ORGANOVO HOLDINGS, INC.
Form 424B5
October 19, 2016
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Registration No. 333-202382

The information in this preliminary prospectus supplement is not complete and may be changed. This preliminary prospectus supplement and the accompanying prospectus are not offers to sell these securities, and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED OCTOBER 19, 2016

PROSPECTUS SUPPLEMENT

(To Prospectus dated March 17, 2015)

Shares

Common Stock

We are offering shares of our common stock. Our common stock is traded on the Nasdaq Global Market under the symbol ONVO. On October 18, 2016, the last reported sale price of our common stock was $3.53 per share.

Investing in our common stock involves a high degree of risk. Please read Risk Factors beginning on page S-9 of this prospectus supplement and in the documents incorporated by reference into this prospectus supplement or the accompanying prospectus and any free writing prospectus that we have authorized for use in connection with this offering.

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

	PER SHARE	TOTAL
Public Offering Price	$	$
Underwriting Discounts and Commissions [(1)]	$	$
Proceeds to Us (Before Expenses)	$	$

(1) The underwriters will also be reimbursed for certain expenses incurred in this offering. See Underwriting for details.

Delivery of the shares of common stock to purchasers will be made on or about , 2016. The underwriters may also purchase up to an additional shares of common stock from us at the public offering price, less the underwriting discounts and commissions payable by us, within 30 days of the date of this prospectus supplement. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $ and the total proceeds, before expenses, to us will be $.

Joint Book-Running Managers

Jefferies **Evercore ISI**

Lead Manager

Raymond James

Co-Manager

BTIG

Prospectus Supplement dated October , 2016

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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 or incorporated by reference in this prospectus supplement or the accompanying prospectus. We have not authorized, and the underwriters have not authorized, anyone to provide you with information that is different. The information contained or incorporated by reference in this prospectus supplement or the accompanying prospectus 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 or incorporated by reference in this prospectus supplement and the accompanying prospectus 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 Company and similar designations refer to Organovo Holdings, Inc. and its subsidiaries on a consolidated basis.

In addition to disclosing financial results that are determined in accordance with U.S. GAAP, we provide net cash utilization as a supplemental measure to help investors evaluate our fundamental operational performance. We define net cash utilization as the net decrease in cash and cash equivalents during the reporting period (which was ($1.8

million) during the second quarter of fiscal 2017) less proceeds from the sale of common stock and the exercise of warrants and stock options during the reporting period (which was $5.0 million during the second quarter of fiscal 2017) . Net cash utilization is an operational measure that should be considered as additional financial information regarding our operations. This operational measure should not be considered without also considering our results prepared in accordance with U.S. GAAP, and should not be considered as a substitute for, or superior to,

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our U.S. GAAP results. We believe net cash utilization is a relevant and useful operational measure because it provides information regarding our cash utilization rate. Our management uses net cash utilization to manage the business, including in preparing our annual operating budget, financial projections and compensation plans. We believe that net cash utilization is also useful to investors because similar measures are frequently used by securities analysts, investors and other interested parties in their evaluation of companies in similar industries. However, there is no standardized measurement of net cash utilization, and net cash utilization as we present it may not be comparable with similarly titled operational measures used by other companies. Due to these limitations, our management does not view net cash utilization in isolation but also uses other measurements, such as cash used in operating activities and revenues to measure operating performance.

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, 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-9, 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.

Overview

We are an early commercial stage company focused on 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 (3D) human tissues by utilizing our proprietary platform technology to create human tissue constructs in 3D that mimic native human tissue composition, architecture, and function. We believe we can leverage our novel 3D human tissue models to improve the current industry standard cell-based and animal model testing approaches to drug discovery and development by creating 3D tissues constructed solely of human cells. We believe our foundational approach to the 3D printing of living tissues, as disclosed in peer-reviewed scientific publications, and the continuous evolution of our core bioengineering technology platform combine to provide us with the opportunity to fill many critical gaps in commercially available preclinical human tissue modeling and tissue transplantation.

Our foundational proprietary technology, grounded in over a decade of peer-reviewed scientific publications, 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 related to the 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 and Clemson University. We have continued to develop our technology and grow our intellectual property portfolio. In addition to our in-licensed patents, we own outright more than 90 additional patents and pending patent applications around the world. We believe that our broad and exclusive commercial rights to patented and patent-pending 3D bioprinting technology, 3D tissues and applications provides us with a strong and defensible market position for the successful commercialization of 3D bioprinted human tissues serving a broad array of unmet preclinical and clinical needs.

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. We developed the NovoGen MMX Bioprinter (our first-generation 3D bioprinter) less than two years after commencing operations, and the Bioprinter was named one of the Best Inventions of 2010 by TIME Magazine and won a number of engineering innovation awards. Our first tissue product, exVive3D Liver, Bioprinted Human Tissue, was launched in 2014 and received the CONNECT Most Innovative Product award for 2014 in Life Sciences (Diagnostics & Research Tools). The exVive3D Liver was also selected as one of the Top 10 Innovations of 2014 by The Scientist magazine. We were selected by MIT s Technology Review magazine among the Most Innovative Companies of 2012, by Inc. Magazine as one of the Most Audacious Companies in 2013, by Fast Company as one of the most innovative companies in healthcare for 2015, and as a Technology Pioneer for 2015 by the World Economic Forum in Davos, Switzerland. We

believe these corporate achievements provide strong validation for the commercial potential of our 3D bioprinting platform and the tissues it produces.

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Our Platform Technology

Our platform technology is centered on multiple 3D bioprinting technologies, which we have utilized to develop our proprietary instrument platform, our NovoGen Bioprinters®. Our 3D bioprinting technologies enable a wide array of tissue compositions and architectures to be created, using purely cellular bio-ink (building blocks comprised of only living cells), biocompatible hydrogels, or combinations of the two. A key distinguishing feature of our bioprinting platform is the ability to generate complex 3D tissues that have all or some of their components comprised entirely of cells. Prior to the invention of our NovoGen bioprinting platform, the most common fabrication method for 3D tissues was the use of biomaterial scaffolding into which cells were incorporated. While useful for some applications, scaffold-based engineered tissues lack features of native tissue that are critical to function such as dense cellularity, wherein cells have intimate contact with neighboring cells, and an intricate architecture created by the spatial arrangement of specific cellular compartments relative to each other. Our 3D bioprinting platform can deliver tissues that are truly three-dimensional with a cellularity and architecture that closely resembles native tissue. Moreover, most tissues can be generated using human cells as inputs, yielding functional models of human tissue that can be used *in vitro* for drug discovery and development. In the future, complex bioprinted human tissues may also address unmet clinical needs by serving as tissue grafts for the augmentation or replacement of functional mass in tissues and organs that have sustained significant damage by trauma or disease.

Our Research & Development Programs

We are focused on developing product and service offerings in the following categories:

- A suite of standardized, 3D human tissues for the preclinical assessment of drug effects, including applications in predictive toxicology, absorption, distribution, metabolism, excretion (ADME), and drug metabolism and pharmacokinetics (DMPK).
- Highly customized human tissues as living, dynamic models of human biology or disease, for use in drug discovery and development.
- Three-dimensional human tissues for clinical applications, such as blood vessels for bypass grafting, nerve grafts for nerve damage repair and functional tissue patches for the repair or replacement of damaged tissues and organs.

Our Market Opportunity

We believe that our proprietary 3D bioprinting platform enables us to deliver novel functional human tissues to the drug discovery and development market and to multiple clinical markets:

1) **Standardized, Normal 3D Human Tissues for Predictive Toxicology and Preclinical Testing:** We believe that our NovoGen MMX Bioprinter delivers highly differentiated 3D tissues for use in assays aimed at predicting human clinical outcomes. Our products in this area may replace or complement traditional two-dimensional (2D) cell culture based cell assays, or cellular co-culture systems. Because our 3D tissues are made of human cells and reproduce many aspects of *in vivo* tissue architecture and function, we believe they may provide advantages over

non-human animal models with respect to prediction of *in vivo* human outcomes. Bioprinted 3D human tissue products may be provided to the market as kits that are sold by us or distributed by a partner. Additionally, our tissue products may be marketed as a compound screening service, for customers who prefer to provide their compounds to a testing laboratory that will conduct short- or long-term tests involving the exposure of our bioprinted 3D human tissues to their compound(s) and providing them with results and samples. The compound screening service may be conducted by us or may be offered by one or more partners, such as contract research organizations (CROs).

Our 3D tissue products are designed to be compatible with a broad range of *in vitro* preclinical tests, including some aspects of assessments of ADME, DMPK, and predictive toxicology. DMPK testing is a subset of ADME. Determining the DMPK properties of a drug helps the drug developer to better predict its safety and efficacy. The ADME and DMPK properties of a drug essentially determine the bioavailability of

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that drug, including how long and at what concentrations it is exposed to the target tissue(s). Toxicology testing is a further requirement to assess the potential for a particular drug to seriously damage one or more organs systems while it is present in the body. Many aspects of preclinical drug testing can be altered significantly by age, genetics, disease state, and the presence of other drugs or chemicals. Most companies perform preclinical ADME, DMPK, and toxicology tests using a combination of biochemical and cell-based assays and animal testing. 3D bioprinted tissue products may replace or complement traditional cell based assays that typically employ primary hepatocytes, intestinal cell lines, renal epithelial cells and cell lines grown in traditional two-dimensional formats. Because 3D bioprinted tissues share more features with native tissue *in vivo* than standard 2D cell cultures, and they persist for extended time periods *in vitro* (>40 days), we believe they can provide highly differentiated and valuable outcomes and give clients human preclinical data with greater depth and accuracy than has previously been possible. In July 2016, we announced a publication in the scientific journal, PLOS One, which demonstrated the superiority of our 3D bioprinted human liver tissues to effectively model drug-induced liver injury and distinguish between highly-related compounds with different toxicity profiles.

Additional opportunities in this area include the testing of environmental toxins and cosmetic products on living human tissues. Due to ethical concerns and regulatory considerations, there is a growing market opportunity for the use of 3D human tissue models as alternatives to non-human animal studies. For example, human skin models have substantial potential value as a means to test the effects of candidate cosmetic products prior to commercialization. We have established a collaborative research program in this field with the intention of developing products and services for this type of testing. In addition, many of the standard tissue models developed within this aspect of our business may be used to assess the potential human health impacts and toxicological properties of a large number of chemical products, environmental toxins, or biowarfare agents.

2) **Specialized 3D Tissue Models for Drug Discovery and Development:** Our NovoGen bioprinting platform, comprised of multicellular inputs (bio-ink) and a family of bioprinters with unique capabilities, can produce highly specialized human tissues that model physiology or disease. We have used our bioprinting platform to create a wide array of human tissues, including blood vessels, liver tissues, skin tissues, kidney tissues, lung tissues, and tumor tissues. 3D bioprinted tissues possess unique features, including cell type-specific compartments, prevalent intercellular tight junctions, and microvascular structures. These features facilitate the development of complex, multicellular disease models for use in the development of targeted therapeutics for cardiovascular disease, lung disease, liver disease, kidney disease, and oncology. Market opportunities within this aspect of our business may include externally-partnered or internally-directed drug discovery and the clinical development and commercialization of new molecular entities using highly customized 3D tissue models.

3) **Implantable 3D Tissues for Therapeutic Use:** Cell- and tissue-based therapeutic products have advanced through research and development via multiple strategic approaches, with current clinical efforts in the field focused on systemic or localized delivery of cell suspensions or surgical installation of combination products that consist of a predominant biomaterial component and cellular component(s). The architectural precision and flexibility of our bioprinting platform may facilitate the prototyping, optimization, development, and clinical use of three-dimensional tissue constructs. Importantly, our platform enables all or part of a three-dimensional tissue to be generated without dependence on scaffolding or biomaterial components, using only living cells as raw materials. The ultimate goal is to construct surgically implantable tissues that restore significant functional mass to a damaged tissue or organ after delivery. It is our belief that, in most cases, whole organ replacement will not be required to achieve meaningful clinical outcomes and address unmet medical needs. Three-dimensional tissues with tightly defined architecture and composition can create a new product category within cell and tissue

therapies. Tissue products may include bioprinted tissues (patches, tubes, etc.) or hybrids comprised of bioprinted tissues and device component(s). We may develop specific tissue targets with partners through technology licenses and royalty-bearing deals and self-fund the development of additional tissue targets through preclinical and clinical development.

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Research Collaborations

We currently have research collaborations with pharmaceutical, biotechnology and cosmetic companies, academic and research institutions and government agencies. These collaborations are focused on a variety of research projects, including: developing tissue-based drug discovery assays and tissues, developing more clinically predictive *in vitro* three-dimensional cancer models, exploring the use of our 3D liver tissues in toxicology, and exploring the use of 3D skin for testing skin care products. Our collaborations with pharmaceutical and biotechnology companies generally involve the partner providing research funding to cover, in part or in full, the scope of work. This funding is typically reflected as revenues in our financial statements. Upon entering into a collaboration, we disclose the financial details only to the extent that they are material to our business. Our academic and research institute collaborations typically involve both us and the academic partner contributing resources directly to projects, but also may involve sponsored research agreements where we fund specific research programs. We may also contribute a bioprinter and technical support or a bioprinter plus research headcount, depending on the project scope.

Our Products and Product Candidates

We have utilized and intend to utilize our bioprinting technology to develop functional human tissues that can be employed in drug discovery and development, biological research and as therapeutic implants. Our first commercial tissue offered is exVive3D Human Liver Tissue, which was designed to be used for predictive preclinical testing of drug compounds. In April 2014, we announced that we had initiated contracting with pharmaceutical and biotechnology companies for toxicity research services using our 3D Human Liver Tissue. In November 2014, we began to offer 3D Human Liver services more broadly. We currently focus on contract research services, though we also intend to offer our 3D Human Liver Tissue directly to end user customers as a product in a kit for toxicological and other testing over time. Our second commercial product is our exVive3D Human Kidney Tissue. Similar to our 3D Human Liver Tissue, we designed our 3D Human Kidney Tissue to be used for predictive preclinical testing of drug compounds. In September 2016, we commenced commercial contracting for our exVive3D Human Kidney Tissue. In October 2016, we announced that we had selected 3D bioprinted human liver tissue for direct transplantation to patients as our first therapeutic product candidate and our intent to pursue this opportunity with a formal preclinical development program.

Intellectual Property

Our success depends in large part on our ability to establish and protect our proprietary technologies and our products and services. We rely on a combination of patents, trademarks, trade secrets and a variety of contractual mechanisms such as confidentiality, material transfer, licenses, and invention assignment agreements, to protect our intellectual property. Our intellectual property portfolio for our core technology was initially built through licenses from the University of Missouri-Columbia (MU) and the Medical University of South Carolina. We have subsequently expanded our intellectual property portfolio by filing patent applications and negotiating additional licenses and purchases.

We own or hold exclusive licenses to 13 issued U.S. patents and 24 pending U.S. patent applications. Outside of the U.S., we own or hold exclusive licenses to 26 issued patents and over 100 pending applications, related to our bioprinting technology and its various uses in areas of tissue creation, *in vitro* testing, and utilization in drug discovery, including filings covering specific tissue constructs.

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Select Preliminary Second-Quarter 2017 Results

On October 11, 2016, we reported preliminary unaudited revenue and net cash utilization results for the fiscal second quarter of 2017. Our preliminary fiscal second quarter total revenue was approximately $1.4 million, consisting largely of product and service revenue. This result reflects a 357 percent increase in total revenue versus the comparable period of fiscal 2016 and a 54 percent increase versus the fiscal first quarter of 2017. Additionally, we reported the following preliminary unaudited revenue, cash and cash equivalents balance and net cash utilization results for the fiscal second quarter of 2017:

- Our product and service revenue was approximately $1.0 million, up 400 percent from the prior-year period, largely driven by an increase in customer contracts for our tissue research services.

- Our collaborations and grant revenue totaled approximately $0.4 million, primarily supported by a milestone achievement from our agreement with Merck & Co. to develop multiple custom tissue models.

- Our preliminary cash and cash equivalents balance was approximately $51.7 million as of the end of the fiscal second quarter, which compares to $53.5 million for the fiscal first quarter. Our preliminary net cash utilization during the period was approximately $6.8 million. During the fiscal second quarter, we generated net proceeds of approximately $4.5 million from the issuance of 997,181 shares of common stock in at-the-market (ATM) offerings at a weighted average price of $4.67 per share and approximately $0.5 million from the exercise of stock options and warrants.

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 information contained under Risk Factors beginning on page S-9 of this prospectus supplement and in the documents incorporated by reference into this prospectus supplement.

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

- 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 revenues and operating expenses, which could lead to cash shortfalls and require us to secure additional financing sooner than planned.

- We need to secure additional funds to support our operations and the implementation of our business plan.

- The select financial results presented in the prospectus supplement under the caption Summary Select Preliminary Second-Quarter 2017 Results are preliminary, and our actual operating results and financial position may differ significantly from these preliminary announced results.

- Our platform technology and our drug discovery, biological research, therapeutic tools, products and services are new and unproven.

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

- Our ability to successfully commercialize any drug discovery, biological research, therapeutic tools, products or services we develop is subject to a variety of risks.

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

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

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

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- We currently rely on third-party suppliers for some of our materials, including our supply of human cells, and we may rely on third-party manufacturers in the future to produce our tools and products.

- 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.

- Any therapeutic implants we develop will be subject to extensive, lengthy and uncertain regulatory requirements, which could adversely affect our ability to obtain regulatory approval in a timely manner, or at all.

- We may not be able to protect our intellectual property rights throughout the world.

- If we are not able to adequately protect our proprietary rights, our business could be harmed.

Corporate Background

We are operating the business of our subsidiaries, including Organovo, Inc., our wholly-owned subsidiary, which we acquired in February 2012. Organovo, Inc. was incorporated in Delaware in April 2007. Our common stock has traded on the Nasdaq Global Market under the symbol ONVO since August 8, 2016. Prior to that time it traded on the NYSE MKT under the symbol ONVO and prior to that was quoted on the OTC Market. Our wholly-owned subsidiary, Samsara Sciences, Inc., was incorporated in Delaware in December 2014.

Our principal executive offices are located at 6275 Nancy Ridge Dr., San Diego, California 92121 and our phone number is (858) 224-1000. Our Internet website can be found at http://www.organovo.com. The information found on our Internet website is not part of this prospectus supplement.

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THE OFFERING

Common stock offered by us:	shares.
Common stock to be outstanding after this offering:	shares (or shares if the underwriters option to purchase additional shares is exercised in full).
Underwriters option to purchase additional shares:	We have granted the underwriters an option to purchase up to additional shares of our common stock. This option is exercisable, in whole or in part, for a period of 30 days from the date of this prospectus supplement.
Use of proceeds:	We intend to use the net proceeds from this offering for general corporate purposes, including research and development, the development and commercialization of our products, general administrative expenses, and working capital and capital expenditures. We may also use the net proceeds to invest in or acquire complementary businesses, products or technologies, although we have no current commitments or agreements with respect to any such investments or acquisitions as of the date of this prospectus supplement. See Use of Proceeds on page S-12 of this prospectus supplement.
NASDAQ listing:	Our common stock is listed on the Nasdaq Global Market under the symbol ONVO.
Risk Factors:	Our business and an investment in our common stock involve significant risks. See Risk Factors beginning on page S-9 of this prospectus supplement for a discussion of factors you should read and carefully consider before investing in our common stock.

Outstanding Shares

The number of shares to be outstanding after this offering is based on 92,389,730 shares of common stock outstanding as of June 30, 2016 and excludes the following as of such date:

- 10,008,297 shares of common stock issuable upon the exercise of outstanding stock options, having a weighted average exercise price of $4.72 per share;
-

1,046,813 shares of our common stock issuable upon the exercise of outstanding warrants with a weighted average exercise price of $2.29 per share;

- 519,850 shares of our common stock issuable upon vesting and settlement of restricted stock units; and

- 5,575,475 shares available for issuance pursuant to the 2012 Equity Incentive Plan.

Additionally, the number shares to be outstanding after this offering does not reflect certain issuances and actions that occurred after June 30, 2016 and during the quarter ended September 30, 2016, including (i) the issuance and sale of 997,181 shares of our common stock pursuant to our at-the-market sales program, at a weighted average price of $4.67 per share, (ii) the issuance of restricted stock units for 645,900 shares of our common stock pursuant to our 2012 Equity Incentive Plan, (iii) the issuance of stock options exercisable for 1,386,500 shares of our common stock pursuant to our 2012 Equity Incentive Plan, at a weighted average exercise price of $4.04 per share and (iv) 1,500,000 shares of common stock that were authorized and reserved for issuance by our board of directors and stockholders pursuant to our newly adopted 2016 Employee Stock Purchase Plan.

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

- No exercise of the underwriters option to purchase additional shares of our common stock; and
- No exercise of outstanding stock options or warrants to purchase shares of common stock or the issuance of shares of common stock pursuant to vesting and settlement of restricted stock units after June 30, 2016.

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RISK FACTORS

You should carefully consider the risk factors set forth below, under the caption Risk Factors in the accompanying prospectus and under the caption Risk Factors in our Annual Report on Form 10-K for the fiscal year ended March 31, 2016, which is incorporated by reference in this prospectus supplement and the accompanying prospectus. See Where You Can Find More Information and Incorporation of Certain Information by Reference. Before making any investment decision, you should carefully consider these risks as well as other information we include or incorporate by reference in this prospectus supplement and the accompanying prospectus. The risks and uncertainties we describe are not the only ones facing us. Additional risks and uncertainties that we are unaware of or that we believe are not material at the time could also materially adversely affect our business, financial condition or results of operations. In any case, the value of our common stock could decline, and you could lose all or part of your investment. See also the information contained under the heading Special Note Regarding Forward-Looking Information immediately below.

Risks Related to our Business and Financial Results

Our actual operating results and financial position may differ significantly from our select preliminary unaudited revenue and net cash utilization results for the fiscal second quarter of 2017.

In this prospectus supplement under the caption Summary Select Preliminary Second-Quarter 2017 Results, we present our preliminary unaudited revenue and net cash utilization results for the fiscal second quarter of 2017. These financial and operating results are preliminary results derived from our internal books and records. These preliminary results have been prepared solely by our management, and our auditors have not audited these preliminary financial and operating results.

These preliminary financial and operating results are subject to adjustments in the ongoing review by us and our external auditors. Such adjustments could result in material changes in the financials that we actually report in our quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2016. As a result, the preliminary unaudited revenue and net cash utilization results for the fiscal second quarter of 2017 should be viewed with caution and with the understanding that such results are subject to change until the final results are reported. In addition, our preliminary results for the fiscal second quarter of 2017 are not necessarily indicative of our operating results for the fiscal year ending March 31, 2017 or any other future periods.

Risks Related to This Offering

Management will have broad discretion as to the use of the net proceeds from this offering, and we may not use the proceeds effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of our product candidates and cause the price of our common stock to decline.

You will experience immediate and substantial dilution in the net tangible book value per share of the common stock you purchase.

Since the price per share of our common stock being offered is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock

you purchase in this offering. After deducting underwriting discounts and commissions and offering expenses payable by us, and based on a net tangible book value of our common stock of $0.58 per share as of June 30, 2016, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of $ per share in the net tangible book value of common stock. See the section entitled Dilution below for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering.

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share in this offering. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders,

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including investors who purchase shares of common stock in this offering. The price per share at which we sell additional shares of our common stock or securities convertible into common stock in future transactions may be higher or lower than the price per share in this offering.

Our stockholders may be diluted by the exercise of outstanding options or warrants to purchase common stock.

As of June 30, 2016, we had outstanding stock options to purchase 10,008,297 shares of our common stock, issuable at a weighted average exercise price of $4.72 per share, outstanding warrants to purchase 1,046,813 shares of our common stock at a weighted average exercise price of $2.29 per share, and 519,850 shares of our common stock issuable upon vesting and settlement of outstanding restricted stock units. You may incur dilution upon the issuance of shares upon exercise of such outstanding options or warrants or vesting and settlement of outstanding restricted stock units.

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SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION

This prospectus supplement and the accompanying prospectus and the documents incorporated herein by reference contain, or will contain, forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Exchange Act.

Any statements contained in this prospectus supplement and the accompanying prospectus and the documents incorporated herein by reference that do not describe historical facts constitute forward-looking statements. These forward-looking statements relate to anticipated future events, future results of operations or future financial performance, and include, but are not limited to: statements relating to our select preliminary financial results for the fiscal second quarter of 2017; the market opportunity for our product and service offerings; the expected benefits and efficacy of our product and service offerings; our ability to successfully develop new product and service offerings based on our technology; the availability of the additional funding necessary to support our operations and to allow us to implement our business plans; and our ability to complete the additional preclinical studies required to submit an IND to pursue the use of our human liver tissue as a therapeutic tissue. In some cases, you can identify forward-looking statements by terminology such as may, might, will, should, intends, expects, plans, goa anticipates, believes, estimates, predicts, potential, or continue or the negative of these terms or other compar terminology.

These forward-looking statements are based on our current expectations, but 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 factors that could cause our actual future results to differ materially from current expectations include, but are not limited to: we may not be successful in growing demand for and increasing revenues from our existing products and services; our products and services may not meet customer expectations and demands; we may not be successful in developing new products and/or services based on our technology on a timely basis, or at all; we may not successfully complete the contracts and recognize the revenue represented by the contracts included in our previously reported total contract bookings; we may not be successful in securing additional contracted collaborative relationships; the final results of our preclinical studies, which may be different from results obtained in our prior studies or interim preclinical data results, may not support further clinical development of our therapeutic tissues; we may not be successful in securing the additional funds required to support our long-term development plans; we may not successfully protect our intellectual property; and the risk of further adjustments to our select preliminary financial results for the fiscal second quarter of 2017. These factors and other considerations are described in greater detail in the Risk Factors section of this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein. You should consider these Risk Factors, as well as any Risk Factors that we include in our future filings with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, incorporated by reference into this prospectus supplement and the accompanying 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.

As a result, you should not place undue reliance on these forward-looking statements, which speak only as of the date that they were made. The cautionary statements made in this prospectus regarding forward-looking 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 the forward-looking statements to conform to actual results or later events or circumstances or to reflect the occurrence of unanticipated events. Thus, you should not assume that our silence over time means that actual events are bearing out

as expressed or implied in such forward-looking statements.

You should read this prospectus supplement, the accompanying prospectus, the documents we have filed with the SEC that are incorporated by reference and any free writing prospectus that we have authorized for use in connection with this offering completely and with the understanding that our actual future results may be materially different from what we currently expect. We qualify all of the forward-looking statements in the foregoing documents by these cautionary statements.

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USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately $ million, or approximately $ million if the underwriters exercise in full their option to purchase additional shares of common stock, after deducting underwriting discounts and commissions and offering expenses payable by us.

We intend to use the net proceeds from this offering for general corporate purposes, including research and development, the development and commercialization of our products, general administrative expenses, and working capital and capital expenditures. We may also use the net proceeds to invest in or acquire complementary businesses, products or technologies, although we have no current commitments or agreements with respect to any such investments or acquisitions as of the date of this prospectus supplement.

We have not determined the amounts we plan to spend on any of the areas listed above or the timing of these expenditures. As a result, our management will have broad discretion to allocate the net proceeds from this offering. Pending application of the net proceeds as described above, we intend to invest the net proceeds of the offering in short-term, investment-grade, interest-bearing securities.

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DIVIDEND POLICY

We have never declared or paid any dividends on our common stock and do not anticipate paying any in the foreseeable future. We currently intend to retain all of our future earnings, if any, to finance the operation and expansion of our business. Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including future earnings, capital requirements, financial conditions, future prospects, contractual restrictions and covenants and other factors that our board of directors may deem relevant.

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DILUTION

Our net tangible book value as of June 30, 2016 was approximately $53.7 million, or $0.58 per share of common stock. If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the public offering price per share and our pro forma net tangible book value per share after this offering. We calculate net tangible book value per share by dividing our net tangible book value, which is tangible assets less total liabilities, by the number of outstanding shares of our common stock.

After giving effect to the sale of shares of our common stock at the public offering price of $ per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of June 30, 2016 would have been approximately $ million, or $ per share. This represents an immediate increase in net tangible book value of $ per share to existing stockholders and immediate dilution in net tangible book value of $ per share to new investors participating in this offering at the public offering price. The following table illustrates this dilution on a per share basis:

Public offering price per share		$
Net tangible book value per share as June 30, 2016	$ 0.58	
Increase per share attributable to investors purchasing our common stock in this offering	$	
As adjusted net tangible book value per share as of June 30, 2016, after giving effect to this offering		$
Dilution in net tangible book value per share to investors purchasing our common stock in this offering		$

The information above assumes that the underwriters do not exercise their option to purchase additional shares. If the underwriters exercise their option to purchase additional shares in full at the public offering price of $ per share, the as adjusted net tangible book value would increase to approximately $ million, or $ per share, representing an increase to existing stockholders of approximately $ per share, and there would be an immediate dilution of approximately $ per share to new investors.

The dilution table above is based on 92,389,730 shares of common stock outstanding as of June 30, 2016 and excludes the following as of such date:

- 10,008,297 shares of common stock issuable upon the exercise of outstanding stock options, having a weighted average exercise price of $4.72 per share;

- 1,046,813 shares of our common stock issuable upon the exercise of outstanding warrants with a weighted average exercise price of $2.29 per share;

- 519,850 shares of our common stock issuable upon vesting and settlement of restricted stock units; and

- 5,575,475 shares available for issuance pursuant to the 2012 Equity Incentive Plan.

Additionally, the dilution table above does not reflect certain issuances and actions that occurred after June 30, 2016 and during the quarter ended September 30, 2016, including (i) the issuance and sale of 997,181 shares of our common stock pursuant to our at-the-market sales program, at a weighted average price of $4.67 per share, (ii) the issuance of restricted stock units for 645,900 shares of our common stock pursuant to our 2012 Equity Incentive Plan, (iii) the issuance of stock options exercisable for 1,386,500 shares of our common stock pursuant to our 2012 Equity Incentive Plan, at a weighted average exercise price of $4.04 per share and (iv) 1,500,000 shares of common stock that were authorized and reserved for issuance by our board of directors and stockholders pursuant to our newly adopted 2016 Employee Stock Purchase Plan.

To the extent stock options, warrants or restricted stock units outstanding as of June 30, 2016 or issued after such date have been or may be exercised or settled, or other shares have been issued, including the shares issued pursuant to our at-the-market sales program, there may be further dilution to investors. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

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UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated October , 2016, between us and Jefferies LLC, as the representative of the underwriters named below, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of shares of common stock shown opposite its name below:

UNDERWRITERS	NUMBER OF SHARES
Jefferies LLC	
Evercore Group L.L.C.	
Raymond James & Associates, Inc.	
BTIG, LLC	
Total	

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commission and Expenses

The underwriters have advised us that they propose to offer the shares of common stock to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of $ per share of common stock. The underwriters may allow, and certain dealers may reallow, a discount from the concession not in excess of $ per share of common stock to certain brokers and dealers. After the offering, the initial public offering price, concession and reallowance to dealers may be reduced by the representative. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

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The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters option to purchase additional shares.

	PER SHARE	TOTAL