CHAMPIONS ONCOLOGY, INC.
Form 10-K
July 30, 2018

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

Form 10-K
(Mark One)
þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended April 30, 2018
or
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission file number 001-11504

CHAMPIONS ONCOLOGY, INC.
(Exact name of registrant as defined in its charter)

Delaware	52-1401755
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One University Plaza, Suite 307 Hackensack, New Jersey (Address of principal executive offices)	07601 (Zip Code)

Registrant's telephone number, including area code:
(201) 808-8400

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 $0.001 per share	Nasdaq Capital Market

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

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

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 þ

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 þ No ¨

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 submit and post such files). Yes þ No ¨

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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth 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
	Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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

The approximate aggregate market value of the voting stock held by non-affiliates of the Registrant as of October 31, 2017 was $18.6 million based on the closing price of the Registrant's Common Shares as quoted on the Nasdaq Capital Market as of that date.

The number of Common Shares of the Registrant outstanding as of July 13, 2018 was 11,025,609.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement for its 2018 Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended, are incorporated by reference into Part III of this Form 10-K.

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FOR THE YEAR ENDED APRIL 30, 2018

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

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, 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 sta this Annual Report include statements about our business strategies and products 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 Annual Report 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

We are engaged in the development and sale of advanced technology solutions and products to personalize the development and use of oncology drugs. Utilizing our TumorGraft Technology Platform, we provide select services to pharmaceutical and biotechnology companies seeking personalized approaches to drug development. By performing studies to predict the efficacy of oncology drugs, our Platform facilitates drug discovery with lower costs and increased speed of drug development as well as increased adoption of existing drugs. The current oncology drug development paradigm is challenging for the pharmaceutical and biotechnology industry. We believe that on average, the clinical trial process in oncology currently:

- costs more than $1.2 billion;
- takes approximately 8 years to complete;
- has a 93% failure rate; and
- results in approved compounds that cost more than $11,000 per month.

Our platform provides a novel approach to simulating the results of human clinical trials used in developing oncology drugs. According to a 2013 study conducted by Cutting Edge Information, it can cost up to $100,000 per patient in oncology clinical trials and the typical cost for each phase of development per year increases from approximately $3 million in the pre-clinical setting to approximately $150 million in phase III. Simulating trials before executing them provides benefits to both pharmaceutical companies and patients. Pharmaceutical companies can lower the risk of spending resources on drugs that do not show significant anti-cancer activities and increase the chance that the clinical development path they pursue will be focused on an appropriate patient population and a successful combination with other drugs.

TumorGraft Technology Platform

Our clinical trial simulation platform consists of processes, physical tumors, and information that we use to personalize the development and use of oncology drugs. Each tumor from individual patients that we have preserved for future implantation in mice, along with the patient data and molecular information associated with these tumors, are referred to as “TumorGrafts” or “Patient Derived XenoGrafts” or “PDX Models”. Our process technology involves the following:

- implantation of human tumor fragments in immune-deficient mice;
- expansion of the original human tumor into a larger colony of mice through the passage of the tumor to a limited number of 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; and

- permanent cryo-preservation of fragments of tumor tissue for future use in additional clinical trial simulations.

A growing body of evidence demonstrates the power of PDX to predict the response of individual patients to oncology drugs. Our platform has demonstrated a positive predictive value of approximately 87% and negative predictive value of approximately 94%. As a result, we believe our PDX platform results in simulated clinical studies with approximately 90% accuracy in predicting human response with approximately 90% lower costs than a human clinical trial while shortening the timelines from 2-3 years for human trial to 6 months for PDX studies.

TumorBank

The collection of TumorGrafts that we have built is referred to as our "TumorBank". We currently have approximately 1,500 PDX Models in our TumorBank that we believe reflect characteristics of patients who enroll in clinical trials (late stage, pretreated and metastic). We implant tumors in mice to provide pharmaceutical and biotechnology companies the opportunity to test oncology compounds on multiple tumors to test efficacy and simulate the results of human clinical trials.

Increasing breadth and depth of the TumorBank is an important strategic effort of the company. We invest significant research and development resources to increase the number of PDX Models in our TumorBank and add unique and different sub-types of cancer that we have not historically addressed. In addition, we are also developing an extensive database of information about the tumors in our TumorBank. We expect that this database will include certain information about the patient (e.g. age, gender), the response of the tumors to different oncology drugs or drug combinations, mutational status of key oncogenes, and other genetic and epigenetic data about each tumor. We expect that such data could be valuable to companies seeking to develop new cancer drugs.

Based on our extensive knowledge of the industry, we believe that we are a leading provider of Patient Derived XenoGrafts and a pioneer in the use of PDX Models for use with efficacy studies, patients and clinical trial simulations. Our research and development efforts and customer sponsored platform development has contributed to the acceptance of the accuracy of PDX Models as a valuable tool in the development and use of oncology drugs.

Our Strategy

Our strategy is to use TumorGrafts as a platform technology to drive multiple synergistic revenue streams. We continue to build this platform with investments in research and development. Our goal is to populate our TumorBank and its related database with tumors and information we receive from patients, research collaborations and validation studies. The tumors and information in the TumorBank are then available for work with pharmaceutical company customers. In addition, we are looking for additional opportunities to utilize the data we are gathering about the tumors to develop proprietary biomarkers and signatures of response that can predict the resistance or sensitivity of individual patients to oncology drugs.

Translational Oncology Solutions Business

Our Translational Oncology Solutions ("TOS") business utilizes our technology platform to assist pharmaceutical and biotechnology companies with their drug development process. We provide studies, or license tumors for use in studies, which we believe may predict the efficacy of experimental oncology drugs or approved drugs as stand-alone therapies or in combination with other drugs and can stimulate the results of human clinical trials. 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, may be 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 I or II of a clinical trial, can help guide the clinical development path of new compounds or find new indications or combinations for compounds that are already approved by the United States Food and Drug Administration, or FDA. We believe that the results may lead to lower costs and shorter timeframes for drug development.

We have performed studies for approximately 200 different pharmaceutical and biotechnology companies over the past seven years. We have a high rate of repeat business. Typical studies range in price from $50,000 to $250,000 with increasing number of studies in the $500,000 range. Revenue from this business has grown at a cumulative annual growth rate of 41% since the current management team joined the company in fiscal 2010.

Our sales and marketing efforts are dependent on a dedicated sales force that sells our services directly to pharmaceutical and biotechnology companies. We have a team of nine professionals dedicated to this sales and marketing effort. The team is focused

on identifying and selling studies to new customers as well as increasing our revenue from existing customers. We spend significant resources in informing our current customers and reaching out to new contacts within companies that we currently serve. These efforts are aimed at moving our customers along the adoption curve for PDX-based clinical trial simulation and increasing the number of studies and the average study size of our existing customers. Our success in these efforts is demonstrated by the growing number of customers who have increased their annual spend on our services over the past three years.

For the year ended April 30, 2018, revenues from our TOS products totaled approximately $18.8 million, an increase of approximately 37.2% from the previous year.

Personalized Oncology Solutions Business

Our Personalized Oncology Solutions ("POS") business, which supports our TOS business, offers physicians and patients information to help guide the development of personalized treatment plans. Our core products, TumorGraft implants and drug panels, utilize TumorGraft technology to empirically test the response of a patient's tumor to multiple oncology drugs or drug combinations. The response of the tumors in the mice is tracked over time and analyzed to determine which drug or drug combination is providing the highest level of tumor growth inhibition in the mice. This process simulates the results of multiple, simultaneous clinical trials in which a patient might consider participating. By providing this product, we achieve an important goal of adding PDX Models to our TumorBank, and gain valuable data about the accuracy of PDX Models in predicting patient response and in building the operational capabilities to collect, implant and grow tumors from patients, physicians and hospitals around the United States and internationally. Our data, which is currently limited in nature, indicates that there may be a correlation between the response to drugs of a tumor in a mouse with the response to drugs of a tumor in a patient.

In addition to our core TumorGraft POS products, we offer non-core related POS products to our customers, including personalized tumor boards and gene sequencing. Personalized tumor boards are designed to provide access to oncologists with expertise in particular tumor types. We also provide access to gene sequencing that analyzes the genetic makeup of patient's tumor for the purpose of identifying potentially useful drugs.

As previously disclosed, our POS business is not the focus of our growth moving forward. We continue to offer the POS products in support of our TOS business.

For the year ended April 30, 2018, revenues from our POS business totaled approximately $1.5 million, a decrease of approximately 15.4% from the previous year.

Our Growth and Expansion Strategy

Our strategy is to continue to use TumorGrafts as a platform technology to drive multiple synergistic revenue streams. Our current strategy for growth has three components:

- Growing our TumorBank: We grow our TumorBank in two ways. First, we increase the number of TumorGrafts in the bank for our existing tumor types to ensure customers are finding the specific models they need for their studies. Second, we add new tumor types to the bank to enable studies in tumor types that we have not historically been able to run for our pharmaceutical and biotechnology customers.
- Adding new PDX technologies: The fields of oncology research and drug development are evolving. To keep up with new approaches, we add new technologies to our PDX platform. We are currently investing in developing ImmunoGrafts, a new PDX model that is developed in a mouse with a humanized immune system. These models are built to specifically serve the needs of pharmaceutical and biotechnology companies developing immune oncology drugs. This is a relatively new area of oncology research that has shown significant promise and is attracting a significant amount of research and development interest.

- Increasing the scale of studies: We have facilitated studies for over 200 pharmaceutical and biotechnology companies. We believe there is significant opportunity to grow our revenue by increasing the size of the studies these customers run. To accomplish this, we are developing new study designs that offer solutions to compounds that are in phase I and phase II clinical trials. We believe that the increased budgets of these drugs, as compared to drugs in the pre-clinical stage, will enable us to sell larger studies.

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 in our industry is intense and based

significantly on scientific, technological, and market forces, which include the effectiveness of the technology and products and the ability to commercialize technological developments. 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 non-competitive 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.

Research and Development

For the years ended April 30, 2018 and 2017, we spent approximately $4.4 million and $4.3 million, respectively, to develop our TumorGraft Technology Platform. We continue to expand our TumorBank through the inclusion of tumor tissue and implanted models through research collaborations and relationships with hospitals and academic institutions. Our research and development efforts were focused on increasing our understanding of our TumorGraft models, their clinical predictability, improving growth and tumor take rates, and other biological and molecular characteristics of the models.

Government Regulation

The research, development, and marketing of our products, the performance of our POS testing services, and the operation of our facilities are generally subject to federal, state, local, or foreign legislation, including licensure of our laboratory located in Rockville, Maryland by the State of Maryland and compliance with federal, state, local or foreign legislation applicable to the use of live animals in scientific testing, research and education.

The FDA has claimed regulatory authority over laboratory developed tests such as our POS products, but has generally not exercised it. The FDA has announced regulatory and guidance initiatives that could increase federal regulation of our business. We are subject to federal and international regulations with regard to shipment of hazardous materials, including the Department of Transportation and the International Air Transit Authority. These regulations require interstate, intrastate, and foreign shipments comply with applicable labeling, documentation, and training requirements.

Employees

As of July 15, 2018, we had 92 full-time employees, including 25 with doctoral or other advanced degrees. Of our workforce, 77 employees are engaged in research and development and laboratory operations, 9 employees are engaged in sales and marketing, and 6 employees 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

We were incorporated as a merger and acquisition company under the laws of the State of Delaware on June 4, 1985, under the name “International Group, Inc.” In September 1985, the Company completed a public offering and shortly thereafter acquired the world-wide rights to the Champions sports theme restaurant concept and changed its name to “Champions Sports, Inc.” In 1997, the Company sold its Champions service mark and concept to Marriott International, Inc. and until 2005, was a consultant to Marriott International, Inc. and operated one Champions Sports Bar Restaurant. In January 2007, the Company changed its business direction to focus on biotechnology and subsequently

changed its name to Champions Biotechnology, Inc. On May 18, 2007, the Company acquired Biomerk, Inc., at which time we began focusing on our current line of business. In April 2011, the Company changed its 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. Information on our website is not part of this Annual Report. Through our website, we make available, free of charge, access to all reports filed with the United States Securities and Exchange Commission, or SEC, including our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q, our Current Reports on Form 8-K, our Proxy Statements on Schedules 14A 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.

Item 1A. Risk Factors

You should carefully consider the risks described below together with all of the other information included in this Annual Report. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known, or those we currently consider insignificant, may also impair our business operations in the future.

Risks Related to Our Business

We historically incurred losses from operating activities, may require significant capital and may never achieve sustained profitability.

For the years ended April 30, 2018 and 2017, the Company had a net loss of approximately $1.5 million and $6.9 million, respectively. As of April 30, 2018, the Company has an accumulated deficit of approximately $70.8 million. As of April 30, 2018, we had negative working capital of $2.4 million and cash and cash equivalents of $856,000. We believe that our cash and cash equivalents on hand, together with continued improved cash flows from operations, are adequate to fund our operations through at least August 2019.

The amount of our losses and liquidity requirements may vary significantly from year-to-year and quarter-to-quarter and will depend on, among other factors:

- the cost of continuing to build out our TumorGraft Technology Platform;
- the cost and rate of progress toward growing our TOS businesses;
- the cost and rate of progress toward building our sales forces;
- the cost of increasing our research and development;
- the cost of renting our laboratory and animal testing facilities and payment for associated services;
- the timing and cost of obtaining and maintaining any necessary regulatory approvals;
- the cost of expanding and building out our infrastructure; and
- the cost incurred in hiring and maintaining qualified personnel.

Currently, the Company derives revenue from TOS products and POS products, while pursuing efforts to further develop bioinformatics from its TumorBank and its TumorGraft Technology Platform. In addition, we are building our sales and marketing operations to grow the sales of our TOS products. Our POS products are not the focus of our growth moving forward.

To become sustainably profitable, we will need to generate revenues to offset our operating costs, including our research and development and general and administrative expenses. We may not achieve or, if achieved, sustain our revenue or profit objectives. Our losses may increase in the future, and, ultimately, we may have to cease operations.

In order to grow revenues, we must invest capital to implement our sales and marketing efforts and to successfully develop our bioinformatics from our TumorBank and our TumorGraft Technology Platform. Because we do not have sufficient history of commercial efforts, our sales and marketing efforts may never generate significant increases in revenues or achieve profitability and it is likely that we will be required to raise additional capital to continue our operations as currently contemplated. If we must devote a substantial amount of time to raising capital, it will delay our ability to achieve our business goals within the time frames that we now expect, which could increase the amount of capital we need. In addition, the amount of time expended by our management on fundraising distracts them from concentrating on our business affairs. If we require additional capital and are not successful in raising the needed

capital, we may have to cease operations.

We may incur greater costs than anticipated, which could result in sustained losses.

We use reasonable efforts to assess and predict the expenses necessary to pursue our business strategies. However, implementing our business strategies may require more employees, capital equipment, supplies or other expenditure items than management has predicted. Similarly, the cost of compensating additional management, employees and consultants or other operating costs may be more than we estimate, which could result in ongoing and sustained losses.

We may not be able to implement our business strategies which could impair our ability to continue operations.

Implementation of our business strategies will depend in large part on our ability to (i) attract and maintain a significant number of customers; (ii) effectively provide acceptable services to our customers; (iii) develop and license new products and technologies; (iv) maintain appropriate internal procedures, policies, and systems; (v) hire, train, and retain skilled employees and management; (vi) continue to operate despite increasing competition in our industry; and (vii) establish, develop and maintain our name recognition. Our inability to obtain or maintain any or all these factors could impair our ability to implement our business strategies successfully, which could have material adverse effects on our results of operations and financial condition.

Our business could be adversely impacted by changes in FDA's regulatory oversight of laboratory-developed tests such as our POS services that are currently under consideration or by other changes in the regulatory requirements applicable to our POS services imposed by the FDA or regulatory authorities in other countries in which our services are provided.

The FDA has claimed regulatory authority over all laboratory-developed tests, or LDTs, such as our POS services, but has generally not exercised its regulatory authority for most LDTs performed by CLIA-certified laboratories such as our facilities. The FDA has announced several regulatory and guidance initiatives that may impact our business, including by increasing FDA's regulation of LDTs.

On July 31, 2014 the FDA notified Congress of the FDA's intent to issue a draft oversight framework for LDTs based on risk to patients rather than whether they were made by a conventional manufacturer or a single laboratory. This draft oversight framework includes pre-market review for higher-risk LDTs, like those used to guide treatment decisions, including the many companion diagnostics that have entered the market as LDTs. In addition, under the draft framework, the FDA would continue to exercise enforcement discretion for low-risk LDTs and LDTs for rare diseases, among others. The framework would be phased in over many years. If this framework is implemented, these initiatives may lead to an increased regulatory burden on our Company, which may result in a requirement for FDA review and clearance or approval of our POS services. Any increased regulatory burdens would probably result in an increase in the cost of our POS services and could keep us from selling POS services until such time as any required FDA clearance or approval is obtained. If our POS services become subject to FDA's approval and oversight as medical devices, the additional regulatory burdens may be significant, and may require the addition of experienced medical device quality, regulatory and compliance personnel to assume these burdens. Any POS services that we provide in other countries may be similarly subject to regulation by foreign regulatory agencies, which would also increase our costs. These matters could hurt our business and our financial results.

Our laboratories are subject to regulation and licensure requirements, and the healthcare industry is highly regulated; we may face substantial penalties, and our business activities may be impacted, if we fail to comply.

Our TumorGraft products are performed in laboratories that are subject to state regulation and licensure requirements. Such regulation and requirements are subject to change, and may result in additional costs or delays in providing our products to our customers. In addition, the healthcare industry in general is highly regulated in the United States at both the federal and state levels. We seek to conduct our business in compliance with all applicable laws, but many of the laws and regulations potentially applicable to us are vague or unclear. These laws and regulations may be interpreted or applied by an authority in a way that could require us to make changes in our business. We may not be able to obtain all regulatory approvals needed to operate our business or sell our products. If we fail to do so, we could be subject to civil and criminal penalties or fines or lose the authorizations necessary to operate our business, as well as incur additional liabilities from third parties. If any of these events happened, they could hurt our business and financial results.

If our laboratory facilities are damaged or destroyed, or we have a dispute with one of our landlords, our business would be negatively affected.

We currently utilize one laboratory in Rockville, Maryland. We opened the lab during the first quarter of fiscal 2018 and transitioned our activities from the Baltimore lab to this new facility. If this facility was to be significantly damaged or destroyed, we could suffer a loss of our ongoing and future drug studies, as well as our TumorBank. In addition, we lease for the laboratory from a third party. If we had a dispute with our landlord or otherwise could not utilize this space, it would take time to find and move to a new facility, which could negatively affect our results of operations.

Any health crisis impacting our colony of laboratory mice could have a negative impact on our business.

Our TumorGraft operations depend on having a colony of live mice available. If this population experienced a health crisis, such as a virus or other pathogen, such crisis would affect the success of our existing TOS and POS business and future business, as we would have to rebuild the population and repeat current TumorGrafts.

We have limited experience marketing and selling our products and may need to rely on third parties to successfully market and sell our products and generate revenues.

Currently, we rely on the internet, word of mouth, and a small sales force to market our services. We have to compete with other pharmaceutical, biotechnology and life science technology and service companies to recruit, hire, train, and retain marketing and sales personnel. However, there can be no assurance that we will be able to develop in-house sales, and as a result, we may not be able to generate product revenue.

We will continue to be dependent upon key employees.

Our success, currently, is dependent upon the efforts of several full-time key employees, the loss of the services of one or more of which would have a material adverse effect on our business and financial condition. We intend to continue to develop our management team and attract and retain qualified personnel in all functional areas to expand and grow our business. This may be difficult in the healthcare industry where competition for skilled personnel is intense.

Because our industry is very competitive and many of our competitors have substantially greater capital resources and more experience in research and development, we may not succeed in selling or increasing sales of our products and technologies.

We are engaged in a rapidly changing and highly competitive field. Potential competitors in the United States and abroad are numerous and include providers of clinical research services, most of which have substantially greater capital resources and more experience in research and development capabilities. Furthermore, new companies will likely enter our market from the United States and abroad, as scientific developments surrounding other pre-clinical and clinical services grow in the multibillion dollar oncology marketplace. Our competitors may succeed in selling their products to our pharmaceutical and biotech customers more effectively than we sell our products. In addition, academic institutions, hospitals, governmental agencies, and other public and private research organizations also may conduct similar research, seek patent protection, and may develop and commercially introduce competing products or technologies on their own or through joint ventures. If one or more of our competitors succeeds in developing similar technologies and products that are more effective or successful than any of those that we currently sell or will develop, our results of operations will be significantly adversely affected.

If we are unable to protect our intellectual property, we may not be able to compete as effectively.

It is important in the healthcare industry to obtain patent and trade secret protection for new technologies, products, and processes. Our success will depend, in part, upon our ability to obtain, enjoy, and enforce protection for any products we have, develop or acquire under United States and foreign patent laws and other intellectual property laws, preserve the confidentiality of our trade secrets, and operate without infringing the proprietary rights of third parties. Where appropriate, we will seek patent protection for certain aspects of our technology. However, while our TumorGraft Technology Platform is proprietary and requires significant know-how to both initiate and operate, it is not patented. It is, therefore, possible for competitors to develop other implantation procedures, or to discover the same procedures utilized by us, that could compete with us in our market.

It also is unclear whether efforts to secure our trade secrets will provide useful protection. While we will use reasonable efforts to protect our trade secrets, our employees or consultants may unintentionally or willfully disclose our proprietary information to competitors resulting in a loss of protection. Enforcing a claim that someone else illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Finally, our competitors may independently develop equivalent knowledge, methods and know-how.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

We rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also seek to enter into confidentiality and invention assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Our trade secrets may also be obtained by third parties by other means, such as breaches of our physical or computer security systems. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor,

we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Claims by others that our products infringe their patents or other intellectual property rights could adversely affect our financial condition.

The healthcare industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Patent applications are maintained in secrecy in the United States and also are maintained in secrecy outside the United States until the application is published. Accordingly, we can conduct only limited searches to determine whether our technology infringes the patents or patent applications of others. Any claims of patent infringement asserted by third parties would be time-consuming and could likely:

- result in costly litigation;
- divert