international patent application. The patent application was terminated in April 2011.

#### Research and Development

For the years ended April 30, 2011 and 2010, we spent approximately \$2,951,000 and \$2,622,000, respectively, on research and development to develop its Tumorgraft Technology Platform and complete preclinical trials related to its four drug compounds. The increase from 2010 to 2011 was primarily related to increased spending on our technology platform and tumorgraft testing on in-licensed compounds.

#### Government Regulation

The research, development and marketing of products are subject to federal, state, local, or foreign legislation or regulation, including the interpretation of and compliance with existing, proposed, and future regulatory requirements imposed by the United States Food and Drug Administration ("FDA") and by comparable authorities in other countries.

#### **Employees**

As of April 30, 2011, we had 18 full-time employees, including 7 with doctoral or other advanced degrees. Of our workforce, 6 employees are engaged in research and development and laboratory operations, 7 are engaged in sales and marketing and 5 are engaged in finance and administration. None of our employees are represented by a labor union or covered by collective bargaining agreements. We have never experienced a work stoppage and believe our relationship with our employees is good.

### Company History

Our predecessor was incorporated under the laws of the State of Delaware on June 4, 1985, as "International Group, Inc." In September 1985, we completed a public offering and shortly thereafter, acquired the world-wide rights to the Champions sports-theme restaurant concept and changed our name to "Champions Sports, Inc." In November 1997, we sold our Champions service mark and concept to Marriott International, Inc. and until 2005, were a consultant to Marriott International, Inc. and operated one Champions sports bar restaurant. In January 2007, we changed our business direction to focus on biotechnology and subsequently changed our name to Champions Biotechnology, Inc. In April 2011, we changed our name to Champions Oncology, Inc. to reflect the Company's new strategic focus on developing advanced technologies to personalize the development and use of oncology drugs.

#### Available Information

Our internet website address is www.championsoncology.com. Through our website, we make available, free of charge, access to all reports filed with the U.S. Securities and Exchange Commission ("SEC"), including our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q, our Current Reports on Form 8-K, and amendments to those reports, as filed with or furnished to the SEC pursuant to Section 13(a) or 15(d) of the Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Copies of any materials we file with, or furnish to, the SEC can also be obtained free of charge through the SEC's website at http://www.sec.gov or at the SEC's Public Reference Room at 100 F Street, N.E., Room 1580, Washington,

DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

## **PART IV**

# Item 15. Exhibits, Financial Statement Schedules

# (a)1. Financial Statements.

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# (a)2. Financial Statement Schedules

All schedules have been omitted because they are not applicable.

# (a)3. Exhibits required to be filed by Item 601 of Regulation S-K.

Exhibit No.	
3.1	Amended and Restated Articles of Incorporation (incorporated by reference to Appendix A to the Company's Information Statement on Schedule 14C filed March 7, 2011, File No. 0-17263)
3.2	Amended and Restated Bylaws, as amended incorporated by reference to Exhibit 3.1 to the Company Current Report on Form 8-K filed February 22, 2011, File No. 0-17263)
10.1	Employment Agreement dated October 25, 2010 between the Company and Joel Ackerman (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed October 29, 2010, File No. 0-17263)
10.2	Employment Agreement dated October 25, 2010 between the Company and Ronnie Morris, M.D. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed October 29, 2010, File No. 0-17263)
10.3	Agreement dated March 16, 2011 between the Registrant and Cephalon, Inc. [Portions omitted and filed separately with the Securities and Exchange Commission]*
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Code of Ethics (incorporated by reference to Exhibit 14 of the April 30, 2008 Form 10-KSB, File No. 0-17263)

- 21 Subsidiaries of the Registrant
- 31.1 Rule 15d-14(a) Certification of Principle Executive Officer\*
- 31.2 Rule 15d-14(a) Certification of of Principal Financial Officer\*
- 32.1 Section 1350 Certifications\*

<sup>\*</sup> Filed herewith

## **SIGNATURES**

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

# CHAMPIONS ONCOLOGY, INC.

March 13, 2012 /s/ Joel Ackerman Joel Ackerman Chief Executive Officer (Principal Executive Officer)