

ORGANOVO HOLDINGS, INC.

Form 424B3

April 04, 2013

Table of Contents

Filed Pursuant to Rule 424(b)(3)

Registration No. 333-182101

PROSPECTUS

## ORGANOVO HOLDINGS, INC.

**15,347,987 shares of Common Stock**

**16,747,987 shares of Common Stock issuable upon the exercise of Warrants**

This prospectus relates to the resale by certain selling security holders of Organovo Holdings, Inc. of up to 32,095,974 shares of our common stock in connection with the resale of:

up to 15,347,987 shares of our common stock which were issued in our private placement (the Offering) of units consisting of (i) one share of our common stock and (ii) one warrant to purchase one share of our common stock at an exercise price of \$1.00 per share (the Units), with closings of the Offering occurring on each of February 8, 2012 (the Initial Closing), February 29, 2012 and March 16, 2012 and shares of common stock issued to certain of the selling security holders on the date of the Initial Closing of the Offering in connection with the conversion of our \$1,500,000 in principal amount of 6% convertible promissory notes due March 31, 2012 (the Bridge Notes) into 1,525,387 Units and 100,000 shares of common stock issued to a consultant;

up to 15,247,987 shares of our common stock issuable upon the exercise of warrants issued to the selling security holders in our Offering of Units (excluding warrants issued to our placement agents in the Offering) and shares of common stock issuable upon the exercise of warrants issued to certain of the selling security holders on the date of the Initial Closing of the Offering in connection with the conversion of the Bridge Notes into 1,525,387 Units; and

up to 1,500,000 shares of our common stock issuable upon the exercise of warrants issued to certain selling security holders in connection with the original issuance of our Bridge Notes that were converted into 1,500,000 new warrants on the date of the Initial Closing, each exercisable at a price of \$1.00 per share of our common stock.

The selling security holders may offer to sell the shares of common stock being offered in this prospectus at fixed prices, at prevailing market prices at the time of sale, at varying prices, or at negotiated prices. We do not know when or in what amount the selling security holders may offer the securities for sale. The selling security holders may sell any, all or none of the securities offered by this prospectus. We provide more information about how the selling security holders may sell or otherwise dispose of their shares of common stock in the section entitled Plan of Distribution. The selling security holders will pay all brokerage fees and commissions and similar expenses. We will pay all expenses (except brokerage fees and commissions and similar expenses) relating to the registration of the shares with the Securities and Exchange Commission.

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We will not receive proceeds from the sale of shares by the selling security holders. Any proceeds received by us from the exercise of warrants by the selling security holders will be used for general corporate purposes.

Our common stock is traded on the OTCQX under the symbol ONVO. On March 25, 2013, the closing sale price of our common stock on the OTCQX was \$3.75 per share.

**Investing in our securities involves significant risks. See Risk Factors beginning on page 6.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

**The date of the prospectus is April 4, 2013.**

**Table of Contents**

**TABLE OF CONTENTS**

<u>Forward-Looking Statements</u>	ii
<u>Prospectus Summary</u>	1
<u>Risk Factors</u>	6
<u>Use of Proceeds</u>	19
<u>Selling Security Holders</u>	20
<u>Plan of Distribution</u>	29
<u>Description of Securities</u>	32
<u>Legal Matters</u>	35
<u>Where You Can Find More Information</u>	35
<u>Interest of Named Experts and Counsel</u>	35
<u>Incorporation of Certain Information by Reference</u>	35

**ORGANOVO HOLDINGS, INC. HAS NOT REGISTERED THE SHARES OF COMMON STOCK THAT MAY BE SOLD BY THE SELLING SECURITY HOLDERS UNDER THE SECURITIES LAWS OF ANY STATE. SELLING SECURITY HOLDERS, AND ANY BROKERS OR DEALERS, EFFECTING TRANSACTIONS IN THE SHARES SHOULD CONFIRM THAT THE SHARES HAVE BEEN REGISTERED UNDER THE SECURITIES LAWS OF THE STATE OR STATES IN WHICH SALES OF THE SHARES OCCUR AS OF THE TIME OF SUCH SALES, OR THAT THERE IS AN AVAILABLE EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THE SECURITIES LAWS OF SUCH STATES.**

**THIS PROSPECTUS IS NOT AN OFFER TO SELL ANY SECURITIES OTHER THAN THE SHARES OF COMMON STOCK FOR SALE BY THE SELLING SECURITY HOLDERS. THIS PROSPECTUS IS NOT AN OFFER TO SELL SECURITIES IN ANY CIRCUMSTANCES IN WHICH SUCH AN OFFER IS UNLAWFUL.**

You should rely only on the information contained in this prospectus or incorporated by reference in this prospectus and in any applicable prospectus supplement. Neither we nor the selling security holders have authorized anyone to provide you with different information. We and the selling security holders take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. The information contained in this prospectus, any applicable prospectus supplement and the documents incorporated by reference herein or therein are accurate only as of the date such information is presented. You should also read this prospectus together with the additional information described under the heading Where You Can Find More Information. This prospectus may be supplemented from time to time to add, update or change information in this prospectus. Any statement contained in this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in such prospectus supplement modifies or supersedes such statement. Any statement so modified will be deemed to constitute a part of this prospectus only as so modified, and any statement so superseded will be deemed not to constitute a part of this prospectus.

The registration statement containing this prospectus, including the exhibits to the registration statement, provides additional information about us and the securities offered under this prospectus. The registration statement, including the exhibits, can be read on the SEC's website or at the SEC offices mentioned under the heading Where You Can Find More Information.

In this prospectus, Organovo, the Company, we, us, and our refer to Organovo Holdings, Inc., a Delaware corporation, unless the context otherwise requires.

**Table of Contents**

**FORWARD-LOOKING STATEMENTS**

This prospectus and other materials we have filed or will file with the SEC contain, or will contain, certain forward-looking statements within the meaning of Section 27A of the Securities Act, and Section 21E of the Securities Exchange Act of 1934 (the Exchange Act ). These statements relate to anticipated future events, future results of operations or future financial performance. These forward-looking statements include, but are not limited to, statements relating to our ability to raise sufficient capital to finance our planned operations, market acceptance of our technology and product offerings, our ability to attract and retain key personnel, our ability to protect our intellectual property, and estimates of our cash expenditures for the next 12 to 36 months. In some cases, you can identify forward-looking statements by terminology such as may, might, will, should, intends, expects, plans, goals, projects, anticipates, believes, estimates, predicts, potential, or continue or the ne other comparable terminology.

These forward-looking statements are only predictions, are uncertain and involve substantial known and unknown risks, uncertainties and other factors which may cause our (or our industry s) actual results, levels of activity or performance to be materially different from any future results, levels of activity or performance expressed or implied by these forward-looking statements. The Risk Factors section of this prospectus sets forth detailed risks, uncertainties and cautionary statements regarding our business and these forward-looking statements. You should consider these Risk Factors as well as any Risk Factors that we include in any of our future filings with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, incorporated by reference into this prospectus before making an investment decision. Any of the risks, as well as additional risks and uncertainties not currently known to us or that we currently deem immaterial, could materially and adversely affect our results of operations or financial condition.

We cannot guarantee future results, levels of activity or performance. You should not place undue reliance on these forward-looking statements, which speak only as of the date that they were made. These cautionary statements should be considered with any written or oral forward-looking statements that we may issue in the future. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to reflect actual results, later events or circumstances or to reflect the occurrence of unanticipated events.

## **Table of Contents**

### **PROSPECTUS SUMMARY**

*The following summary highlights selected information contained in this prospectus. Because it is a summary, it does not contain all of the information you should consider before making an investment decision. We encourage you to carefully read this prospectus in its entirety and the documents to which we refer you. The following summary is qualified in its entirety by reference to the detailed information appearing elsewhere in this prospectus.*

#### **Overview**

We have developed and are commercializing a platform technology for the generation of functional human tissues that can be employed in drug discovery and development, biological research, and as therapeutic implants for the treatment of damaged or degenerating tissues and organs. We intend to introduce a paradigm shift in the approach to the generation of three-dimensional human tissues, by creation of constructs in 3D that have the potential to replicate native human biology. We can improve on previous technologies by moving away from monolayer 2D cell cultures and by enabling all or part of the tissues we create to be constructed solely of cells. We believe our demonstrated expertise in printing various fully cellular human tissues as disclosed in peer-reviewed scientific publications provides a strong foundation upon which other tissues can be built to replicate human biology and human disease. We believe that our broad and exclusive commercial rights to patented and patent-pending 3D bioprinting technology, combined with strengths in engineering and biology, put us in an ideal position to provide a wide array of products for use in research, drug discovery and regenerative medicine therapies.

Our foundational proprietary technology derives from research led by Dr. Gabor Forgacs, the George H. Vineyard Professor of Biological Physics at the University of Missouri. We have a broad portfolio of intellectual property rights covering principles, enabling instrumentation applications and methods of cell based printing, including exclusive licenses to certain patented and patent pending technologies from the University of Missouri-Columbia, Clemson University, and Becton Dickinson and Company, and outright ownership of six pending patent applications (the patents and patent rights described in this paragraph are sometimes collectively referred to as the Intellectual Property Rights ). We believe that our portfolio of Intellectual Property Rights provides a strong and defensible market position for our commercialization of 3D bioprinting technology.

We believe we have the potential to build and maintain a sustainable business by leveraging our core technology platform across a variety of applications. We have entered into multiple collaborative research agreements with pharmaceutical corporations. We have also secured five federal grants in the aggregate amount of approximately \$955,000, including Small Business Innovation Research grants to support the development of our technology. The Company developed the NovoGen MMX Bioprinter (our first-generation 3D bioprinter) within two and one half years of commencing operations. We were selected by MIT's Technology Review magazine among the Most Innovative Companies of 2012. We believe these corporate achievements provide strong validation for the commercial viability of our technology.

#### **The Technology**

Our technology is centered around multiple 3D bioprinting technologies utilizing our bioprinting instrument, the NovoGen MMX Bioprinter. Our 3D bioprinting technologies enable a wide array of tissue compositions and architectures to be created, using combinations of cellular bio-ink (building blocks comprised solely of cells), hydrogel (building blocks comprised of biocompatible gels), or hybrid bio-ink (building blocks comprised of a mixture of cells and material such as hydrogel). A key distinguishing feature of our bioprinting platform is the ability to generate three-dimensional constructs that have all or some of their components comprised entirely of

## **Table of Contents**

cells. The fully-cellular feature of our technology enables architecturally and compositionally defined functional human tissues to be generated for in vitro use in drug discovery and development to potentially replicate the functional biology of native human tissue. Furthermore, fully cellular constructs may offer specific advantages for regenerative medicine applications where bioactive cells are required and three-dimensional configuration is necessary, such as augmenting or replacing functional mass in tissues and organs that have sustained acute or chronic damage.

We intend to deliver the following products to the market:

Three-dimensional models of human tissue for utilization in traditional absorption, distribution, metabolism, excretion (ADME) / toxicology (TOX) / and drug metabolism and pharmacokinetics (DMPK) testing in drug development.

Specific models of human biology or pathophysiology, in the form of three-dimensional human tissues, for use in drug discovery and development.

Three-dimensional human tissues for use as therapeutic regenerative medicine products, such as blood vessels for bypass grafting, nerve grafts for nerve damage repair and regenerative patches for treatment of heart disease.

3D bioprinters for use in medical research.

A portfolio of consumables for use in 3D bioprinting.

We have entered into collaborations with multiple corporate and academic partners that we believe provide validation of the value of our 3D bioprinting technology.

## **Market Opportunity**

We believe that our bioprinting technology is uniquely positioned to provide functional human tissues for use in drug discovery and development as well as a broad array of tissues suitable for therapeutic use in regenerative medicine applications. While there are rapid-prototyping printers currently available that build three dimensional structures out of polymers (often used for prototyping of plastic parts for tools or devices), these instruments are not specifically designed or intended for use with purely cellular inks in building biologic tissues and we do not believe that the firms working on these instruments have the required biology expertise to create tissues using these instruments

There are multiple addressable markets for our technology platform:

- 1) **Specialized Models for Drug Discovery and Development**: The NovoGen MMX Bioprinter can produce highly specialized functional human tissues that can be utilized to model a specific tissue physiology or pathophysiology. Our bioprinting technology has demonstrated the ability to create human blood vessel constructs, and to create fully human tissue containing microvascular structures. These capabilities are anticipated to broaden the scope and scale of 3D tissues that can be generated, and to facilitate the development of disease models in such areas as cardiovascular disease, oncology, and fibrosis.
- 2) **Biological Research Tools**: Absorption, distribution, metabolism, excretion (ADME) testing is used to determine which factors enhance or inhibit how a potential drug compound reaches the blood stream. Distribution of a compound can be affected by binding to plasma proteins; age, genetics, and other factors can influence metabolism of a compound; and the presence of certain disease states can have effects on excretion of a compound. Many companies perform ADME studies utilizing various cell-based assays or automated bioanalytical techniques. Drug metabolism and pharmacokinetics (DMPK) testing is a subset of ADME. Determining the DMPK properties of a drug helps the drug developer to



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## Table of Contents

understand its safety and efficacy. Toxicology (TOX) testing is a further requirement to determine the detrimental effects of a particular drug on specific tissues. We believe that the NovoGen MMX Bioprinter is positioned to deliver highly differentiated products for use in traditional cell-based ADME / TOX / DMPK studies. Products in this arena may replace or complement traditional cell based assays that typically employ primary hepatocytes, intestinal cell lines, renal epithelial cells and cell lines grown in a traditional two-dimensional format. Importantly, the combination of tissue-like three-dimensionality and human cellular components is believed to provide an advantage over non-human animal systems toward predicting in vivo human outcomes.

- 3) **Regenerative Medicine:** The field of regenerative medicine is advancing via multiple strategic approaches in development and practice, including cell therapies and scaffold-based products (+/- cells). The architectural precision and flexibility of our technology may facilitate the optimization, development, and clinical use of three-dimensional tissue constructs. Importantly, our technology offers a next-generation strategy whereby three-dimensional structures can be generated without the use of scaffolding or biomaterial components. The ultimate goal is to enable fully cellular constructs to be generated in a configuration compatible with surgical modes of delivery, thereby enabling restoration of significant functional mass to a damaged tissue or organ.

We believe that our technology can capitalize, via strategic partnerships, on additional market opportunities in the provision of enabling tools for drug discovery and development as well as the discovery and development of therapeutic implants that augment or replace damaged tissues and organs. We believe there are multiple short- and long-term revenue opportunities for us in these areas, including direct sales of 3D human tissue constructs for drug screening and development, licensing fees for commercial access to our technology, and royalties from product enablement, particularly in the area of therapeutic products for regenerative medicine.

## **Corporate Background**

Real Estate Restoration and Rental, Inc. ( RERR ), our predecessor company, was incorporated in 2007 in the state of Nevada. On December 28, 2011, RERR entered into an Agreement and Plan of Merger pursuant to which RERR merged with its newly formed, wholly owned subsidiary, Organovo Holdings, Inc. ( Merger Sub ), a Nevada corporation (the RERR Merger ). Upon the consummation of the RERR Merger, the separate existence of Merger Sub ceased and RERR, the surviving corporation in the RERR Merger, became known as Organovo Holdings, Inc. ( Holdings-Nevada ).

As permitted by Chapter 92A.180 of Nevada Revised Statutes, the sole purpose of the RERR Merger was to effect a change of RERR 's name. Upon the filing of Articles of Merger with the Secretary of State of Nevada on December 28, 2011 to effect the RERR Merger, RERR 's articles of incorporation were deemed amended to reflect the change in RERR 's corporate name.

On January 30, 2012, Holdings-Nevada entered into an Agreement and Plan of Merger pursuant to which Holdings-Nevada merged with and into its newly formed, wholly owned subsidiary, Organovo Holdings, Inc. ( Holdings-Delaware or Pubco ), a Delaware corporation (the Reincorporation Merger ). Upon the consummation of the Reincorporation Merger, the separate existence of Holdings-Nevada ceased and Holdings-Delaware was the surviving corporation in the Reincorporation Merger. The sole purpose of the Reincorporation Merger was to change the domicile of Pubco from Nevada to Delaware.

On February 8, 2012, Organovo Acquisition Corp. ( Acquisition Corp. ), a wholly-owned subsidiary of Pubco, merged (the Merger ) with and into Organovo, Inc., a Delaware corporation ( Organovo ). Organovo was the surviving corporation of that Merger. As a result of the Merger, Pubco acquired the business of Organovo, and will continue the existing business operations of Organovo.



## **Table of Contents**

### **Risks Associated with Our Business**

Investing in our common stock involves substantial risk. Before participating in this offering, you should carefully consider all of the information in this prospectus, including the risks discussed in Risk Factors immediately following this summary. In particular:

We have a limited operating history and a history of operating losses, and expect to incur significant additional operating losses;

We need to secure additional financing to support our planned operations;

We are an early-stage company with an unproven business strategy and may never achieve commercialization of our research tools and therapeutic products or profitability;

Our success and our collaborators' ability to sell therapeutic products will depend to a large extent upon reimbursement from health care insurance companies;

Our research tools are new and unproven and may not allow us or our collaborators to develop successful commercial products;

Our proprietary tissue creation technology, drug discovery and research tools are subject to the risks associated with new and rapidly evolving technologies.

The commercialization of therapeutic or other life science products developed using our research tools is subject to a variety of risks of failure inherent in their development or commercial viability, including the possibility that any such products will (i) fail to be found through the use of research tools; (ii) be found to be toxic or ineffective; (iii) fail to receive necessary regulatory approvals; (iv) be difficult or impossible to manufacture on a large scale; (v) be economically infeasible to market; (vi) fail to be developed prior to the successful marketing of similar products by competitors; or (vii) be impossible to market because they infringe the proprietary rights of third parties or compete with superior products marketed by third parties;

If we are unable to enter into or maintain strategic collaborations with third parties, we may have difficulty selling our research tools and therapeutic products and we may not generate sufficient revenue to achieve or maintain profitability; and

We cannot control our collaborators' allocation of resources or the amount of time that our collaborators devote to developing our programs or potential products, which may have a material adverse effect on our business.

We will depend on our patent portfolio, our licensed technology and other trade secrets in the conduct of our business and must ensure that we do not violate the patent or intellectual property rights of others.

### **Corporate Information**

Our offices are located at 6275 Nancy Ridge Drive, Suite 110, San Diego, California 92121. Our telephone number is (858) 550-9994. Our website can be found at [www.organovo.com](http://www.organovo.com). The information contained in or that can be accessed through our website is not part of this prospectus.



**Table of Contents**

**The Offering**

**Key Facts of the Offering**

Common stock being offered by the selling security holders:	15,347,987
Total shares of common stock outstanding: <sup>(1)</sup>	64,646,665
Number of shares of common stock issuable upon the exercise of warrants held by the selling security holders registered on this prospectus:	16,747,987
Use of Proceeds:	We will not receive any of the proceeds from the sale of our shares by the selling security holders. Any proceeds received by us from the exercise of warrants by the selling security holders will be used for general corporate purposes.
OTCQX Symbol:	ONVO
Risk Factors:	Investing in our securities involves a high degree of risk and purchasers of our securities may lose their entire investment. See Risk Factors below and the other information included elsewhere in this prospectus or incorporated herein for a discussion of factors you should carefully consider before deciding to invest our securities.

(1) The number of shares of our common stock outstanding is based on the number of shares of our common stock outstanding as of March 25, 2013, including the shares of common stock held by the selling security holders. This number does not include:

4,333,889 shares of common stock issuable upon exercise of outstanding warrants at prices ranging from \$1.00 to \$3.24 per share, including the warrants held by the selling security holders;

3,622,317 shares of common stock issuable upon exercise of outstanding options, at a weighted average exercise price of \$2.11 per share, which were issued under our 2008 Equity Incentive Plan and 2012 Equity Incentive Plan; and

1,712,505 shares of our common stock which remain available for grant and possible subsequent issuance under our 2012 Equity Incentive Plan.

Unless otherwise indicated, all information in this prospectus assumes that no options, warrants or shares of common stock were issued after March 25, 2013, and no outstanding options or warrants were exercised after March 25, 2013. In addition, unless otherwise indicated, all information in this prospectus assumes that the warrants issued in connection with this offering to the investors in the Units and our placement agents and financial advisor have not been exercised.

**Table of Contents**

**RISK FACTORS**

*Any investment in our common stock involves a high degree of risk. You should consider carefully the following information about these risks, together with the other information contained in this prospectus, before you decide to buy our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our operations. If any of the following risks actually occur, our business would likely suffer and the trading price of our common stock could decline, and you may lose all or part of the money you paid to buy our common stock.*

**Risks related to our Business and our Industry**

***We have a limited operating history and a history of operating losses, and expect to incur significant additional operating losses.***

We were incorporated in 2007, opened our laboratories in San Diego, California in January, 2009 and have only a limited operating history. Therefore, there is limited historical financial information upon which to base an evaluation of our performance. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations. We have generated operating losses since we began operations, including \$9.3 million and \$2.3 million for the years ended December 31, 2012 and 2011, respectively. As of December 31, 2012, we had incurred cumulative operating losses of \$13.7 million and cumulative net losses totaling \$50.2 million. We expect to incur substantial additional operating losses over the next several years as our research, development, and commercial activities increase. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Our ability to generate revenue and achieve profitability will depend on, among other things, entering into customer relationships with strategic partners, successful completion of the preclinical and clinical development of our partners' product candidates; obtaining necessary regulatory approvals by our partners or us from the FDA and international regulatory agencies; successful manufacturing, sales, and marketing arrangements; and raising sufficient funds to finance our activities. We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected.

***We will need to secure additional financing to support our planned operations.***

We will require additional funds for our anticipated operations and if we are not successful in securing additional financing, we may be required to delay significantly, reduce the scope of or eliminate one or more of our research or development programs, downsize our general and administrative infrastructure, or seek alternative measures to avoid insolvency, including arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, product candidates or products.

***We are an early-stage company with an unproven business strategy and may never achieve commercialization of our research tools and therapeutic products or profitability.***

Our strategy of using our research tools for the collaborative development of therapeutic products is unproven. Our success will depend upon our ability to enter into additional collaboration agreements on favorable terms, to determine which research tools and therapeutic products have potential value, and to select an appropriate commercialization strategy for each research tool and potential therapeutic product we or our collaborators choose to pursue. If we are not successful in implementing our strategy to commercialize our research tools and potential therapeutic products, we may never achieve, maintain or increase profitability.

***Our success and our collaborators' ability to sell therapeutic products will depend to a large extent upon reimbursement from health care insurance companies.***

Our success may depend, in part, on the extent to which reimbursement for the costs of therapeutic products and related treatments will be available from third-party payers such as government health administration authorities,

## **Table of Contents**

private health insurers, managed care programs, and other organizations. Over the past decade, the cost of health care has risen significantly, and there have been numerous proposals by legislators, regulators, and third-party health care payers to curb these costs. Some of these proposals have involved limitations on the amount of reimbursement for certain products. Similar federal or state health care legislation may be adopted in the future and any products that we or our collaborators seek to commercialize may not be considered cost-effective. Adequate third-party insurance coverage may not be available for us or our collaborative partners to establish and maintain price levels that are sufficient for realization of an appropriate return on investment in product development.

### ***Our research tools are new and unproven and may not allow us or our collaborators to develop successful commercial products***

Our research tools involve new and unproven approaches. We have not proven that our research tools will enable us or our collaborators to identify therapeutic products with commercial potential, or to develop or commercialize such therapeutic products. Even if we or our collaborators are successful in identifying therapeutic products based on discoveries made using our research tools, we or our collaborators may not be able to discover or develop commercially viable products. To date, no one has developed or commercialized any therapeutic or other life science product based on our research tools. If our research tools do not assist in the discovery and development of such therapeutic products, our current and potential collaborators may lose confidence in us and our research tools and our business may suffer as a result.

If our collaborators, licensees and customers do not successfully develop or commercialize therapeutic or other life science products using our research tools, we may not generate revenues from those customers. In addition, we may experience unforeseen technical complications, unrecognized defects and limitations in the productions of our research tools. These complications could materially delay or limit the use of those tools, substantially increase the anticipated cost of manufacturing them or prevent us from implementing research projects at high efficiency levels.

### ***Our products and services are subject to the risks associated with new and rapidly evolving technologies.***

Our proprietary tissue creation technology, drug discovery and research tools are subject to the risks associated with new, rapidly evolving technologies. In addition, the process of developing new technologies and products is complex, and if we are unable to develop enhancements to, and new features for, our existing products or acceptable new products that keep pace with technological developments or industry standards, our products may become obsolete, less marketable and less competitive.

### ***The commercialization of therapeutic or other life science products developed using our research tools is subject to a variety of risks.***

Development of therapeutic and other life science products based on our or our collaborators' use of our technologies will be subject to risks of failure inherent in their development or commercial viability. These risks include the possibility that any such products will:

fail to be found through the use of research tools;

be found to be toxic;

be found to be ineffective;

fail to receive necessary regulatory approvals;

be difficult or impossible to manufacture on a large scale;

be economically infeasible to market;



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**Table of Contents**

fail to be developed prior to the successful marketing of similar products by competitors; or

be impossible to market because they infringe the proprietary rights of third parties or compete with superior products marketed by third parties.

We expect that our drug discovery collaborative partners or other clients that utilize our research tools will be required to submit their research for regulatory review in order to proceed with human testing of drug candidates. This review by the FDA and other regulatory agencies may result in timeline setbacks or complete rejection of an application to begin human studies, such as an Investigative New Drug (IND) application. Should our collaborative partners or other clients face such setbacks, we would be at risk of not being paid if there were agreed upon milestone and royalty payments. The risks of non-approval for our partners or other clients will include the inherent risks of unfavorable regulator opinion of a drug candidate's safety or efficacy, as well as the risk that the data generated by our platform technology is not found to be suitable to support the safety or efficacy of the drug. In addition, our platform technology is subject to the requirements of Good Laboratory Practice (GLP) to provide suitable data for INDs and other regulatory filings; no regulatory review of data from this platform has yet been conducted and there is no guarantee that our technology will be acceptable under GLP.

***If we are unable to enter into or maintain strategic collaborations with third parties, we may have difficulty selling our research tools and therapeutic products and we may not generate sufficient revenue to achieve or maintain profitability.***

Since we do not currently possess the resources necessary to develop, obtain approvals for or commercialize potential therapeutic products based on our technology, we must enter into collaborative arrangements to develop and commercialize these products. If we are not able to enter into these arrangements or implement our strategy to develop and commercialize therapeutic and other life science products based upon our research tools, we may not generate sufficient revenues to achieve or maintain profitability. Additionally, we may not be able to negotiate future collaborative arrangements on acceptable terms, if at all.

***We cannot control our collaborators' allocation of resources or the amount of time that our collaborators devote to developing our programs or potential products, which may have a material adverse effect on our business.***

Our agreements with our collaborators typically allow them significant discretion in electing whether to pursue product development, regulatory approval, manufacturing and marketing of the products they may develop with the help of our technology. We cannot control the amount and timing of resources our collaborators may devote to our programs or potential products. As a result, we cannot be certain that our collaborators will choose to develop and commercialize these products or that we will realize any milestone payments, royalties and other payments to which we may become entitled. In addition, if a partner is involved in a business combination, such as a merger or acquisition, or if a partner changes its business focus, its performance pursuant to its agreement with us may suffer and, as a result, we may not generate any revenues from royalty, milestone and similar provisions that may be included in our collaborative agreement with that partner.

***Any termination or breach by or conflict with our collaborators or licensees could harm our business.***

If we or any of our collaborators or licensees fail to renew or terminate any of our collaboration or license agreements or if either party fails to satisfy its obligations under any of our collaboration or license agreements or complete them in a timely manner, we could lose significant sources of revenue, which could result in volatility in our future revenue.

In addition, our agreements with our collaborators and licensees may have provisions that give rise to disputes regarding the rights and obligations of the parties. These and other possible disagreements could lead to termination of the agreement or delays in collaborative research, development, supply or commercialization of certain products, or could require or result in litigation or arbitration. Moreover, disagreements could arise with

## **Table of Contents**

our collaborators over rights to our intellectual property or our rights to share in any of the future revenues of products developed by our collaborators. These kinds of disagreements could result in costly and time-consuming litigation. Any such conflicts with our collaborators could reduce our ability to obtain future collaboration agreements and could have a negative impact on our relationship with existing collaborators, adversely affecting our business and revenues. Finally, any of our collaborations or license agreements may prove to be unsuccessful.

***Our collaborators could develop competing research, reducing the available pool of potential collaborators and increasing competition, which may adversely affect our business and revenues.***

Our collaborators and potential collaborators could develop research tools similar to our own, reducing our pool of possible collaborative parties and increasing competition. Any of these developments could harm our product and technology development efforts, which could seriously harm our business. In addition, we may pursue opportunities in fields that could conflict with those of our collaborators. Developing products that compete with our collaborators or potential collaborators products could preclude us from entering into future collaborations with our collaborators or potential collaborators. Any of these developments could harm our product development efforts and could adversely affect our business and revenues.

***If restrictions on reimbursements and health care reform limit our collaborators actual or potential financial returns on therapeutic products that they develop based on our platform technology, our collaborators may reduce or terminate their collaborations with us.***

Our collaborators abilities to commercialize therapeutic and other life science products that are developed through the research tools or services that we provide may depend in part on the extent to which coverage and adequate payments for these products will be available from government payors, such as Medicare and Medicaid, private health insurers, including managed care organizations, and other third-party payors. These payors are increasingly challenging the price of medical products and services. Significant uncertainty exists as to the reimbursement status of newly approved therapeutic and other life science products, and coverage and adequate payments may not be available for these products.

In recent years, officials have made numerous proposals to change the health care system in the U.S. These proposals included measures to limit or eliminate payments for some medical procedures and treatments or subject the pricing of pharmaceuticals and other medical products to government control. Government and other third-party payors increasingly attempt to contain health care costs by limiting both coverage and the level of payments of newly approved health care products. In some cases, they may also refuse to provide any coverage of uses of approved products for disease indications other than those for which the FDA has granted marketing approval. Governments may adopt future legislative proposals and federal, state or private payors for healthcare goods and services may take action to limit their payments for goods and services. Any of these events could limit our ability to form collaborations or collaborators and our ability to commercialize therapeutic products successfully.

***We and our collaborators are subject to extensive and uncertain regulatory requirements, which could adversely affect our ability to obtain regulatory approval in a timely manner, or at all, for products that we identify or develop.***

Therapeutic and other life science products are subject to an extensive, lengthy and uncertain regulatory approval process by the Food and Drug Administration (FDA) and comparable agencies in other countries. The regulation of new products is extensive, and the required process of laboratory testing and human studies is lengthy and expensive. The burden of these regulations will fall on our collaborating partners, or may be shared with us, to the extent that we are developing proprietary products that are the result of a collaboration effort. The burden of these regulations will fall on us to the extent we are developing proprietary products on our own. We may not be able to obtain FDA approvals for those products in a timely manner, or at all. We may encounter significant



## **Table of Contents**

delays or excessive costs in our efforts to secure necessary approvals or licenses. Even if we obtain FDA regulatory approvals, the FDA extensively regulates manufacturing, labeling, distributing, marketing, promotion and advertising after product approval. Moreover, several of our product development areas may involve relatively new technology and have not been the subject of extensive product testing in humans. The regulatory requirements governing these products and related clinical procedures remain uncertain and the products themselves may be subject to substantial review by foreign governmental regulatory authorities that could prevent or delay approval in those countries. Regulatory requirements ultimately imposed on our products could limit our ability to test, manufacture and, ultimately, commercialize our products and thereby could adversely affect our financial condition and results of operations.

### ***Our business depends upon the success of our research tools as alternatives to current research tools.***

Our success depends on commercial acceptance of our research tools. We believe that adoption of our research tools by our current and future collaborators will be essential for commercial acceptance of our research tools. We cannot assure you that our research tools will be adopted, or if adopted, that they will be broadly accepted by pharmaceutical, biotechnology and diagnostic companies or various academic institutions.

We believe that recommendations by health care professionals and health care payors will be essential for commercial acceptance of our collaborators or our products. We cannot assure you that the products we or our collaborators develop will achieve commercial acceptance among patients, physicians or third-party payors. Our inability to achieve commercial acceptance would materially adversely affect our business, financial condition and results of operations.

### ***We face intense competition which could result in reduced acceptance and demand for our research tools and products.***

The biotechnology industry is subject to intense competition and rapid and significant technological change. We have many potential competitors, including major drug companies, specialized biotechnology firms, academic institutions, government agencies and private and public research institutions. Many of these competitors have significantly greater financial and technical resources, experience and expertise in research and development, preclinical testing, designing and implementing clinical trials; regulatory processes and approvals; production and manufacturing; and sales and marketing of approved products than we have experienced to date. Principal competitive factors in our industry include the quality and breadth of technology; management and the execution of strategy; skill and experience of employees, ability to recruit and retain skilled, experienced employees; intellectual property portfolio; the range of capabilities, including target identification, validation, drug and device discovery, development, manufacturing, marketing; and the availability of substantial capital resources to fund discovery, development and commercialization activities.

Large and established companies compete in the biotech market. In particular, these companies have greater experience and expertise than we have in securing government contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale and marketing approved products than we have currently.

Smaller or early-stage companies and research institutions may also prove to be significant competitors, particularly through collaborative arrangements with large and established biotech or other companies, or the obtaining of substantial private financing. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel.

In order to effectively compete, we will have to make substantial investments in development, testing, manufacturing and sales and marketing or partner with one or more established companies. There is no assurance that we or our collaborators will be successful in commercializing and gaining significant market share for any products developed in part through use of our technology. Our technologies, products and services also may be rendered obsolete or noncompetitive as a result of products and services introduced by our competitors.

## **Table of Contents**

### ***We may have product liability exposure from the sale of our research tools and therapeutic products or the services we provide.***

We may have exposure to claims for product liability. Product liability coverage is expensive and sometimes difficult to obtain. Given our operations to date, we currently do not maintain any product liability insurance coverage. At such point that we determine it is prudent to obtain this insurance, we may not be able to obtain or maintain insurance at a reasonable cost. There can be no assurance that existing insurance coverage will extend to other products in the future. Any product liability insurance coverage may not be sufficient to satisfy all liabilities resulting from product liability claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable items, if at all. Even if a claim is not successful, defending such a claim would be time-consuming and expensive, may damage our reputation in the marketplace, and would likely divert management's attention.

### ***The near and long-term viability of our products and services will depend on our ability to successfully establish strategic relationships.***

The near and long-term viability of our products and services will depend in part on our ability to successfully establish new strategic collaborations with biotechnology companies, pharmaceutical companies, universities, hospitals, insurance companies and government agencies. Establishing strategic collaborations is difficult and time-consuming. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position. If we fail to establish a sufficient number of collaborations on acceptable terms, we may not be able to commercialize our products or generate sufficient revenue to fund further research and development efforts.

Even if we establish new collaborations, these relationships may never result in the successful development or commercialization of any product or service candidates for several reasons both within and outside of our control.

Although our current focus is on providing drug discovery services and research tools in the research setting, we may develop tissue therapeutic products and seek approval to sell them as medical care. Before we could begin commercial manufacturing of any of our product candidates, we or our manufacturers must pass a pre-approval inspection by the FDA and comply with the FDA's current Good Manufacturing Practices. If our manufacturers fail to comply with these requirements, our product candidates would not be approved. If our collaborators fail to comply with these requirements after approval, we would be subject to possible regulatory action and may be limited in the jurisdictions in which we are permitted to sell products.

### ***We will be dependent on third-party research organizations to conduct some of our future laboratory testing, animal and human studies.***

We will be dependent on third-party research organizations to conduct some of our laboratory testing, animal and human studies with respect to therapeutic tissues and other life science products that we may develop in the future. If we are unable to obtain any necessary testing services on acceptable terms, we may not complete our product development efforts in a timely manner. If we rely on third parties for laboratory testing and/or animal and human studies, we may lose some control over these activities and become too dependent upon these parties. These third parties may not complete testing activities on schedule or when we so request. We may not be able to secure and maintain suitable research organizations to conduct our laboratory testing and/or animal and human studies. We are responsible for confirming that each of our clinical trials is conducted in accordance with our general plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. If these third parties do not successfully carry out their contractual duties or

## **Table of Contents**

regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our future product candidates.

### ***We may require access to a constant, steady, reliable supply of products.***

To the extent that we develop products for sale, we may be required to complete clinical trials before we can offer such products for sale. Commercialization of products will require access to, or development of, facilities to manufacture a sufficient supply of our product candidates. If we are unable to manufacture our products in commercial quantities, then we will need to rely on third parties. These third-party manufacturers must also receive FDA approval before they can produce clinical material or commercial products. Our products may be in competition with other products for access to these facilities and may be subject to delays in manufacture if third parties give other products greater priority. In addition, we may not be able to enter into any necessary third-party manufacturing arrangements on acceptable terms, or on a timely basis. Furthermore, we would likely have to enter into a technical transfer agreement and share our know-how with the third party manufacture.

### ***We may rely on third-party suppliers for some our materials.***

We may rely on third-party suppliers and vendors for some of the materials we require in our drug discovery and research tool businesses as well as for the manufacture of any product candidates that we may develop in the future. Any significant problem experienced by one of our suppliers could result in a delay or interruption in the supply of materials to us until such supplier resolves the problem or an alternative source of supply is located. Any delay or interruption could negatively affect our operations.

### ***Violation of government regulations or quality programs could harm demand for our products or services, and the evolving nature of government regulations could have an adverse impact on our business.***

To the extent that our collaborators or customers use our products in the manufacturing or testing processes for their drug and medical device products, such end-products or services may be regulated by the FDA under Quality System Regulations (QSR) or the Centers for Medicare & Medicaid Services (CMS) under Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) regulations. The customer is ultimately responsible for QSR, CLIA '88 and other compliance requirements for their products; however, we may agree to comply with certain requirements, and, if we fail to do so, we could lose sales and customers and be exposed to product liability claims.

Products that are intended for the diagnosis or treatment of disease are subject to government regulation. Our drug discovery and research tool offerings are currently intended for research or investigational uses. Research uses are not subject to FDA or premarket approval or other regulatory requirements. Investigational uses are not subject to FDA premarket approval or most regulatory requirements, but are subject to limited regulatory controls for entities conducting investigational studies.

As we continue to adapt and develop parts of our product line in the future, including tissue-based products in the field of regenerative medicine, the manufacture and marketing of our products will become subject to government regulation in the United States and other countries. In the United States and most foreign countries, we will be required to complete rigorous preclinical testing and extensive human clinical trials that demonstrate the safety and efficacy of a product in order to apply for regulatory approval to market the product.

The steps required by the FDA before our proposed products may be marketed in the United States include performance of preclinical (animal and laboratory) tests; submissions to the FDA of an IDE (Investigational Device Exemption), NDA (New Drug Application), or BLA (Biologic License Application) which must become

## **Table of Contents**

effective before human clinical trials may commence; performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product in the intended target population; performance of a consistent and reproducible manufacturing process intended for commercial use; Pre-Market Approval Application (PMA); and FDA approval of the PMA before any commercial sale or shipment of the product.

The processes are expensive and can take many years to complete, and we may not be able to demonstrate the safety and efficacy of our products to the satisfaction of such regulatory authorities. The start of clinical trials can be delayed or take longer than anticipated for many and varied reasons, many of which are outside of our control. Safety concerns may emerge that could lengthen the ongoing trials or require additional trials to be conducted. Regulatory authorities may also require additional testing, and we may be required to demonstrate that our proposed products represent an improved form of treatment over existing therapies, which we may be unable to do without conducting further clinical studies. Moreover, if the FDA grants regulatory approval of a product, the approval may be limited to specific indications or limited with respect to our distribution. Expanded or additional indications for approved devices or drugs may not be approved, which could limit our revenues. Foreign regulatory authorities may apply similar limitations or may refuse to grant any approval. Consequently, even if we believe that preclinical and clinical data are sufficient to support regulatory approval for our product candidates, the FDA and foreign regulatory authorities may not ultimately grant approval for commercial sale in any jurisdiction. If our products are not approved, our ability to generate revenues will be limited and our business will be adversely affected.

Even if a product gains regulatory approval, such approval is likely to limit the indicated uses for which it may be marketed, and the product and the manufacturer of the product will be subject to continuing regulatory review, including adverse event reporting requirements and the FDA's general prohibition against promoting products for unapproved uses. Failure to comply with any post-approval requirements can, among other things, result in warning letters, product seizures, recalls, substantial fines, injunctions, suspensions or revocations of marketing licenses, operating restrictions and criminal prosecutions. Any of these enforcement actions, any unanticipated changes in existing regulatory requirements or the adoption of new requirements, or any safety issues that arise with any approved products, could adversely affect our ability to market products and generate revenues and thus adversely affect our ability to continue our business.

We also may be restricted or prohibited from marketing or manufacturing a product, even after obtaining product approval, if previously unknown problems with the product or our manufacture are subsequently discovered and we cannot provide assurance that newly discovered or developed safety issues will not arise following any regulatory approval. With the use of any treatment by a wide patient population, serious adverse events may occur from time to time that initially do not appear to relate to the treatment itself, and only if the specific event occurs with some regularity over a period of time does the treatment become suspect as having a causal relationship to the adverse event. Any safety issues could cause us to suspend or cease marketing of our approved products, possibly subject us to substantial liabilities, and adversely affect our ability to generate revenues.

### ***We are subject to various environmental, health and safety laws.***

We are subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, emissions and wastewater discharges, and the use and disposal of hazardous or potentially hazardous substances used in connection with our research, including infectious disease agents. We also cannot accurately predict the extent of regulations that might result from any future legislative or administrative action. Any of these laws or regulations could cause us to incur additional expense or restrict our operations. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts.

## **Table of Contents**

***We will depend on our patent portfolio, our licensed technology and other trade secrets in the conduct of our business and must ensure that we do not violate the patent or intellectual rights of others.***

Our success in large part depends on our ability to maintain the proprietary nature of our technology and other trade secrets. To do so, we and our licensors must prosecute and maintain existing patents, obtain new patents and pursue trade secret and other intellectual property protection. We also must operate without infringing the proprietary rights of third parties or allowing third parties to infringe our rights. Our research, development and commercialization activities, including any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents owned by third parties and as to which we do not hold licenses or other rights. There may be rights that we are not aware of, including applications that have been filed but not published that, when issued, could be asserted against us. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or biologic treatment candidate that is the subject of the suit.

In addition, competitors may infringe our patents or the patents of our collaborators or licensors. As a result, we may be required to file infringement claims to counter infringement for unauthorized use. This can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent owned by us is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover our technology. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at the risk of not issuing.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

***A significant portion of our sales are dependent upon our customers' capital spending policies and research and development budgets, and government funding of research and development programs at universities and other organizations, which are each subject to significant and unexpected decrease.***

Our prospective customers include pharmaceutical and biotechnology companies, academic institutions, government laboratories, and private research foundations. Fluctuations in the research and development budgets at these organizations could have a significant effect on the demand for our products and services. Research and development budgets fluctuate due to changes in available resources, patent expirations, mergers of pharmaceutical and biotechnology companies, spending priorities, general economic conditions, and institutional and governmental budgetary policies, including but not limited to reductions in grants for research by educational institutions. In addition, our business could be seriously damaged by any significant decrease in life sciences research and development expenditures by pharmaceutical and biotechnology companies, academic institutions, government laboratories, or private foundations.

The timing and amount of revenues from customers that rely on government funding of research may vary significantly due to factors that can be difficult to forecast. Research funding for life science research has increased more slowly during the past several years compared to the previous years and has declined in some countries, and some grants have been frozen for extended periods of time or otherwise become unavailable to various institutions, sometimes without advance notice. Government funding of research and development is subject to the political process, which is inherently fluid and unpredictable. Other programs, such as homeland security or defense, or general efforts to reduce the federal budget deficit could be viewed by the United States government as a higher priority. These budgetary pressures may result in reduced allocations to government agencies that fund research and development activities. Past proposals to reduce budget deficits have included reduced National Institute of Health and other research and development allocations. Any shift away from the funding of life sciences research and development or delays surrounding the approval of government budget proposals may cause our customers to delay or forego purchases of our products or services, which could seriously damage our business.

## **Table of Contents**

### **Risks Related to Our Common Stock and Liquidity Risks**

#### ***Our securities are a Penny Stock and subject to specific rules governing their sale to investors***

The SEC has adopted Rule 15c-9 which establishes the definition of a penny stock, for the purposes relevant to our common stock, as any equity security that has a market price of less than \$5.00 per share or with an exercise price of less than \$5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require that a broker or dealer approve a person's account for transactions in penny stocks; and the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must obtain financial information, investment experience and objectives of the person; and make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which, in highlight form sets forth the basis on which the broker or dealer made the suitability determination; and that the broker or dealer received a signed, written agreement from the investor prior to the transaction. Generally, brokers may be less willing to execute transactions in securities subject to the penny stock rules. This may make it more difficult for investors sell shares of our common stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

#### ***The Company has a limited trading history and there is no assurance that an active market in the Company's common stock will continue at present levels or increase in the future.***

There is limited trading activity in our common stock and there is no assurance that an active market will develop in the future. Although our common stock is currently quoted on the OTCQX, the Company has a limited trading history and there is no assurance that an active market in the Company's common stock will continue at present levels or increase in the future. As a result, an investor may find it difficult to dispose of our common stock. There can be no assurance that a more active market for our common stock will develop in the future, or if one should develop, there is no assurance that it will be sustained. This factor limits the liquidity of our common stock, and may have a material adverse effect on the market price of our common stock and on our ability to raise additional capital.

#### ***Compliance with the reporting requirements of federal securities laws can be expensive.***

We are a public reporting company in the United States, and accordingly, subject to the information and reporting requirements of the Exchange Act and other federal securities laws, and the compliance obligations of the Sarbanes-Oxley Act. The costs of preparing and filing annual and quarterly reports and other information with the SEC and furnishing audited reports to stockholders are substantial. In addition, we will incur substantial expenses in connection with the preparation of the Registration Statement and related documents with respect to the registration of resales of the common stock underlying the Original Warrants.

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## **Table of Contents**

***Applicable regulatory requirements, including those contained in and issued under the Sarbanes-Oxley Act of 2002, may make it difficult for us to retain or attract qualified officers and directors, which could adversely affect the management of its business and its ability to obtain or retain listing of our common stock.***

We may be unable to attract and retain those qualified officers, directors and members of board committees required to provide for effective management because of the rules and regulations that govern publicly held companies, including, but not limited to, certifications by principal executive officers. The enactment of the Sarbanes-Oxley Act has resulted in the issuance of a series of related rules and regulations and the strengthening of existing rules and regulations by the SEC, as well as the adoption of new and more stringent rules by the stock exchanges. The perceived increased personal risk associated with these changes may deter qualified individuals from accepting roles as directors and executive officers.

Further, some of these changes heighten the requirements for board or committee membership, particularly with respect to an individual's independence from the corporation and level of experience in finance and accounting matters. We may have difficulty attracting and retaining directors with the requisite qualifications. If we are unable to attract and retain qualified officers and directors, the management of our business and our ability to obtain or retain listing of our shares of common stock on any stock exchange (assuming we elect to seek and are successful in obtaining such listing) could be adversely affected.

***We may have undisclosed liabilities and any such liabilities could harm our revenues, business, prospects, financial condition and results of operations.***

Even though our pre-merger assets and liabilities were transferred to the Split-Off Shareholders in the Split-Off, there can be no assurance that we will not be liable for any or all of such liabilities. Any such liabilities that survived the Merger could harm our revenues, business, prospects, financial condition and results of operations upon our acceptance of responsibility for such liabilities. The transfer of the operating assets and liabilities to PSOS, coupled with the Split-Off of PSOS, will result in taxable income to us in an amount equal to the difference between the fair market value of the assets transferred and the pre-merger tax basis of the assets. Any gain recognized, to the extent not offset by our net operating loss carryforward, if any, will be subject to federal income tax at regular corporate income tax rates.

***If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or detect fraud. Consequently, investors could lose confidence in our financial reporting and this may decrease the trading price of our stock.***

We must maintain effective internal controls to provide reliable financial reports and detect fraud. We have been assessing our internal controls to identify areas that need improvement. We are in the process of implementing changes to internal controls, but have not yet completed implementing these changes. Failure to implement these changes to our internal controls or any others that it identifies as necessary to maintain an effective system of internal controls could harm our operating results and cause investors to lose confidence in our reported financial information. Any such loss of confidence would have a negative effect on the trading price of our stock.

***The price of our common stock may become volatile, which could lead to losses by investors and costly securities litigation.***

The trading price of our common stock is likely to be highly volatile and could fluctuate in response to factors such as:

actual or anticipated variations in our operating results;

announcements of developments by us or our competitors;

the timing of IDE and/or NDA approval, the completion and/or results of our clinical trials

regulatory actions regarding our products

**Table of Contents**

announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

adoption of new accounting standards affecting the our industry;

additions or departures of key personnel;

introduction of new products by us or our competitors;

sales of the our common stock or other securities in the open market; and

other events or factors, many of which are beyond our control.

The stock market is subject to significant price and volume fluctuations. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been initiated against such a company. Litigation initiated against us, whether or not successful, could result in substantial costs and diversion of our management's attention and resources, which could harm our business and financial condition.

***Investors may experience dilution of their ownership interests because of the future issuance of additional shares of our common stock.***

In the future, we may issue additional authorized but previously unissued equity securities, resulting in the dilution of the ownership interests of our present stockholders. We may also issue additional shares of our common stock or other securities that are convertible into or exercisable for our common stock in connection with hiring or retaining employees, future acquisitions, future sales of our securities for capital raising purposes, or for other business purposes. The future issuance of any such additional shares of common stock may create downward pressure on the trading price of our common stock. There can be no assurance that the we will not be required to issue additional shares, warrants or other convertible securities in the future in conjunction with any capital raising efforts, including at a price (or exercise prices) below the price at which shares of our common stock is currently quoted on the OTCQX.

***Our common stock is controlled by insiders***

Our executive officers and directors beneficially own approximately 16% of our outstanding shares of common stock, and Dr. Gabor Forgacs, the father of one of our directors, beneficially owns another 9.7% of our outstanding shares of common stock. Although we are not aware of any voting arrangements between our officers, directors and Dr. Forgacs, such concentrated control may adversely affect the price of our common stock. Investors who acquire our common stock may have no effective voice in the management of our operations. Sales by our insiders or affiliates, along with any other market transactions, could affect the market price of our common stock.

***We do not intend to pay dividends for the foreseeable future.***

We have paid no dividends on our common stock to date and it is not anticipated that any dividends will be paid to holders of our common stock in the foreseeable future. While our future dividend policy will be based on the operating results and capital needs of our business, it is currently anticipated that any earnings will be retained to finance our future expansion and for the implementation of our business plan. As an investor, you should take note of the fact that a lack of a dividend can further affect the market value of our stock, and could significantly affect the value of any investment.



**Table of Contents**

*Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.*

Our certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions:

authorize the issuance of preferred stock which can be created and issued by the board of directors without prior stockholder approval, with rights senior to those of the common stock;

provide for a classified board of directors, with each director serving a staggered three-year term;

prohibit our stockholders from filling board vacancies, calling special stockholder meetings, or taking action by written consent; and

require advance written notice of stockholder proposals and director nominations.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our certificate of incorporation, bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer, or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

**Table of Contents**

**USE OF PROCEEDS**

We will not receive any proceeds from the sale of shares of our common stock by the selling security holders. A portion of the shares covered by this prospectus are issuable upon exercise of warrants to purchase our common stock. Upon any exercise of the warrants for cash, the selling security holders would pay us the exercise price of the warrants. Under certain conditions set forth in the warrants, the warrants are exercisable on a cashless basis. If the warrants are exercised on a cashless basis, we would not receive any cash payment from the selling security holders upon any exercise of the warrants. Instead, the selling security holders would satisfy their obligation to pay the exercise price through a formula-based transfer of warrant shares to us. The additional proceeds we could receive from the exercise of such warrants have not yet been earmarked for any specific use beyond working capital needs because there is no certainty that we will ever receive any proceeds from the exercise of such warrants.

The selling security holders will pay any underwriting discounts and commissions and expenses incurred by the selling security holders for brokerage, accounting, tax or legal services or any other expenses incurred by the selling security holders in disposing of the shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees and fees and expenses of our counsel and our accountants.

**Table of Contents**

**SELLING SECURITY HOLDERS**

We are registering the following shares of common stock:

up to 15,347,987 shares of our common stock which were issued in our private placement (the Offering ) of units consisting of (i) one share of our common stock and (ii) one warrant to purchase one share of our common stock at an exercise price of \$1.00 per share (the Units ), with closings of the Offering occurring on each of February 8, 2012 (the Initial Closing ), February 29, 2012 and March 16, 2012 and shares of common stock issued to certain of the selling security holders on the date of the Initial Closing of the Offering in connection with the conversion of our \$1,500,000 in principal amount of 6% convertible promissory notes due March 31, 2012 (the Bridge Notes ) into 1,525,387 Units and 100,000 shares of common stock issued to a consultant;

up to 15,247,987 shares of our common stock issuable upon the exercise of warrants issued to the selling security holders in our Offering of Units (excluding warrants issued to our placement agents in the Offering) and shares of common stock issuable upon the exercise of warrants issued to certain of the selling security holders on the date of the Initial Closing of the Offering in connection with the conversion of the Bridge Notes into 1,525,387 Units; and

up to 1,500,000 shares of our common stock issuable upon the exercise of warrants issued to certain selling security holders in connection with the original issuance of our Bridge Notes that were converted into 1,500,000 new warrants on the date of the Initial Closing, each exercisable at a price of \$1.00 per share of our common stock.

The selling security holders may sell some, all or none of their shares. We do not know how long the selling security holders will hold the shares offered hereunder before selling them. We currently have no agreements, arrangements or understandings with the selling security holders regarding the sale of any of the shares by them other than the registration rights agreements referenced below in Description of Securities. The shares offered by this prospectus may be offered from time to time by the selling security holders. As used in this prospectus, the term selling security holder includes each of the selling security holders listed below, and any donee, pledgee, transferee or other successor in interest selling shares received after the date of this prospectus from a selling security holder as a gift, pledge, or other non-sale related transfer. The selling security holders may have sold or transferred, in transactions exempt from the registration requirements of the Securities Act, some or all of their shares since the date on which the information in the table is presented. Information about the selling security holders may change over time.

The following table sets forth the name of each selling security holder, the number of shares owned by such selling security holder as of March 25, 2013, the number of shares that may be offered under this prospectus by such selling security holder, and the number of shares of our common stock and the percentage (if one percent or more) of our common stock to be owned by such selling security holder after completion of this offering, assuming that all shares offered hereunder are sold as contemplated herein. The number of shares in the column Shares of Common Stock Being Offered represents all of the shares that a selling security holder may offer under this prospectus, which includes the shares issuable upon exercise of the warrants covered by this prospectus. Except as otherwise disclosed in this prospectus (or as disclosed in any document incorporated by reference) including information incorporated, none of the selling security holders has, or within the past three years has had, any position, office or other material relationship with us. The selling security holders have advised us that they may enter into short sales in the ordinary course of their business of investing and trading securities. The selling security holders participating in the Offering have also advised us that no short sales in our securities were entered into by them during the period beginning when the selling security holders obtained knowledge that we were contemplating a private placement and ending upon the public announcement of the Offering. Other than the costs of preparing and providing this prospectus and a registration fee to the SEC, we are not paying any costs relating to the sales by the selling security holders.

**Table of Contents**

Ownership reflected in this table for each selling security holder is based upon information provided to us by the selling security holder and reflects holdings as of March 25, 2013. The percentages of common stock owned after the Offering are based on 64,646,665 shares of our common stock outstanding as of March 25, 2013. Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Exchange Act. In computing the number of shares owned by and the percentage ownership of a selling security holder, shares of common stock that could be issued upon the exercise of outstanding options, warrants or other rights held by that selling security holder that are currently exercisable or exercisable within 60 days of March 25, 2013 are considered outstanding. However, such shares are not included in the shares outstanding as of March 25, 2013 when computing the percentage ownership of each other selling security holder.

Unless otherwise noted, each person or group identified possesses sole voting and investment power with respect to the shares, subject to community property laws where applicable.

<b>Selling Security Holder</b>	<b>Outstanding Shares of Common Stock</b>	<b>Shares of Common Stock Subject to Warrants</b>	<b>Total Shares of Common Stock Beneficially Owned</b>	<b>Shares of Common Stock Being Offered in the Offering (1)</b>	<b>Common Stock Beneficially Owned After Offering (1)</b>	<b>Percent After Offering</b>
Aaron Lehmann	15,000	15,000	30,000	30,000		*
ABBA Properties Partnership	70,000	70,000	140,000	140,000		*
ACP Partners Fund, LP	125,000	125,000	250,000	250,000		*
ACP X, L.P.	900,000	900,000	1,800,000	1,800,000		*
Allan Rothstein	25,000	25,000	50,000	50,000		*
Andrew Fisher	50,000	50,000	100,000	100,000		*
Andrew H. Kaufman	25,000	25,000	50,000	50,000		*
Ann S. Totten	25,000	25,000	50,000	50,000		*
Arun Virick	5,000	5,000	10,000	10,000		*
Aspire Capital Fund, LLC	250,000	250,000	500,000	500,000		*
Aubrey W. Gladstone & Marianne R. Gladstone	50,000	50,000	100,000	100,000		*
Banque de Luxembourg Client Account	100,000	100,000	200,000	200,000		*
Barbara S. Dickler Trust	50,000	50,000	100,000	100,000		*
Barry Michaels	10,000	10,000	20,000	20,000		*
Bob Baltera	25,000	25,000	50,000	50,000		*
Bradley Resources Company	65,225	80,225	145,450	145,450		*
Bret Shupack	50,000	50,000	100,000	100,000		*
Brian & Debbie Keller	17,000	17,000	34,000	34,000		*
Brian Bauer	25,000	25,000	50,000	50,000		*
Brian Joseph Murphy	25,000	25,000	50,000	50,000		*
Brooks & Carmen McCartney JTWROS	50,000	50,000	100,000	100,000		*
Bruce Levenbrook	10,000	10,000	20,000	20,000		*

**Table of Contents**

<b>Selling Security Holder</b>	<b>Outstanding Shares of Common Stock</b>	<b>Shares of Common Stock Subject to Warrants</b>	<b>Total Shares of Common Stock Beneficially Owned</b>	<b>Shares of Common Stock Being Offered in the Offering (1)</b>	<b>Common Stock Beneficially Owned After Offering (1)</b>	<b>Percent After Offering</b>
Byron C. Hughey	12,500	12,500	25,000	25,000		*
Chenies Investor LLC	20,000	20,000	40,000	40,000		*
Christine Hassuk	15,000	15,000	30,000	30,000		*
Christopher J. Blum & Denise M. Blum JTWROS	30,000	30,000	60,000	60,000		*
Christopher Travelle	25,000	25,000	50,000	50,000		*
Cinema City Inc.	152,826	302,826	455,652	455,652		*
Constance Hoidas	10,000	10,000	20,000	20,000		*
CRL Management LLC	150,000	150,000	300,000	300,000		*
Cynergy Emerging Growth LLC	101,500	201,500	303,000	303,000		*
Daniel W. Armstrong	100,000	100,000	200,000	200,000		*
Daniel W. Hummell & Allaire D. Hummell JTWROS	50,000	50,000	100,000	100,000		*
David & Lillian Barry	15,000	15,000	30,000	30,000		*
David G. Rosen and Julie L. Rosen JTWROS	25,000	25,000	50,000	50,000		*
David Hochman	12,688	25,188	37,876	37,876		*
David Kovacs	75,000	75,000	150,000	150,000		*
Dawn E. Gunter	25,000	25,000	50,000	50,000		*
DCG&T Cust FBO John Dempsey IRA	25,000	25,000	50,000	50,000		*
DCG&T William C. Stone SEP IRA	20,000	20,000	40,000	40,000		*
Deepak H. Aggarwal	10,000	10,000	20,000	20,000		*
Delaware Charter Guarantee & Tr FBO Daniel K. Ho IRA	50,000	50,000	100,000	100,000		*
Delaware Charter Guarantee & Tr FBO Raymond Coppede RO IRA	75,000	75,000	150,000	150,000		*
Delaware Charter Guarantee & Trust Co FBO Bill L. Boad IRA	35,000	35,000	70,000	70,000		*
Delaware Charter Guarantee & Trust Cust FBO Graham C. Short IRA	73,000	73,000	146,000	146,000		*

**Table of Contents**

<b>Selling Security Holder</b>	<b>Outstanding Shares of Common Stock</b>	<b>Shares of Common Stock Subject to Warrants</b>	<b>Total Shares of Common Stock Beneficially Owned</b>	<b>Shares of Common Stock Being Offered in the Offering (1)</b>	<b>Common Stock Beneficially Owned After Offering (1)</b>	<b>Percent After Offering</b>
Delaware Charter Guarantee & Trust Cust FBO Philip J. Benz IRA	22,500	22,500	45,000	45,000		*
Derek J. Sroufe	50,834	100,834	151,668	151,668		*
DIT Equity Holdings, LLC	501,667	601,667	1,103,334	1,103,334		*
Douglas Jay Cohen	100,000	100,000	200,000	200,000		*
Douglas P. Kaufman	25,000	25,000	50,000	50,000		*
ECPC Capital LLC	20,000	20,000	40,000	40,000		*
Edward M. Dunn	100,000	100,000	200,000	200,000		*
Edward N. and Carol Scott Robinson Revocable Trust April 6, 2005	50,750	100,750	151,500	151,500		*
Edward Rosenthal	50,834	100,834	151,668	151,668		*
Elisabeth Stephens	25,417	50,417	75,834	75,834		*
Eric Del Basso	15,000	15,000	30,000	30,000		*
Fabrizio Balestri	20,334	40,334	60,668	60,668		*
FEQ Realty, LLC	201,667	301,667	503,334	503,334		*
Four Jr. Investments LTD.	200,000	200,000	400,000	400,000		*
Gary H. Weitz	35,000	35,000	70,000	70,000		*
George Karfunkel	200,000	200,000	400,000	400,000		*
Gerald & Lynnette Hannahs JTWROS	100,000	100,000	200,000	200,000		*
Gerry Amato	100,000		100,000	100,000		*
Great American Insurance Company	500,000	500,000	1,000,000	1,000,000		*
Great American Life Insurance Company	1,000,000	1,000,000	2,000,000	2,000,000		*
Greg Waisanen	10,000	10,000	20,000	20,000		*
Harry L. Shufflebarger Revocable Trust	25,000	25,000	50,000	50,000		*
Harvey Schilowitz & Linda Schilowitz JTWROS	15,000	15,000	30,000	30,000		*
Henry Baumgart	10,000	10,000	20,000	20,000		*
Henry Rothman	50,225	65,225	115,450	115,450		*
Howard K. Fuguet	20,000	20,000	40,000	40,000		*

**Table of Contents**

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Hyman Belzberg	87,500	87,500	175,000	175,000		*
Ian Stern	10,000	10,000	20,000	20,000		*
Immotrend Inc.	250,000	250,000	500,000	500,000		*
Irwin Lampert	25,000	25,000	50,000	50,000		*
James Calvin MacKenzie LLC	100,000	100,000	200,000	200,000		*
James Lawler & Ali Rafie	50,000	50,000	100,000	100,000		*
Jason Willis & Amanda Willis	25,000	25,000	50,000	50,000		*
Jay Eisen	12,688	25,188	37,876	37,876		*
Jeff and Pam Littrell	25,000	25,000	50,000	50,000		*
Jeffrey Tarrand	5,000	5,000	10,000	10,000		*
JKW Family LTD	225,000	225,000	450,000	450,000		*
Joanne B. Schubert	15,000	15,000	30,000	30,000		*
Joel Kovacs	15,000	15,000	30,000	30,000		*
John Berding	50,000	50,000	100,000	100,000		*
John C. Boyer	40,000	40,000	80,000	80,000		*
John C. Ramsay	100,000	100,000	200,000	200,000		*
John Campo	50,000	50,000	100,000	100,000		*
John E. Dell	100,000	100,000	200,000	200,000		*
John F. Neary	10,000	10,000	20,000	20,000		*
John Menna	40,000	40,000	80,000	80,000		*
John Smith	10,000	10,000	20,000	20,000		*
John T. Winebrenner Trust	50,000	50,000	100,000	100,000		*
Jonathan Ardrey	10,000	10,000	20,000	20,000		*
Kathleen S. McHugh	20,000	20,000	40,000	40,000		*
Keith Eisenstark & Mary Beth Walsh	10,000	10,000	20,000	20,000		*
Kenneth S. Goodwin	10,000	10,000	20,000	20,000		*
Lamar A. Gwaltney	50,834	100,834	151,668	151,668		*
Lance Siegall	20,000	20,000	40,000	40,000		*
Larry W. Schwartz	30,000	30,000	60,000	60,000		*
Lawrence Grossbard	75,000	75,000	150,000	150,000		*
Lee K. Barba	50,000	50,000	100,000	100,000		*

**Table of Contents**

<b>Selling Security Holder</b>	<b>Outstanding Shares of Common Stock</b>	<b>Shares of Common Stock Subject to Warrants</b>	<b>Total Shares of Common Stock Beneficially Owned</b>	<b>Shares of Common Stock Being Offered in the Offering (1)</b>	<b>Common Stock Beneficially Owned After Offering (1)</b>	<b>Percent After Offering</b>
Lester Petracca	100,000	100,000	200,000	200,000		*
Lewis B. Cullman	100,000	100,000	200,000	200,000		*
Lincoln Trust FBO Thomas C. Stephens IRA	176,667	201,667	378,334	303,334	75,000	*
Lon E. Bell	50,000	50,000	100,000	100,000		*
Loren & Vivian Kramer	25,000	25,000	50,000	50,000		*
Louis A. & Brenda K. Romeo	50,000	50,000	100,000	100,000		*
Mark F. Adams	5,000	5,000	10,000	10,000		*
Mark Volkov	15,000	15,000	30,000	30,000		*
Marvin Boehm Family Trust	25,000	25,000	50,000	50,000		*
Mary Divett	20,700	15,000	35,700	30,000	5,700*	*
Mary L. Marcus-West Declaration of Trust	25,000	25,000	50,000	50,000		*
Michael & Sophie Mannarino	50,000	50,000	100,000	100,000		*
Michael Cohen	50,000	50,000	100,000	100,000		*
Michael J. Garnick	175,000	175,000	350,000	350,000		*
Michael J. Pierce	100,000	100,000	200,000	200,000		*
Michael L. and Ann J. Hetzner	10,000	10,000	20,000	20,000		*
Michael Leiter	70,000	70,000	140,000	140,000		*
Michael Lerner	15,000	15,000	30,000	30,000		*
Michael Stephens	25,375	50,375	75,750	75,750		*
Michael T. Dolen	428,296	603,296	1,031,592	1,031,592		*
Michael Willis	60,000	60,000	120,000	120,000		*
Michael Willis and Sharon Willis JTWROS	220,000	220,000	440,000	440,000		*
Michael Zimmerman	25,000	25,000	50,000	50,000		*
Micro Pipe Fund I, LLC	100,000	100,000	200,000	200,000		*
Mitchell Lampert	40,000	40,000	80,000	80,000		*
Mondas Investments Ltd.	101,500	201,500	303,000	303,000		*
Montague Capital LP	785,000	785,000	1,570,000	1,570,000		*
New Century Holdings LLP	25,000	25,000	50,000	50,000		*
NYPPEX Holdings, LLC 401K Retirement Plan	25,000	25,000	50,000	50,000		*



**Table of Contents**

<b>Selling Security Holder</b>	<b>Outstanding Shares of Common Stock</b>	<b>Shares of Common Stock Subject to Warrants</b>	<b>Total Shares of Common Stock Beneficially Owned</b>	<b>Shares of Common Stock Being Offered in the Offering (1)</b>	<b>Common Stock Beneficially Owned After Offering (1)</b>	<b>Percent After Offering</b>
Paul L. Schumacher	20,600	20,600	41,200	41,200		*
Peter C. Gould	25,000	25,000	50,000	50,000		*
Peter Einstein	20,000	20,000	40,000	40,000		*
Peter P. Parthenis Trust	100,000	100,000	200,000	200,000		*
Peter Sabo	25,000	25,000	50,000	50,000		*
Philip Berman & Ingrid Berman JTWROS	25,000	25,000	50,000	50,000		*
Philip M. Cannella	20,000	20,000	40,000	40,000		*
Pierre Charpie	10,000	10,000	20,000	20,000		*
ProActive Capital Resources Group LLC	25,375	50,375	75,750	75,750		*
QIP Holdings LLC	50,000	50,000	100,000	100,000		*
Ralph L. Pawlick	10,000	10,000	20,000	20,000		*
Ramos Lujan Investment Group Corp.	15,000	15,000	30,000	30,000		*
Raymond James Cust FBO Bruce Ferguson IRA	25,000	25,000	50,000	50,000		*
Raymond Vollintine	400,000	400,000	800,000	800,000		*
RBC Capital Markets Cust FBO Laurence G. Allen IRA	50,000	50,000	100,000	100,000		*
Renald J. & Catherine C. Anelle JTWROS	25,000	25,000	50,000	50,000		*
Richard Lieberman	10,000	10,000	20,000	20,000		*
Richard M Spitalny	5,000	5,000	10,000	10,000		*
Richard Neustadter	200,000	200,000	400,000	400,000		*
Richard Todd Gross	50,000	50,000	100,000	100,000		*
RL Vollintine Construction, Inc.	50,000	50,000	100,000	100,000		*
Robert D. Burke	50,000	50,000	100,000	100,000		*
Robert D. deRose and Susan deRose Family Trust	101,884	201,884	303,768	303,768		*
Robert G. Mulchrone Trust	25,000	25,000	50,000	50,000		*
Robert Harris	10,000	10,000	20,000	20,000		*
Robert L. Montgomery	50,750	100,750	151,500	151,500		*
Robert M. Newsome	250,000	250,000	500,000	500,000		*

**Table of Contents**

<b>Selling Security Holder</b>	<b>Outstanding Shares of Common Stock</b>	<b>Shares of Common Stock Subject to Warrants</b>	<b>Total Shares of Common Stock Beneficially Owned</b>	<b>Shares of Common Stock Being Offered in the Offering (1)</b>	<b>Common Stock Beneficially Owned After Offering (1)</b>	<b>Percent After Offering</b>
Robyn Schreiber Irrevocable Trust, Warren Schreiber TTEE	63,500	63,500	127,000	127,000		*
Ron Eller & Beth Eller JTWROS	15,000	15,000	30,000	30,000		*
Royal Palm Investors, LLC	101,884	201,884	303,768	303,768		*
RRC Bio Fund LP	300,000	300,000	600,000	600,000		*
Ryan Modesto	50,000	50,000	100,000	100,000		*
S. Kent Adams	20,000	20,000	40,000	40,000		*
Samuel Belzberg	100,000	100,000	200,000	200,000		*
San Diego Psychiatric Medical Group Inc. Combination Retirement Trust	25,000	25,000	50,000	50,000		*
Scott Anderson	25,000	25,000	50,000	50,000		*
ST Organovo LLC	310,000	310,000	620,000	620,000		*
Stacy Paros Parthenis	50,000	50,000	100,000	100,000		*
Stan Alex Miroshnik	100,000	100,000	200,000	200,000		*
Stan Noah	20,000	20,000	40,000	40,000		*
Stephen A. de Kanter	20,000	20,000	40,000	40,000		*
Steve M. Payne	200,000	200,000	400,000	400,000		*
Terence Oi	25,000	25,000	50,000	50,000		*
The Carnahan Trust	200,000	200,000	400,000	400,000		*
Thomas G. Wales	33,500	33,500	67,000	67,000		*
Tom Stephens	50,750	100,750	151,500	151,500		*
UHURU Capital LLC	100,000	100,000	200,000	200,000		*
Univest Management Inc. EPSP	50,000	50,000	100,000	100,000		*
Vantage FBO Laurence E Lof Roth IRA	50,000	50,000	100,000	100,000		*
Vekoe Partners, LLC	25,000	25,000	50,000	50,000		*
W. Ron Raecker	20,000	20,000	40,000	40,000		*
Wendy S. Flath Revocable Living Trust July 27, 2010	25,417	50,417	75,834	75,834		*
White Rock Capital Partners, LP	500,000	500,000	1,000,000	1,000,000		*
William Belzberg Revocable Living Trust	87,500	87,500	175,000	175,000		*

**Table of Contents**

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William C. Purdon & Debra B. Purdon JTWROS	25,000	25,000	50,000	50,000		*
William N. Strawbridge	20,000	20,000	40,000	40,000		*
William Nowlin	5,000	5,000	10,000	10,000		*
William P. Hogan	20,000	20,000	40,000	40,000		*
William R. Lefever	150,000	150,000	300,000	300,000		*
<b>Total</b>	15,428,687	16,747,987	32,176,674	32,095,974	80,700	*

\* Less than 1.0%

(1) Includes shares of common stock issuable upon the exercise of warrants, and is adjusted to reflect the sale of shares pursuant to this offering.

**Table of Contents**

**PLAN OF DISTRIBUTION**

The selling security holders, which as used herein includes donees, pledgees, transferees, or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling security holder as a gift, pledge, partnership distribution, or other transfer, may, from time to time, sell, transfer, or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market, or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices.

If any of the selling security holders are deemed an underwriter within the meaning of Section 2(11) of the Securities Act in connection with the resale of our securities under this prospectus, any commissions received by such selling security holders and any profit on the resale of the shares of our common stock (including the shares of common stock issuable upon the exercise of the warrants) sold by such security holders while acting as principals will be deemed to be underwriting discounts or commissions. Because it will have been deemed to be an underwriter within the meaning of Section 2(11) of the Securities Act, such selling security holders will be subject to prospectus delivery requirements under the Securities Act.

The selling security holders may use any one or more of the following methods when disposing of shares or interests therein:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

short sales;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

broker-dealers may agree with the selling security holders to sell a specified number of such shares at a stipulated price per share;

a combination of any such methods of sale; and

any other method permitted pursuant to applicable law.

The selling security holders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling security holders to include the pledgee, transferee or other successors in interest as selling security

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holders under this prospectus. The selling security holders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees, or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of our common stock or interests therein, the selling security holders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling security holders may also

## **Table of Contents**

sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling security holders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities that require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling security holders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling security holders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering. Upon any exercise of the warrants by payment of cash, however, we will receive the exercise price of the warrants.

The selling security holders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided that they meet the criteria and conform to the requirements of that rule.

To the extent required, the shares of our common stock to be sold, the names of the selling security holders, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the common stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling security holders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling security holders and their affiliates. In addition, we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling security holders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling security holders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the selling security holders against liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus.

We have agreed to use reasonable efforts to maintain the effectiveness of this registration statement until the earlier of (i) the one year anniversary of the date the registration statement of which this prospectus forms a part is declared effective by the SEC or (ii) until Rule 144 of the Securities Act is available to the selling security holders with respect to all of their shares.

## **Penny Stock Regulations**

You should note that our stock is a penny stock. The SEC has adopted Rule 15g-9, which generally defines penny stock to be any equity security that has a market price (as defined) less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to certain exceptions. Our securities are covered by the penny-stock rules, which impose additional sales-practice requirements on broker-dealers that sell to persons other than established customers and accredited investors. The term accredited investor refers generally to institutions

## **Table of Contents**

with assets in excess of \$5,000,000 or individuals with a net worth in excess of \$1,000,000 or annual income exceeding \$200,000 or \$300,000 jointly with their spouse. The penny-stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized-risk disclosure document in a form prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny-stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker-dealer and salesperson compensation information, must be given to the customer orally or in writing prior to effecting the transaction and must be given to the customer in writing before or with the customer's confirmation. In addition, the penny-stock rules require that, prior to a transaction in a penny stock not otherwise exempt from these rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for the stock that is subject to these penny-stock rules. Consequently, these penny-stock rules may affect the ability of broker-dealers to trade our securities. We believe that the penny-stock rules discourage investor interest in and limit the marketability of our common stock.

### **Blue Sky Restrictions on Resale**

If a selling security holder wants to sell shares of our common stock under this prospectus in the United States, the selling security holders will also need to comply with state securities laws, also known as Blue Sky laws, with regard to secondary sales. As a result, holders may not resell their shares of common stock in the United States without satisfying the applicable state securities law or qualifying for an exemption therefrom, including the exemptions provided under the U.S. National Securities Markets Improvement Act of 1996. The broker for a selling security holder will be able to advise a selling security holder as to which states our common stock is exempt from registration with that state for secondary sales.

Any person who purchases shares of our common stock from a selling security holder under this prospectus who then wants to sell such shares will also have to comply with Blue Sky laws regarding secondary sales. These restrictions and potential costs could be significant burdens to our stockholders seeking to effect resales of our common stock within the United States.

## **Table of Contents**

### **DESCRIPTION OF SECURITIES**

#### **Authorized Capital Stock**

As of March 25, 2013, our authorized capital stock consisted of 150,000,000 shares of Common Stock, par value \$0.001 per share, and 25,000,000 shares of preferred stock, par value \$0.001 per share.

#### **Issued and Outstanding Capital Stock**

As of March 25, 2013, the following securities were issued and outstanding:

64,646,665 shares of common stock;

No shares of preferred stock;

Options to purchase 3,622,317, shares of common stock granted under our equity incentive plans; and

Warrants to purchase 4,333,889, shares of common stock exercisable at prices ranging from \$1.00 to \$3.24 per share.

#### **Description of Common Stock**

The holders of Common Stock are entitled to one vote per share on all matters submitted to a vote of the stockholders, including the election of directors. Generally, all matters to be voted on by stockholders must be approved by a majority (or, in the case of election of directors, by a plurality) of the votes entitled to be cast by all shares of Common Stock that are present in person or represented by proxy. Except as otherwise provided by law, amendments to the certificate of incorporation generally must be approved by a majority of the votes entitled to be cast by all outstanding shares of Common Stock. The certificate of incorporation does not provide for cumulative voting in the election of directors. The Common Stock holders will be entitled to such cash dividends as may be declared from time to time by the Board from funds available. Upon our liquidation, dissolution or winding up, the Common Stock holders will be entitled to receive pro rata all assets available for distribution to such holders.

#### **Description of Preferred Stock**

Our Preferred Stock, par value \$0.001 per share, may be issued from time to time in one or more series pursuant to a resolution or resolutions providing for such issue duly adopted by our Board of Directors (authority to do so being hereby expressly vested in the Board of Directors). The Board of Directors is further authorized, subject to limitations prescribed by law, to fix by resolution or resolutions the designations, powers, preferences and rights, and the qualifications, limitations or restrictions thereof, of any wholly unissued series of Preferred Stock, including without limitation authority to fix by resolution or resolutions the dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions), redemption price or prices, and liquidation preferences of any such series, and the number of shares constituting any such series and the designation thereof, or any of the foregoing.

#### **Registration Rights Agreement**

We were required to file within 90 days of the date of the final Closing of the Offering, a registration statement registering for resale all shares of common stock issued in the Offering, including common stock (i) included in the Units; and (ii) issuable upon exercise of the warrants included in the Units; consistent with the terms and provisions of the Registration Rights Agreement. The holders of any registrable securities removed from the registration statement a result of a Rule 415 or other comment from the SEC shall have piggyback registration rights for the shares of common stock or common stock underlying such warrants with respect to any registration statement filed by us following the effectiveness of the registration statement which would permit the inclusion of these shares. The registration statement was declared effective by the SEC on July 6, 2012.





## **Table of Contents**

We have agreed to use reasonable efforts to maintain the effectiveness of this registration statement until the earlier of (i) the one year anniversary of the date the registration statement of which this prospectus forms a part is declared effective by the SEC or (ii) until Rule 144 of the Securities Act is available to the selling security holders with respect to all of their shares.

### **Anti-Takeover Effects of Provisions of Delaware State Law**

Anti-takeover provisions in our certificate of incorporation and Delaware law could make an acquisition more difficult and could prevent attempts by our stockholders to remove or replace current management.

Anti-takeover provisions of Delaware law and in our certificate of incorporation and our bylaws may discourage, delay or prevent a change in control of our company, even if a change in control would be beneficial to our stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. In particular, under our certificate of incorporation our board of directors may issue up to 25,000,000 shares of preferred stock with rights and privileges that might be senior to our common stock, without the consent of the holders of the common stock. Moreover, without any further vote or action on the part of the stockholders, the board of directors would have the authority to determine the price, rights, preferences, privileges, and restrictions of the preferred stock. This preferred stock, if it is ever issued, may have preference over, and harm the rights of, the holders of common stock. Although the issuance of this preferred stock would provide us with flexibility in connection with possible acquisitions and other corporate purposes, this issuance may make it more difficult for a third party to acquire a majority of our outstanding voting stock. Similarly, our authorized but unissued common stock is available for future issuance without stockholder approval.

### **Warrants**

Set forth below is information concerning the various warrants issued by us to our investors, placement agents, consultants and other persons.

#### ***Warrants issued to investors in the Offering with closings on February 8, February 29 and March 16.***

After the final closing of the Offering, there were warrants issued to purchase 15,247,987 shares of common stock held by investors purchasing Units in the Offering (the Investor Warrants). Each Investor Warrant entitles the holder to purchase one share of common stock at a purchase price of \$1.00 during the five (5) year period commencing on the issuance of the Investor Warrants. We may call the Investor Warrants at any time our common stock trades above \$2.50 for twenty (20) consecutive days following the effectiveness of the registration statement of which this prospectus forms a part covering the resale of the underlying Investor Warrant shares. The Investor Warrants can only be called if a registration statement registering the shares underlying the Investor Warrants is in effect at the time of the call.

The Investor Warrants, at the option of the holder, may be exercised by cash payment of the exercise price to us. The Investor Warrants may be exercised on a cashless basis commencing one year after issuance if no registration statement registering the shares underlying the Investor Warrants is then in effect. The placement agent in the Offering will receive a warrant solicitation fee equal to 5% of the funds solicited by the placement agent upon exercise of the Investor Warrants if we elect to call the Investor Warrants. The exercise price and number of shares of common stock issuable on exercise of the Investor Warrants may be adjusted in certain circumstances including a weighted average adjustment in the event of future issuances of our equity securities at a price less than the exercise price of the Investor Warrant, in the event of a stock dividend, or our recapitalization, reorganization, merger or consolidation.

No fractional shares will be issued upon exercise of the Investor Warrants. If, upon exercise of the Investor Warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round up to the nearest whole number, the number of shares of common stock to be issued to the Investor Warrant holder.

**Table of Contents**

Simultaneous with the Initial Closing of the Offering, former warrant holders and a former noteholder of Organovo were issued warrants to purchase an aggregate of 1,409,750 shares of common stock. These warrants are similar to the Investor Warrants, except that they do not have a call provision or registration rights.

***Warrants issued in exchange for the warrants issued in connection with the Company's bridge financing completed in October and November 2012 (the Bridge Financing).***

There are 1,500,000 warrants outstanding (the New Bridge Warrants), all of which were issued at the Initial Closing of the Offering in exchange for the warrants issued in connection with the Bridge Financing (the Bridge Warrants). The New Bridge Warrants, which are exercisable at a price of \$1.00 per share for a five year period, are substantially similar to the Investor Warrants. Holders of the New Bridge Warrants received the same registration rights with respect to the shares of common stock issuable upon exercise of the New Bridge Warrants as the investors in the Offering.

***Warrants issued to the placement agent in connection with the Bridge Financing and Offering.***

The warrants issued to Spencer Trask Ventures, Inc., our placement agent in the Offering, permit the placement agent or its designees, to purchase for a five-year period, 5,489,040 shares of common stock at an exercise price of \$1.00 per share (the Placement Agent Warrants). Additionally, as compensation for the Bridge Financing, the placement agent was issued Organovo warrants that were subsequently exchanged for Placement Agent Warrants to purchase 610,155 shares of common stock at an exercise price of \$1.00 per share. The Placement Agent Warrants have no registration rights and contain weighted average anti-dilution and immediate cashless exercise provisions.

**Table of Contents**

**LEGAL MATTERS**

The validity of the shares offered by this prospectus and certain other legal matters has been passed upon by DLA Piper LLP (US), San Diego, California.

Mayer Hoffman McCann P.C., an independent registered public accounting firm, has audited our consolidated financial statements as of and for the fiscal years ended December 31, 2012 and 2011 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, as set forth in their report dated March 15, 2013, which is incorporated by reference in this prospectus. Such consolidated financial statements are included in reliance on Mayer Hoffman McCann P.C.'s aforementioned report, given on their authority as experts in accounting and auditing.

**WHERE YOU CAN FIND MORE INFORMATION**

We are subject to the informational requirements of the Exchange Act. Accordingly, we file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any document that we file at the SEC's public reference room at 100 F Street, NE, Washington, DC 20549. Information about the operation of the public reference room may be obtained by calling the SEC at 1-800-SEC-0330. Our SEC filings are also available to you free of charge at the SEC's web site at <http://www.sec.gov>.

You can read and print press releases, financial statements, our most recent annual and quarterly reports and additional information about us, free of charge, at our web site at <http://www.organovo.com>. Our website and the information contained on that site, or connected to that site, are not incorporated into and are not a part of this prospectus.

This prospectus is a part of a registration statement on Form S-3 filed by us with the SEC under the Securities Act. This prospectus does not contain all of the information set forth in the registration statement, certain parts of which are omitted in accordance with the rules and regulations of the SEC. For further information with respect to us and the shares of our common stock offered hereby, please refer to the registration statement. The registration statement may be inspected at the public reference facilities maintained by the SEC at the addresses set forth above. Statements in this prospectus about any document filed as an exhibit are not necessarily complete and, in each instance, you should refer to the copy of such document filed with the SEC. Each such statement is qualified in its entirety by such reference.

**INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE**

The SEC permits us to incorporate into this prospectus information that we file with the SEC in other documents. This means that we can disclose important information to you by referring to other documents that contain that information. The information incorporated by reference is considered to be part of this prospectus. Information contained in this prospectus and information that we file with the SEC in the future and incorporate by reference in this prospectus automatically updates and supersedes previously filed information. We incorporate by reference the documents listed below and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus and prior to the sale of all the shares covered by this prospectus or termination of the offering.

Our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, as filed with the SEC on March 15, 2013;

Our Current Reports on Form 8-K, as filed with the SEC on February 5, 2013 and March 19, 2013;

The description of our Common Stock contained in our Registration Statement on Form 8-A dated March 13, 2012; and

**Table of Contents**

Any other filings we make pursuant to the Exchange Act after the date of filing the initial Registration Statement and prior to effectiveness of the Registration Statement (other than any information in such reports that is deemed to have been furnished to, rather than filed with, the SEC in accordance with SEC rules).

Any statement contained in a document incorporated or deemed to be incorporated by reference into this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, a copy of any or all of the reports or documents that we incorporate by reference in this prospectus (except exhibits to the documents that are not specifically incorporated by reference) at no cost to you, by contacting our Corporate Secretary at 6275 Nancy Ridge Dr., San Diego, CA 92121 or by calling (858) 550-9994. Copies of any of these documents may also be obtained free of charge through our website at [www.organovo.com](http://www.organovo.com).

Table of Contents

*32,05,974 Shares of Common Stock*

**15,347,987 shares of Common Stock**

**16,747,987 shares of Common Stock Issuable Upon the exercise of Warrants**

**PROSPECTUS**

April 4, 2013