ORGANOVO HOLDINGS, INC.
Form 424B5
August 01, 2013
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Filed Pursuant to Rule 424(b)(5)
Registration No. 333-189995

The information in this preliminary prospectus supplement and the accompanying prospectus, relating to an effective registration statement under the Securities Act of 1933, as amended, is not complete and may be changed. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities and we are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED AUGUST 1, 2013

PROSPECTUS SUPPLEMENT

(to the Prospectus Dated July 26, 2013)

Shares

Common Stock

We are offering shares of our common stock. Shares of our common stock trade on the NYSE MKT under the symbol ONVO. On July 31, 2013, the last reported sale price of our common stock was $5.07 per share.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page S-12 of this prospectus supplement.

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

	Per Share	Total
Public Offering Price	$	$
Underwriting Discounts and Commissions	$	$
Proceeds to Organovo (Before Expenses)	$	$

We estimate the total expenses of this offering, excluding the underwriting discounts and commissions, will be approximately $350,000. The underwriters may also purchase up to an additional shares of our common stock from us at the public offering price, less underwriting discounts and commissions, to cover over-allotments, if any, within 30 days of the date of this prospectus supplement.

We anticipate that delivery of the shares of our common stock will be made through the facilities of the Depository Trust Company on or about August , 2013, subject to customary closing conditions.

Joint Book-Runners

Lazard Capital Markets **Oppenheimer & Co.**

Prospectus Supplement dated August , 2013.

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Prospectus Supplement

Prospectus

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ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of this common stock offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference herein. The second part, the accompanying prospectus, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement and the information contained in the accompanying prospectus or any document incorporated by reference therein filed prior to the date of this prospectus supplement, you should rely on the information in this prospectus supplement; provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document incorporated by reference in the accompanying prospectus the statement in the document having the later date modifies or supersedes the earlier statement.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference herein were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

You should rely only on the information contained in this prospectus supplement or the accompanying prospectus, or incorporated by reference herein. We have not authorized, and the underwriters have not authorized, anyone to provide you with information that is different. The information contained in this prospectus supplement or the accompanying prospectus, or incorporated by reference herein is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or of any sale of our common stock. It is important for you to read and consider all information contained in this prospectus supplement and the accompanying prospectus, including the documents incorporated by reference herein and therein, in making your investment decision. You should also read and consider the information in the documents to which we have referred you in the sections entitled Where You Can Find More Information and Incorporation of Certain Information by Reference in this prospectus supplement and in the accompanying prospectus.

We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

Unless otherwise stated, all references in this prospectus supplement and the accompanying prospectus to we, us, our, Organovo, the Compan and similar designations refer to Organovo Holdings, Inc. and its subsidiaries on a consolidated basis.

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This prospectus supplement, the accompanying prospectus, and the information incorporated herein and therein by reference, include trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included or incorporated by reference into this prospectus supplement or the accompanying prospectus are the property of their respective owners.

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PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights certain information about us, this offering and selected information contained elsewhere in or incorporated by reference in this prospectus supplement. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our common stock. For a more complete understanding of our company and this offering, we encourage you to read and consider carefully the more detailed information in this prospectus supplement and the accompanying prospectus, including the information referred to under the heading Risk factors in this prospectus supplement beginning on page S-12 the information incorporated by reference in this prospectus supplement and the accompanying prospectus, and the information included in any free writing prospectus that we have authorized for use in connection with this offering.

Our Business

Overview

We are developing and commercializing 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 utilizing our platform technology to create human tissue constructs in 3D that have the potential to replicate native human biology. We believe 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-Columbia. 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 outright ownership of patents and pending patent applications, see Intellectual Property . 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 and academic medical centers. We have also secured federal grants, 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) less than two years after commencing operations. We were selected by MIT s Technology Review magazine among the Most Innovative Companies of 2012 and by Inc. Magazine as one of the Most Audacious Companies in 2013. We believe these corporate achievements provide strong validation for the commercial viability of our technology.

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Our Platform Technology

Our platform technology is centered around multiple 3D bioprinting technologies utilizing our bioprinting instrument, the NovoGen MMX Bioprinter . Our 3D bioprinting technologies enables 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 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 in the future:

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.

Our 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.

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 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 micro vascular 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

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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 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.

Recent Developments

June 30, 2013 Preliminary Financial Results

We are currently finalizing our financial results for the three months ended June 30, 2013. While complete financial information and operating data as of and for such period are not yet available, based on the information and data currently available, our management preliminarily estimates that for the three months ended June 30, 2013 our net loss was approximately $(3.8) million, compared to a net loss of $(16.1) million for the three months ended March 31, 2013. Additionally, our management estimates that as of June 30, 2013, we had cash and cash equivalents of approximately $12.8 million and an accumulated deficit of approximately $(70.1) million, as compared to $15.6 million and $(66.4) million, respectively, at March 31, 2013. At June 30, 2013, management estimates negative cash flow from operations was approximately $2.7 million, as compared to $2.8 million for the three months ended March 31, 2013.

The preliminary financial data above have been prepared by, and is the responsibility of, our management. Our independent registered public accounting firm has not audited, reviewed, compiled, or performed any procedures with respect to this preliminary financial data and does not express an opinion or any other form of assurance with respect thereto. Because the three months ended June 30, 2013 has recently ended, the financial information presented above for the three months ended June 30, 2013

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reflects estimates based only upon preliminary information available to us as of the date of this prospectus supplement and is not a comprehensive statement of our financial results for the three months ended June 30, 2013. Our financial statements and operating data as of and for the three months ended June 30, 2013 will not be available until after this offering is completed and may differ from the preliminary unaudited financial information we have provided. Such differences may be material. Accordingly, you should not place undue reliance on these preliminary estimates. The estimates for the three months ended June 30, 2013 are not necessarily indicative of any future period and should be read together with Risk Factors, Special Note Regarding Forward-looking Statements, included elsewhere in this prospectus supplement and Management s Discussion and Analysis of Financial Condition and Results of Operations, Selected Historical Financial Data and our financial statements and related notes incorporated by reference into this prospectus supplement and the accompanying prospectus.

Legal Matters

In addition to commitments and obligations in the ordinary course of business, we are subject to various claims and pending and potential legal actions arising out of the normal conduct of our business. We assesses contingencies to determine the degree of probability and range of possible loss for potential accrual in our financial statements. We accrue an estimated loss contingency in our financial statements if it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Because litigation is inherently unpredictable and unfavorable resolutions could occur, assessing litigation contingencies is highly subjective and requires judgments about future events. When evaluating contingencies, we may be unable to provide a meaningful estimate due to a number of factors, including the procedural status of the matter in question, the presence of complex or novel legal theories, and/or the ongoing discovery and development of information important to the matters. In addition, damage amounts claimed in litigation against us may be unsupported, exaggerated or unrelated to possible outcomes, and as such are not meaningful indicators of our potential liability. We regularly review contingencies to determine the adequacy of our accruals and related disclosures. The amount of ultimate loss may differ from these estimates. It is possible that our cash flows or results of operations could be materially affected in any particular period by the unfavorable resolution of one or more of these contingencies. Whether any losses finally determined in any claim, action, investigation or proceeding could reasonably have a material adverse effect on our business, financial condition, results of operations or cash flows will depend on a number of variables, including: the timing and amount of such losses; the structure and type of any remedies; the monetary significance of any such losses, damages or remedies may have on our consolidated financial statements; and the unique facts and circumstances of the particular matter that may give rise to additional factors.

Spencer Trask Matter. On June 28, 2013, we filed a lawsuit for declaratory relief in the Supreme Court for the State of New York (case # 652305/2013) against Spencer Trask Ventures, Inc. (STV) in connection with a Warrant Solicitation Agency Agreement (the WSAA) that we entered into with STV in February 2013. In this action, we are seeking a declaration that the WSAA remains a valid and enforceable agreement. Over the course of several weeks in February 2013, Organovo and STV, through their respective attorneys, negotiated the WSAA pursuant to which we engaged STV as our warrant solicitation agent in connection with our efforts to solicit the exercise of outstanding Organovo warrants during the first quarter of 2013. STV s President signed the WSAA on behalf of STV, and our CEO executed the agreement on behalf of Organovo. Spencer Trask provided services to us pursuant to the WSAA, and we have paid STV for those services.

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Our dispute with Spencer Trask arose in March 2013 after we approached Spencer Trask about exercising their outstanding warrants to help the Company qualify for uplisting its common stock on the NYSE MKT. Previously, Spencer Trask had not asserted any claims for additional compensation as a result of the warrant tender offer we completed in December 2012. In March 2013, we received two demand letters from STV, and a demand for arbitration notice in June 2013. In the first demand letter, STV alleges that it is entitled to compensation (including a cash fee and warrants to purchase common stock) as a result of the warrant tender offer we completed in December 2012 and as a result of the warrant redemption we completed in March 2013. In the second letter, STV alleges it is entitled to damages because we allegedly violated confidentiality provisions in the Placement Agency Agreement (the PAA) we had previously entered into with STV in December 2012 in connection with the private placement financings we completed in February and March 2012 (the Private Placements), by contacting the warrant holders who participated in the warrant tender offer. In response, on June 28, 2013, we filed a lawsuit for declaratory relief in the Supreme Court for the State of New York against STV. Our tender offer was made to warrant holders of record relating to warrants already owned by them and whose identity was public information via a Registration Statement on Form S-1 we were required to file to register the resale of the shares underlying their warrants. For these and other reasons, including applicability of the WSAA, we believe STV is not entitled to compensation under the PAA and there was no violation of confidentiality.

We believe that the assertions made against us by STV are without merit and we intend to continue to vigorously defend against the claims made by STV, including any arbitration matter filed by STV. We have not established a loss contingency accrual for these claims because any potential liability is not probable or estimable. Nonetheless, an unfavorable resolution of these claims could have a material adverse effect on our business, liquidity or financial condition in the reporting period in which such resolution occurs.

Other Legal Matters. In addition to the matter described above, the Company is subject to normal and routine litigation in the ordinary course of business. We have not accrued any loss contingencies for such matters. We intend to defend ourselves in any such matters and do not currently believe that the outcome of such matters will have a material adverse effect on our business, liquidity or financial position.

Board of Directors

On July 25, 2013, Andras Forgacs, a member of our Board of Directors, resigned from the Board, effective on July 25, 2013. Mr. Forgacs was serving as a Class II director, with his term expiring at our Annual Meeting of Stockholders scheduled for August 21, 2013. There are no disagreements between Mr. Forgacs and the Company relative to his resignation. Mr. Forgacs holds approximately 1.2% of our outstanding common stock and while he is subject to Rule 144 limitations and a black-out period surrounding the filing of our Quarterly Report on Form 10-Q, he has not entered into a lock-up agreement in connection with this offering.

Risk Factors

An investment in our common stock is subject to a number of risks and uncertainties. Before investing in our common stock, you should carefully consider the following, as well as the more detailed discussion of risk factors and other information included in this prospectus supplement.

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

We will 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 profitability.

We may not be able to correctly estimate our future operating expenses, which could lead to cash shortfalls.

Our drug discovery, biological research and therapeutic tools and products are new and unproven.

Our technology, tools and products are subject to the risks associated with new and rapidly evolving technologies and industries.

The commercialization of our drug discovery and biological research tools and products is subject to a variety of risks.

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, Inc. was the surviving corporation of that Merger. As a result of the Merger, Pubco acquired the business of Organovo, and continued the existing business operations of Organovo as Organovo Holdings, Inc.

On July 11, 2013, our common stock began trading on the NYSE MKT under the symbol ONVO and the quotation of our common stock on the OTCQX was terminated following the closing of trading on July 10, 2013.

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Our principal executive offices are located at 6275 Nancy Ridge Dr., San Diego, California 92121 and our phone number is (858) 550-9994. Our Internet address can be found at http://www.organovo.com. The information found on our Internet site is not part of this prospectus supplement.

Change in Fiscal Year End

On March 31, 2013, our Board of Directors approved a change in our fiscal year end from December 31st to March 31st. As a result of this change, we filed a Transition Report on Form 10-K for the three-month transition period ended March 31, 2013. References to any of our previous fiscal years mean the fiscal years ending on December 31st.

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THE OFFERING

Common stock offered by us in this offering	shares
Option to purchase additional shares	We have granted the underwriters an option for a period of up to 30 days from the date of this prospectus supplement to purchase up to additional shares of common stock at the public offering price less the underwriting discounts and commissions to cover over-allotments, if any.
Common stock to be outstanding immediately after this offering	shares (or shares if the underwriters exercises in full their over-allotment option to purchase additional shares)
Use of proceeds	We intend to use all of the net proceeds from this offering for general corporate purposes, including research and development, the development and commercialization of our products, general administrative expenses, license or technology acquisitions, and working capital and capital expenditures. See Use of Proceeds on page S-29 of this prospectus supplement.
NYSE MKT	ONVO
Risk factors	Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page S-12 of this prospectus supplement.

Outstanding Shares

The number of shares of common stock to be outstanding immediately after this offering as shown above assumes that all of the shares offered hereby are sold and is based on 64,686,919 shares of common stock outstanding as of March 31, 2013. This number of shares excludes, as of March 31, 2013:

- 3,618,567 shares of common stock issuable upon the exercise of outstanding stock options, having a weighted average exercise price of $2.11 per share; and
- 4,283,889 shares of our common stock issuable upon the exercise of outstanding warrants with a weighted-average exercise price of $1.17 per share.

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Unless otherwise indicated, all information in this prospectus supplement assumes:

- that the underwriters do not exercise their option to purchase up to additional shares of our common stock to cover over-allotments, if any; and
- no options, restricted stock awards, warrants, or shares of common stock were issued after March 31, 2013, no outstanding options or warrants were exercised after March 31, 2013 and no outstanding restricted stock awards vested after such date.

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RISK FACTORS

An investment in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should consider carefully the risks described below, together with other information in this prospectus supplement, the accompanying prospectus, the information and documents incorporated by reference, and in any free writing prospectus that we have authorized for use in connection with this offering. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us, or that we currently see as immaterial, may also harm our business.

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 and future prospects. Our future prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations and competing in new and rapidly developing technology areas. We have generated operating losses since we began operations, including $4.0 million for the three months ended March 31, 2013 and $9.3 million, $2.3 million and $1.2 million for the years ended December 31, 2012, 2011 and 2010, respectively. As of March 31, 2013, we had incurred cumulative operating losses of $17.7 million and cumulative net losses totaling $66.4 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, successfully developing drug discovery and biological research tools and products that are more effective than existing technologies; entering into collaborative relationships with strategic partners; obtaining any necessary regulatory approval for our drug discovery, biological research and therapeutic tools and products; entering into successful manufacturing, sales, and marketing arrangements; and raising sufficient funds to finance our activities and business plan. 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 will 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. We expect that we will be required to issue additional equity or debt securities or enter into other commercial arrangements, including relationships with corporate and other partners, to secure the additional financial resources to support our development efforts and future operations. Depending upon market conditions, we may not be successful in raising sufficient additional capital on a timely basis, or at all. If we fail to obtain sufficient additional financing, or enter into relationships with others that provide additional financial resources, we will not be able to develop our technology and products on our planned timeline, or at all, and 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

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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. In such event, our business, prospects, financial condition and results of operations would be adversely affected.

We are an early-stage company with an unproven business strategy, and may never achieve profitability.

We are in the early stages of using our proprietary platform technology to develop and commercialize 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. Our success will depend upon our ability to enter into additional collaboration agreements on favorable terms, to determine which drug discovery, biological research and therapeutic tools and products can be successfully developed with our platform technology, obtain any necessary regulatory approvals for such tools and products, and to select an appropriate commercialization strategy for the tools and products we or our collaborators choose to pursue. If we are not successful in implementing our development and commercialization strategies, which are new and unproven, we may never achieve, maintain or increase profitability.

We may not be able to correctly estimate our future operating expenses, which could lead to cash shortfalls.

Our operating expenses may fluctuate significantly in the future as a result of a variety of factors, many of which are outside of our control. These factors include:

- the time and resources required to develop our drug discovery, biological research and therapeutic tools and products;
- the time and cost of obtaining any necessary regulatory approvals;
- the cost to create effective sales and marketing capabilities;
- the expenses we incur to maintain and improve our platform technology;
- the costs to attract and retain personnel with the skills required for effective operations; and
- the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation.

In addition, our budgeted expense levels are based in part on our expectations concerning future revenues from sales of our tools and products and from collaborations with third parties. However, we may not correctly predict the amount or timing of future revenues. In addition, we may not be able to adjust our operations in a timely manner to compensate for any unexpected shortfall in our revenues. As a result, a significant shortfall in our planned revenues could have an immediate and material adverse effect on our business and financial condition.

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Our drug discovery, biological research and therapeutic tools and products are new and unproven.

Our drug discovery and biological research tools and products involve new and unproven models and approaches. We have not proven that our tools and products will enable us or our collaborators to conduct drug discovery and biological research more effectively than through the use of existing technologies. Our success depends on commercial acceptance of our drug discovery and biological research tools and products. Even if we or our collaborators are successful in their drug discovery and biological research efforts, we or our collaborators may not be able to discover or develop commercially viable products therefrom. To date, no one has developed or commercialized any therapeutic or other life science products based on our drug discovery and biological research tools and products. If our drug discovery and biological research products and tools do not assist in the discovery and development of such therapeutic or life science products, our current and potential collaborators may lose confidence in us and our drug discovery and biological research tools and products. Our inability to achieve and maintain commercial acceptance for our tools and products would materially adversely affect our business, financial condition and results of operations.

Our technology, tools and products are subject to the risks associated with new and rapidly evolving technologies and industries.

Our proprietary tissue creation technology and our drug discovery, biological research and therapeutic tools and products are subject to the risks associated with new, rapidly evolving technologies and industries. We may experience unforeseen technical complications, unrecognized defects and limitations in the development and commercialization of our tools and products. These complications could materially delay or limit the use of those tools and products, substantially increase the anticipated cost of manufacturing them or prevent us or our collaborators from implementing their drug discovery or biological research projects successfully or at all. In addition, the process of developing new technologies, tools and products is complex, and if we are unable to develop enhancements to, and new features for, our existing tools and products or acceptable new tools and products that keep pace with technological developments or industry standards, our tools and products may become obsolete, less marketable and less competitive.

The commercialization of our drug discovery and biological research tools and products is subject to a variety of risks.

The commercialization of our drug discovery and biological research tools and products are subject to risks and uncertainties, including:

failing to provide enhanced results over existing technologies;

failing to be cost effective;

failing to receive necessary regulatory approvals;

being difficult or impossible to manufacture on a large scale;

being costly to commercialize or market;

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failing to develop our tools and products before the successful marketing of similar tools and products by competitors; or

infringing the proprietary rights of third parties or competing with superior products marketed by third parties.

If any of these risks and uncertainties occur, our efforts to commercialize our drug discovery and biological research tools and products may be unsuccessful, which would harm our business and results of operations.

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.

In addition, 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.

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

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products, or could require or result in litigation or arbitration. Moreover, disagreements could arise with 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 payers, such as Medicare and Medicaid, private health insurers, including managed care organizations, and other third-party payers. These payers 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 payers 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 payers 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.

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Any theraputic implants we develop 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. We may not be able to obtain FDA approvals for those products in a timely manner, or at all. We may encounter significant 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.

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

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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.

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

We may 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

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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 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 will require access to a constant, steady, reliable supply of human cells to successfully commercialize our tools and products.

Commercialization of our tools and products will require that we have access to a constant, steady and reliable supply of human cells. We will also require access to, or development of, facilities to manufacture a sufficient supply of our tools and products. If we are unable to manufacture our products in commercial quantities, our business and future results will suffer.

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

We may rely on third-party suppliers and vendors for some of the materials we require in our drug discovery and biological research products and 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

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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