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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Fiscal Year Ended March 31, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Transition Period from _____to _____

Commission File No. 001-35996

ORGANOVO HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**27-1488943**
(State or other jurisdiction of incorporation or organization)	*(IRS Employer Identification No.)*
440 Stevens Ave, Suite 200 **Solana Beach, CA** *(Address of principal executive offices)*	**92075** *(Zip code)*

Registrant's telephone number, including area code: 858-224-1000

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.001 per share	ONVO	The Nasdaq Capital Market

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "accelerated filer", "large accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates based on the closing stock price as reported on the Nasdaq Global Market on September 30, 2019, the last trading day of the registrant's second fiscal quarter, was $29,234,151. For purposes of this computation only, shares of common stock held by each executive officer, director, and 10% or greater stockholders have been excluded in that such persons may be deemed affiliates.

The number of outstanding shares of the registrant's common stock, as of May 1, 2020 was 130,558,098.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required for Part III of this report is incorporated herein by reference to the definitive proxy statement for the 2020 annual meeting of the registrant's stockholders, expected to be filed within 120 days of the end of the registrant's fiscal year.

Organovo Holdings, Inc.

Annual Report on Form 10-K

For the Year Ended March 31, 2020

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Important Information Regarding Forward-Looking Statements

Portions of this Annual Report on Form 10-K (including information incorporated by reference) ("Annual Report") include "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995, based on our current beliefs, expectations and projections regarding any strategic transaction process; negative effects on our business due to COVID-19; the ability to advance, if we elect to do so, our research and development activities and pursue development of any of our pipeline products; our technology: our product and service development opportunities and timelines: our business strategies: customer acceptance and the market potential of our technology: products and services: our future capital requirements: our future financial performance: and other matters. This includes, in particular, Item 1. "Business" and Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report, as well as other portions of this Annual Report. The words "believe," "expect," "anticipate," "project," "could," "would," and similar expressions, among others, generally identify "forward-looking statements," which speak only as of the date the statements were made. The matters discussed in these forward-looking statements are subject to risks, uncertainties and other factors that could cause our actual results to differ materially from those projected, anticipated or implied in the forward-looking statements. As a result, you should not place undue reliance on any forward-looking statements. The most significant of these risks, uncertainties and other factors are described in Item 1A. "Risk Factors" of this Annual Report. Except to the limited extent required by applicable law, we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I

Item 1. Business.

Overview

Organovo Holdings, Inc. ("Organovo Holdings," "we," "us," "our," "the Company" and "our Company") is an early-stage biotechnology company that has historically focused on pioneering the development of bioprinted human tissues that emulate key aspects of human biology and disease. We have focused on developing our *in vivo* liver tissues to treat end-stage liver disease and a select group of life-threatening, orphan diseases, for which there are limited treatment options other than organ transplantation. We have also explored the development of other potential pipeline *in vivo* tissue constructs in-house and through collaborations with academic and government researchers. Our current limited operations comprise of managing certain collaborations with research institutions and universities with respect to our NovoGen Bioprinters® for research purposes. Our NovoGen Bioprinters® are automated devices that enable the fabrication of 3D living tissues comprised of mammalian cells. We believe that the use of our bioprinting platform by major research institutions may help to advance the capabilities of the platform and generate new applications for bioprinted tissues. In some instances, an academic institution or other third party has provided funding to support the academic collaborator's access to our technology platform. This funding is typically reflected as collaboration revenues in our financial statements. However, we are not currently generating any revenues from these collaborations. Our research collaborations typically involve both us and the academic partner contributing resources directly to projects, but also involves sponsored research agreements where we fund specific research programs. We also continue to retain certain key management, employees and consultants, our core intellectual property and licenses, and proprietary equipment.

Strategic Alternatives Process

In August 2018, following a pre-pre-Investigational New Drug ("IND") application meeting with the Food and Drug Administration (the "FDA") regarding our lead liver therapeutic candidate, we announced that we were concentrating our financial resources around supporting our healthy liver therapeutic tissue development, and that we would continue to opportunistically generate revenue to support our therapeutics program by leveraging our cell and *in vitro* tissue platform including providing funded access to our developmental *in vitro* liver tissue platform to clients for their own R&D programs.

In August 2019, after a rigorous assessment of our liver therapeutic tissue program, we concluded that the variability of biological performance and related duration of potential benefits no longer supported an attractive opportunity due to redevelopment challenges and lengthening timelines to compile sufficient data to support an IND filing. As a result, we suspended development of our lead program and all other related in-house pipeline development activities. Our board of directors also engaged a financial advisory firm to explore our available strategic alternatives, including evaluating a range of ways to generate value from our technology platform and intellectual property, our commercial and development capabilities, our listing on The Nasdaq Capital Market, and our remaining financial assets. These strategic alternatives included possible mergers and business combinations, sales of part or all of our assets, and licensing and partnering arrangements. We implemented various restructuring steps to manage our resources and extend our cash runway, including reducing commercial activities related to our liver tissues, except for sales of primary human cells out of inventory, negotiating an exit from our long-term facility lease, selling various assets, and reducing our workforce. Additionally, in November 2019, we sold certain inventory and equipment and related proprietary information held by our wholly-owned subsidiary, Samsara Sciences, Inc. ("Samsara"), and as a result of such sale, Samsara ceased its operations.

After conducting a diligent and extensive process of evaluating strategic alternatives and identifying and reviewing potential candidates for a strategic acquisition or other transaction, which included the receipt of more than 27 non-binding indications of interest from interested parties and careful evaluation and consideration of those proposals, and following extensive negotiation with Tarveda Therapeutics, Inc. ("Tarveda"), on December 13, 2019, we entered into a merger agreement with Tarveda (the "Merger Agreement"). Pursuant to the Merger Agreement, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, our wholly-owned merger subsidiary would merge (the "Merger") into Tarveda, with Tarveda surviving the Merger. The Merger Agreement included various conditions to the consummation of the Merger, including approval by our stockholders at a special meeting of stockholders (the "Special Meeting").

On April 7, 2020 at the Special Meeting, the Merger was not approved by our stockholders. As a result, we are currently reconsidering our strategic alternatives and may pursue one of the following courses of action, which include but are not limited to the following actions:

- Pursue another strategic transaction similar to the Merger. We may resume our process of evaluating other candidate companies interested in pursuing a strategic transaction and, if a candidate is identified, focus our attention on negotiating and completing such strategic transaction with such candidate.

- Continue to operate and expand our business. We could elect to continue to operate and expand our business and pursue licensing or partnering transactions or utilize our intellectual property and platform technology to pursue the redevelopment of our liver tissues or the development of therapeutic tissues currently being studied by our collaborators. Due to the early development stage of our, and our collaborators', potential therapeutic tissues, any such redevelopment or development efforts would require a significant amount of time and financial resources, and would be subject to all the risk and uncertainties involved in the development of novel, early stage therapeutic products, research tools, and drug screening technologies. There is no assurance that we could raise sufficient capital to support these efforts, that our development efforts would be successful commercially in the case of research applications or that we could successfully obtain any required regulatory approvals required to market any therapeutic product we pursue. We would also need to increase qualified scientific, sales and marketing, and administrative staffing, lease a suitable facility and make other expenditures necessary to support these efforts.

- Dissolve and liquidate our assets. If we are unable, or do not believe that we will be able, to find a suitable candidate for another strategic transaction or continue to operate our business, we may dissolve and liquidate our assets, subject to approval by our stockholders. In that event, we would be required to pay all of our debts and contractual obligations and to set aside certain reserves for potential future claims. If we dissolve and liquidate our assets, there can be no assurance as to the amount or timing of available cash that will remain for distribution to our stockholders after paying our debts and other obligations and setting aside funds for our contingent liabilities.

Our Platform Technology

Our 3D human tissue platform is enabled by our proprietary NovoGen Bioprinters® and related technologies for preparing bio-inks and bioprinting multicellular tissues with complex architecture. Our foundational proprietary technology, grounded in over a decade of peer-reviewed scientific publications, derives from research led by Dr. Gabor Forgacs, one of our founders and a former George H. Vineyard Professor of Biological Physics at the University of Missouri-Columbia ("MU"). We have a broad portfolio of intellectual property rights covering the principles, enabling instrumentation, applications, and methods of cell-based printing, including exclusive licenses to certain patented and patent pending technologies from MU and Clemson University. We own more than 100 patents and pending applications worldwide covering specific tissue designs, uses, and methods of manufacture.

The NovoGen Bioprinter® Platform

Our NovoGen Bioprinters® are automated devices that enable the fabrication of 3D living tissues comprised of mammalian cells. A custom graphic user interface GUI facilitates the 3D design and execution of scripts that direct precision movement of multiple dispensing heads to deposit defined cellular building blocks called bio-ink. Bio-ink can be formulated as a 100% cellular composition or as a mixture of cells and other matter (hydrogels, particles). Our NovoGen Bioprinters® can also dispense pure hydrogel formulations, provided the physical properties of the hydrogel are compatible with the dispensing parameters. Most typically, hydrogels are deployed to create void spaces within specific locations in a 3D tissue or to aid in the deposition of specific cell types. We are able to employ a wide variety of proprietary cell- and hydrogel-based bio-inks in the fabrication of tissues. Our NovoGen Bioprinters® also serve as important components of our tissue prototyping and manufacturing platform, as they are able to rapidly and precisely fabricate intricate small-scale tissue models for *in vitro* use as well as larger-scale tissues suitable for *in vivo* use.

Generation of bio-ink comprising human cells is the first step in our standard bioprinting. A wide variety of cells and cell-laden hydrogels can be formulated into bio-ink and bioprinted tissues, including cell lines, primary cells, and stem/progenitor cells. The majority of tissue designs employ two or more distinct varieties of bio-ink, usually comprised of cells that represent distinct compartments within a target tissue. For example, a 3D liver tissue might consist of two to three distinct bio-inks that are each made from a single cell type, a combination of cell types, and/or a combination of primary cells and one or more bio-inert hydrogels that serve as physical supports for the bioprinted tissue during its maturation period, or to transiently occupy negative spaces in a tissue design.

Research Collaborations

We continue to collaborate with several academic institutions by providing them with access to our NovoGen Bioprinters® for research purposes, including: Yale School of Medicine, University of California, San Francisco, Knight Cancer Institute at Oregon Health & Science University, and the University of Virginia. We believe that the use of our bioprinting platform by major research institutions may help to advance the capabilities of the platform and generate new applications for bioprinted tissues. In some instances, an academic institution or other third party has provided funding to support the academic collaborator's access to our technology platform. This funding is typically reflected as collaboration revenues in our financial statements. Our research collaborations typically involve both us and the academic partner contributing resources directly to projects, but also involves sponsored research agreements where we fund specific research programs. We are not currently generating any revenues from these collaborations.

Intellectual Property

We rely on a combination of patents, trademarks, trade secrets, confidential know-how, copyrights and a variety of contractual mechanisms such as confidentiality, material transfer, licenses, research collaboration, limited technology access, and invention assignment agreements, to protect our intellectual property. Our intellectual property portfolio for our core technology was initially built through licenses from MU and the Medical University of South Carolina. We subsequently expanded our intellectual property portfolio by filing patent and trademark applications worldwide and negotiating additional licenses and purchases.

We solely own or hold exclusive licenses to 22 issued U.S. patents and more than 45 issued international patents in foreign jurisdictions including Australia, Canada, China, France, Great Britain, Germany, Hong Kong, Israel, Japan, South Korea, the Netherlands, Russia, Singapore and Switzerland. We solely or jointly own or hold exclusive licenses to 19 pending U.S. patent applications and more than 80 pending international applications in foreign jurisdictions including Australia, Canada, China, the European Patent Office, Hong Kong, India, Japan, South Korea and New Zealand. These patent families relate to our bioprinting technology and our engineered tissue products and services, including our various uses in areas of tissue creation, *in vitro* testing, utilization in drug discovery, and *in vivo* therapeutics.

In-Licensed Intellectual Property

In 2009 and 2010, we obtained world-wide exclusive licenses to intellectual property owned by MU and the Medical University of South Carolina, which now includes 6 issued U.S. patents, 2 pending U.S. applications, 16 issued international patents and 1 pending international application. Dr. Gabor Forgacs, one of our founders and a former George H. Vineyard Professor of Biophysics at MU, was one of the co-inventors of all of these works (collectively, the "**Forgacs Intellectual Property**"). The Forgacs Intellectual Property provides us with intellectual property rights relating to cellular aggregates, the use of cellular aggregates to create engineered tissues, and the use of cellular aggregates to create engineered tissue with no scaffold present. The intellectual property rights derived from the Forgacs Intellectual Property also enables us to utilize our NovoGen Bioprinter® to create engineered tissues.

In 2011, we obtained an exclusive license to a U.S. patent (U.S. Pat. No. 7,051,654) owned by the Clemson University Research Foundation that provides us with intellectual property rights relating to methods of using ink-jet printer technology to dispense cells and relating to the creation of matrices of bioprinted cells on gel materials.

In 2015, we obtained world-wide exclusive licenses to intellectual property owned by The University of Queensland (collectively, "**UniQuest Intellectual Property**") relating to technologies for producing kidney cells and kidney organoids from induced pluripotent stem cells ("iPSCs"). At the time, Professor Melissa Little and her team at The University of Queensland developed a method of growing kidney tissue from iPSCs for potential use in drug screening, disease modeling and cell therapy. Professor Little's research was eventually published in 2015 in the prestigious scientific journal *Nature*. Currently, the UniQuest Intellectual Property includes 2 pending U.S. patent applications, 2 issued international patents and 15 pending international patent applications.

The patent rights we obtained through these exclusive licenses are not only foundational within the field of 3D bioprinting but provide us with favorable priority dates. We are required to make ongoing royalty payments under these exclusive licenses based on net sales of products and services that rely on the intellectual property we in-licensed. For additional information regarding our royalty obligations see "Note 4. Licensing Agreements and Research Contracts" in the Notes to Consolidated Financial Statements included in this Annual Report.

Company Owned Intellectual Property

In addition to the intellectual property we have in-licensed, we have historically innovated and grown our intellectual property portfolio.

With respect to our bioprinting platform, we have 7 issued U.S. patents and 13 issued foreign patents directed to our NovoGen Bioprinter® and methods of bioprinting: U.S. Patent Nos. 8,931,880; 9,149,952; 9,227,339; 9,315,043; 9,499,779; 9,855,369; and 10,174,276; Australia Patent Nos. 2011318437, 2015202836, 2016253591, and 2013249569; China Patent Nos. ZL201180050831.4 and ZL201480054148.1; European Patent No. 2838985; Hong Kong Patent No. HK1187024; Israel Patent No. 225392; Japan Patent Nos. 6333231 and 6566426; Russia Patent No. 2,560,393; Singapore Patent No. 11201600770R. We have additional U.S. continuation applications pending in these families as well foreign counterpart applications in multiple countries.

Our ExVive™ Human Liver Tissue is protected by U.S. Patent Nos. 9,222,932, 9,442,105 and 10,400,219; Singapore Patent No. 11201507202Y; Israel Patent No. 241055; Australia Patent Nos. 2014236780 and 2017200691; Canada Patent No. 2,903,844; Russia Patent No. 2625016; and China Patent No. 201480028365.3. Our ExVive™ Human Kidney Tissue is protected by U.S. Patent Nos. 9,481,868 and 10,094,821; and European Patent No. 3204488. We have additional U.S. patent applications pending in these families, as well as foreign counterpart applications in multiple countries. We currently have pending numerous patent applications in the U.S. and globally that are directed to additional tissue types, their methods of fabrication, and specific applications.

Additionally, in 2013, we purchased the exclusive rights to "Perfusion Bioreactors for Culturing Cells" (U.S. Patent No. 7,767,446, Japan Patent No. 4,914,835, and Australia Patent No. 2,005,287,162) from Becton Dickinson and Company. This patent represents the acquisition of bioreactor technology for the support of our 3D tissues for use in drug discovery and development.

COVID-19

In December 2019 a respiratory illness caused by a novel strain of coronavirus, SARS-CoV-2, causing the Coronavirus Disease 2019, also known as COVID-19 or coronavirus emerged. While initially the outbreak was largely concentrated in China it has spread globally. Global health concerns relating to the COVID-19 pandemic have been weighing on the macroeconomic environment, and the pandemic has significantly increased economic volatility and uncertainty. The pandemic has resulted in government authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns.

The extent to which COVID-19 impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak and travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns. In particular, the continued COVID-19 pandemic could adversely impact our operations, including among others, the timing and ability to pursue strategic alternatives, given the impact it may have on the manufacturing and supply chain, sales and marketing and clinical trial operations of potential strategic partners, and the ability, if we elect to do so, to advance our research and development activities and pursue development of any of our pipeline products, each of which could have an adverse impact on our business and our financial results. However, our employees and consultants have been working remotely prior to the COVID-19 pandemic and we currently believe our operations have not otherwise been negatively impacted by the pandemic.

Employees

As of May 1, 2020, we had 6 employees, all of which were full-time. We have also retained 10 of our former employees as consultants.

Corporate Information

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 Stock Market under the symbol "ONVO" since August 8, 2016 and we currently trade on The Nasdaq Capital Market. 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 principal executive offices are located at 440 Stevens Ave, Suite 200, Solana Beach, CA 92075 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 Annual Report.

Available Information

Our investor relations website is located at http://ir.organovo.com. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Reports filed with the Securities and Exchange Commission (the "SEC") pursuant to the Exchange Act, including annual and quarterly reports, and other reports we file, are available free of charge, through our website. The content of our website is not intended to be incorporated by reference into this report or in any other report or document that we file. We make them available on our website as soon as reasonably possible after we file them with the SEC. The reports we file with the SEC are also available on the SEC's website (http://www.sec.gov).

Item 1A. Risk Factors.

Investment in our common stock involves a substantial degree of risk and should be regarded as speculative. As a result, the purchase of our common stock should be considered only by persons who can reasonably afford to lose their entire investment. Before you elect to purchase our common stock, you should carefully consider the risk and uncertainties described below in addition to the other information incorporated herein by reference. Additional risks and uncertainties of which we are unaware or which we currently believe are immaterial could also materially adversely affect our business, financial condition or results of operations. If any of the risks or uncertainties discussed in this Annual Report occur, our business, prospects, liquidity, financial condition and results of operations could be materially and adversely affected, in which case the trading price of our common stock could decline, and you could lose all or part of your investment.

Risks Related to COVID-19

We face risks related to health epidemics, including the recent COVID-19 pandemic, which could have a material adverse effect on our business and results of operations.

In December 2019 a respiratory illness caused by a novel strain of coronavirus, SARS-CoV-2, causing the Coronavirus Disease 2019, also known as COVID-19 or coronavirus emerged. While initially the outbreak was largely concentrated in China it has spread globally. Global health concerns relating to the COVID-19 pandemic have been weighing on the macroeconomic environment, and the pandemic has significantly increased economic volatility and uncertainty. The pandemic has resulted in government authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns. The extent to which the coronavirus impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak and travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns. The continued COVID-19 pandemic could adversely impact our operations, including among others, the timing and ability to pursue strategic alternatives, given the impact it may have on the manufacturing and supply chain, sales and marketing and clinical trial operations of potential strategic partners, and the ability, if we elect to do so, to advance our research and development activities and pursue development of any of our pipeline products, each of which could have an adverse impact on our business and our financial results.

In addition, the stock market has been unusually volatile during the COVID-19 pandemic and such volatility may continue. Our stock price has also experienced volatility during this time, including occasional significant increases and decreases, and such increases and decreases may repeat or continue for the foreseeable future.

There are no comparable recent events which may provide guidance as to the effect of the COVID-19 pandemic, and, as a result, the ultimate impact of the pandemic, or any similar health epidemic that may occur in the future, is highly uncertain and subject to change. We do not yet know the full extent of COVID-19's impact on our business, our operations, or the global economy as a whole. However, the effects may have a material adverse impact on our future results of operations.

Risks Related to a Strategic Transaction Process

We may be unsuccessful in completing an alternative strategic transaction on terms that are favorable, or at all, and we may be unable to establish a viable operating business.

On April 7, 2020 our stockholders voted against the proposed Merger with Tarveda. As a result, we may be subject to a number of material risks, and our business and stock price could be adversely affected, as follows:

- We have incurred significant expenses related to the proposed Merger with Tarveda, and expect to continue to incur additional significant expenses in order to potentially execute a transaction with an alternative strategic partner; and

- Our common stock could be delisted from The Nasdaq Capital Market, which could have an adverse effect on the value of our common stock and any future ability to raise capital.

To date, we currently have limited business operations and our assets currently consist primarily of cash, cash equivalents and marketable securities, our intellectual property portfolio, license and collaboration agreements and our listing on The Nasdaq Capital Market. Given the failure to obtain stockholder approval to consummate the Merger with Tarveda, our board of directors may elect to pursue an alternative strategic transaction similar to the proposed Merger with Tarveda. We have incurred significant expenses related to the proposed Merger with Tarveda and attempting to complete an alternative transaction will require significant costs and be time consuming. If our board of directors determines to pursue an alternative transaction, the terms of any such alternative transaction may not be favorable to us and our stockholders, and we can make no assurances that such an alternative transaction would occur at all. Given the level of investment and time that would be required to redesign our liver tissue product or pursue the development of products and services pursuant to our collaboration agreements, it is unlikely that we would be able to obtain the funding required to recommence our product development activities on terms favorable to our stockholders, or at all.

Risks Related to our Business

The development of new biopharmaceutical products involves a lengthy and complex process.

We previously focused the majority of our resources on the development of our liver tissue candidate. In addition to our liver tissue candidate, we conducted initial research and development activities on several other tissue candidates. Each of our therapeutic tissue candidates were in the early stages of research and development and would have required substantial financial resources, development, preclinical testing, clinical trials, manufacturing scale-up and regulatory approval prior to being ready for sale. If we decide to renew our focus on developing our liver tissue candidate and expend funds for such development, this process could take many years of effort without any assurance of ultimate success. Product development efforts with respect to a tissue candidate could fail for many reasons, including:

- the failure of the tissue candidate in preclinical or clinical studies, including failing to demonstrate sufficient durability and functionality to support further development activities;
- the inability to satisfy the regulatory requirements to successfully submit an IND with the FDA;
- adverse patient reactions to the tissue candidate or indications of other safety concerns;
- insufficient clinical trial data to support the effectiveness or superiority of the tissue candidate;
- inability to manufacture sufficient quantities of the tissue candidate for development, clinical, or commercialization activities in a timely and cost-efficient manner;
- failure to obtain, or delays in obtaining, the required regulatory approvals for the tissue candidate, the facilities or the process used to manufacture the tissue candidate;
- changes in the regulatory environment, including pricing and reimbursement, that make development of a new product or of an existing product for a new indication no longer attractive;
- the failure to obtain or maintain satisfactory drug reimbursement rates by governmental or third-party payers; and
- the development of a competitive product or therapy.

The 3D bioprinted tissue candidates that we were developing represent new therapeutic approaches that could be subject to heightened regulatory scrutiny, delays in clinical development and/or delays in achieving the regulatory approvals required for commercialization.

Our liver tissue candidate represented a new approach to treating liver disease, inborn errors of metabolism, and other diseases. Similarly, our other early stage therapeutic tissue candidates represented new therapeutic approaches in their respective disease areas. However, we were unable to achieve satisfactory results with the liver tissue candidate which we were developing. As a result, the development of these therapeutic tissue candidates would be subject to a number of challenges, including:

- obtaining regulatory approval from the FDA and other regulatory authorities, which have limited experience with regulating the development and commercialization of 3D bioprinted human tissues developing and deploying consistent and reliable processes for manufacturing 3D bioprinted tissues for implantation into patients;
- utilizing these tissue candidates in combination with other therapies, which may increase the risk of adverse side effects;
- developing processes for the safe administration of these tissues, including long-term follow-up for all patients who receive these tissue candidates;
- sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process these tissue candidates that are free from viruses and other pathogens that may increase the risk of adverse side effects;
- developing a manufacturing process and distribution network that can provide a stable supply with a cost of goods that allows for an attractive return on investment;

- qualifying, engaging, and training clinical trial investigators and institutions who will be able to implement the institutionally-approved protocols, recruit and treat patients, and generate data in accordance with targeted goals and timelines; and

- establishing sales and marketing capabilities after obtaining any regulatory approval to gain market acceptance, and obtaining adequate coverage, reimbursement and pricing by third-party payors and government authorities.

The regulatory approval process for novel tissue candidates, such as our therapeutic tissue candidates, can be more expensive and take longer than for other, better known or extensively studied product candidates.

Further, the manufacturing processes we would be required to use in connection with our therapeutic tissue candidates may not yield a sufficient supply of satisfactory products that are safe, effective, scalable, or profitable.

Moreover, actual or perceived safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved, of physicians to subscribe to the novel treatment options.

Physicians, hospitals and third-party payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Physicians may not be willing to undergo training to adopt novel therapies, may decide the therapy is too complex to adopt without appropriate training and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of a new therapy do not or will not outweigh its costs.

We have not yet tested any bioprinted therapeutic tissue candidates in clinical trials. Results in early preclinical studies may not be indicative of results obtained in later preclinical studies. Similarly, results from early clinical trials may not be indicative of results obtained in later clinical trials.

Our tissue candidates involve novel technologies and have never been evaluated in clinical trials. It is unknown how translatable the preclinical animal models used in our preclinical studies are to humans. If we elect to resume the development of our therapeutic tissues, we would be required to demonstrate through adequate and well-controlled clinical trials that our tissue candidates are safe and effective, with a favorable risk-benefit profile, for use in their target indications before we could have sought regulatory approvals for their commercial sale. Initial positive results we have observed for our tissue candidates in preclinical animal models may not be predictive of results from our later preclinical trial results, nor of results from future clinical trials in humans. For example, in May 2019, we announced that data generated from a larger group of animal studies differed from our earlier pilot studies and put into question the durability and functionality of our liver tissue candidate. In August 2019, we announced our decision to stop pursuing the development of our liver tissue candidate following our completion of additional studies that did not resolve the durability and functionality issues we had identified. We also announced that as a result of these adverse study results, our board of directors determined that it is in the best interests of our stockholders to explore our available strategic alternatives, rather than to continue to pursue our therapeutic liver tissue and other early stage development projects.

Our experience manufacturing therapeutic tissues is limited. We believe that manufacturing issues, including technical or quality issues or issues, contributed to the viability and functionality issues with our liver tissue candidate, and our ultimate decision to stop the development of this tissue. There is no assurance that we can solve these and any future manufacturing issues.

Before initiating a clinical trial or commercializing any of our tissue candidates, we would have been required to demonstrate to the FDA that the chemistry, manufacturing and controls for our tissue products meet applicable requirements. Because no bioprinted tissue product has been approved in the United States, there is no manufacturing facility that has demonstrated the ability to comply with FDA requirements, and therefore the timeframe and requirements for demonstrating compliance to the FDA's satisfaction is uncertain.

Bioprinted tissue manufacturing is an emerging industry. To our knowledge, there are no contract manufacturing organizations with experience in manufacturing bioprinted tissue products under GMP conditions. We have conducted all of our manufacturing internally.

We conducted all of our research in research facilities and we were in the process of implementing applicable FDA manufacturing requirements. However, we have limited experience as a company in developing a manufacturing facility that meets all applicable GMP requirements, and we may never have been successful in developing our own manufacturing facility.

Manufacturing our therapeutic tissue candidates is complicated and presents novel technical challenges. We believe that manufacturing issues, including technical or quality issues, contributed to the viability and functionality issues with our liver tissue candidate, and our ultimate decision to stop the development of this tissue. If we elect to resume the development of our therapeutic tissues, we may encounter problems achieving adequate quantities and quality of clinical-grade materials to conduct our clinical trials, or to meet FDA, European Medicines Agency or other applicable standards or specifications with consistent and acceptable production yields and costs.

We have not scaled up the manufacturing process for our therapeutic liver tissue beyond the scale used for research and nonclinical studies. The time and efforts required for us to develop and validate our manufacturing process to support clinical use would potentially delay our ability to develop this program in accordance with our expected timelines.

In order to manufacture and supply any of our tissue candidates on a commercial scale in the future, we would be required to bolster our quality control and quality assurance capabilities, including by augmenting our manufacturing processes and adding personnel. We may encounter problems hiring and retaining the experienced specialist scientific and manufacturing personnel needed to operate our manufacturing process, which could result in additional delays in our production or difficulties in maintaining compliance with applicable regulatory requirements. Further, if we engage in scale-up manufacturing of any approved product, we may encounter unexpected issues relating to the manufacturing processes, donor variability, or the quality, purity or stability of the product, and we may be required to refine or alter our manufacturing processes to address these issues. Resolving these issues could result in significant additional delays and result in significantly increased costs.

Further, any unresolved problems in our manufacturing process could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our ability to successfully enter into a strategic partnership or collaboration related to, or otherwise license or sell the assets or intellectual property associated with, our *in vivo* therapeutic tissues and manufacturing technologies on favorable terms, or at all.

We obtained our clinical grade livers from a single source, and if we elect to resume the development of our therapeutic liver tissue, we will need to reestablish a commercial source for our clinical grade livers or isolated cells to support our clinical trials and/or commercialization.

Our liver tissue candidate was manufactured using human primary liver cells from non-transplantable livers we receive from the International Institute for the Advancement of Medicine. We relied upon this single source to obtain the clinical grade non-transplantable livers that served as the starting materials for manufacturing the liver cells we used in our therapeutic liver tissue. The availability and quality of clinical grade livers may be sporadic and unpredictable. As a result, if we elect to renew our focus on development of our therapeutics tissues, we will need to reestablish a commercial source for our clinical grade livers or isolated cells to supply our clinical program or meet commercial demand, and our development plans may be delayed or stalled, which would significantly harm our business. In addition, in order to preserve resources, we discontinued our ability to isolate liver cells from donated organs by restructuring our operations and dissolving our Samsara subsidiary. In order to recommence isolating liver cells from donated organs, we would need to reestablish the access to cell isolation capabilities either through an external collaboration or internally, which could require significant time and financial resources.

Our liver tissue candidate included primary cells from two donors. If the FDA did not authorize us to include cells from more than one donor, our development timeline would be delayed.

Our NovoTissues Liver product was manufactured using cells from a liver donor and cells from an umbilical cord donor. Under 21 CFR §1271, cells from more than one donor cannot be combined in the manufacturing process absent a waiver from the FDA. We applied to the FDA for a waiver authorizing us to include cells from two donors in manufacturing our therapeutic liver tissue for clinical trials. As a result, even if we elected to resume the development of our therapeutic liver tissues, we would be required to redesign our therapeutic liver tissue unless we received a waiver from the FDA. This decision by the FDA could result in additional development costs and a delay in our development timeline, in which case our business would be materially harmed.

If we elect to resume the development of our therapeutic tissues, we may not enjoy the market exclusivity benefits of any orphan drug designation.

Under the Orphan Drug Act, the first product with an orphan drug designation receives market exclusivity, which prohibits the FDA from approving the "same" drug for the same indication. The FDA has stated that drugs can be the "same" even when they are not identical, but has not provided guidance with respect to how it will determine "sameness" in the context of 3D bioprinted tissues. If we elected to continue to pursue the development of our therapeutic tissues, it could be possible that another bioprinted therapeutic tissue product could be approved for the treatment of a disease one of our orphan products is intended to treat before our product is approved, which means that we would not obtain orphan drug exclusivity and could also potentially be blocked from approval until

the first product's orphan drug exclusivity for a product expires or until we demonstrated, if we could, that our product is superior. Further, if we obtained orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved and granted orphan drug exclusivity, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care.

If we elect to resume the development of our therapeutic tissues, a competitor may achieve regulatory approval before we do or develop therapies that are more advanced or effective than ours, which would harm our business and financial condition, and our ability to successfully market or commercialize any tissue candidates.

The biotechnology and pharmaceutical industries, including the fields of gene therapies, cellular therapies, and engineered tissue products, are characterized by rapid technological progress, competition, and a strong emphasis on intellectual property. We are aware of several companies focused on developing gene therapies and cellular therapies for use in treating end stage liver disease and/or inborn errors of metabolism. If we elect to resume the development of our therapeutic tissues, we may face competition from large or specialty pharmaceutical and biotechnology companies, academic research institutions, government agencies, and public and private research institutions.

Some of our potential competitors, alone or with their strategic partners, have greater financial, technical and other resources than we do, such as larger research and development, clinical, marketing and manufacturing organizations. Mergers and acquisitions in these industries may result in even greater concentration of resources among a smaller number of competitors. If we elect to resume the development of our therapeutic tissues, these competitors may obtain FDA or other regulatory approval for their products more rapidly than us, which could result in our competitors establishing a strong market position before we would be able to enter the market, if ever. Further, new or advanced technologies may render our tissue candidates uneconomical or obsolete. Our competitors could also develop products that are safer, more effective, have fewer or less side effects, or are more convenient or less expensive than any tissue candidates that we elected to develop.

If we elect to resume the development of our in vitro tissues business, such business would depend on new and unproven technology and approaches, and we may be unable to establish it as a profitable, standalone business.

Our *in vitro* products and services involve new and unproven models and approaches. We began offering our first commercial product (and related research services), our ExVive™ Human Liver Tissue, on a limited basis in April 2014 and more broadly in November 2014. We began offering our second product (and related research services), our ExVive™ Human Kidney Tissue, for predictive preclinical testing of drug compounds in September 2016. In May 2019, we announced plans to conduct additional preclinical studies necessary to optimize our manufacturing processes and complete additional preclinical studies that would generate consistent scientific data regarding the prolonged functionality and therapeutic benefits of our *in vivo* liver tissues. After a rigorous assessment of our liver therapeutic tissue program following completion of these additional studies, we concluded that the variability of biological performance and related duration of potential benefits presented development challenges and lengthy timelines that no longer supported an attractive opportunity. As a result, we suspended development of our lead program. We also suspended development of all other related pipeline development activity.

Our commercial products reflected a novel approach to preclinical testing of drug compounds and disease modeling, and even if we elect to resume the development of our products there is no assurance that they would perform as expected or as would be required by our customers. The commercial acceptance of, and the results of our efforts to increase customer awareness and demand for, our drug discovery and biological research tools, products and services, did not result in our development of a profitable, standalone business. In addition, we experienced that some of our customers continued to require unique features, cell sourcing, validation data, or greater degrees of reproducibility than we were able to achieve to date, in order to utilize our commercial products in their drug discovery, biological research or development programs. Even if we or our customers are successful in our respective efforts, we or our customers may not be able to discover or develop commercially viable therapeutics or other products therefrom. Based on these and other risks, there is no assurance that, if we elect to resume the development of our *in vitro* tissues business, that we would be successful in our efforts to advance the programs and commercialize our products.

The successful commercialization of our in vitro products and services is subject to a variety of risks.

If we elect to pursue the commercialization of our *in vitro* products and services, any such efforts would be subject to risks and uncertainties, including:

- failing to develop products or services that are effective, reproducible, and competitive;
- failing to demonstrate the commercial and technical viability of any products or services that we successfully develop, failing to meet customer expectations or requirements or otherwise failing to achieve market acceptance of such products or services;

- failing to be cost effective and timely;
- being unable to implement features or functionality required by customers;
- being difficult or impossible to manufacture on a large scale;
- being unable to establish and maintain supply and manufacturing relationships with reliable third parties;
- being unable to obtain a sufficient supply of human cells for our products, services and research and development activities on a timely basis and at acceptable quality levels and costs;
- failing to develop our products and services before the successful marketing of similar products and services by competitors;
- being unable to hire and retain qualified personnel; and
- infringing the proprietary rights of third parties or competing with superior products marketed by third parties.

If we elect to resume the development and commercialization of our *in vitro* products, any of these or any other risks and uncertainties could occur, our efforts to commercialize our *in vitro* products and services may be unsuccessful, which would harm our business and results of operations. Further, these risks may prevent us from successfully entering into a strategic partnership or collaboration related to, or otherwise license or sell the assets or intellectual property associated with, our *in vivo* therapeutic liver tissue on favorable terms, or at all. If we fail to do so, any strategic transaction we consummate may offer limited value for our business and proprietary technology and may not enhance stockholder value.

If we elect to resume the development and commercialization of our in vitro products, we would face intense competition which could result in reduced acceptance and demand for our in vitro products and services.

The biotechnology industry is subject to intense competition and rapid and significant technological change. There are many potential competitors for our *in vitro* products and services, 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 the following areas than we have, including:

- research and technology development;
- product identification and development;
- regulatory processes and approvals;
- production and manufacturing;
- securing government contracts and grants to support their research and development efforts;
- sales and marketing of products, services and technologies; and
- identifying and entering into agreements with potential collaborators.

Principal competitive factors in our industry include: the quality, scientific and technical support, price and breadth of technology and services; management and the execution of product development and commercialization strategies; skill and experience of employees, including the ability to recruit and retain skilled, experienced employees; intellectual property portfolio; range of capabilities, including product identification, development, regulatory approval, manufacturing and marketing; and the availability of substantial capital resources to fund these activities.

In order to effectively compete, we would need to make substantial investments in our research and technology development, product identification and development, testing and regulatory approval, manufacturing, customer awareness activities, publications of our technology and results in scientific publications and sales and marketing activities. If we elected to do so, there is no assurance that we would be successful in commercializing and gaining significant market share for any products or services we offer 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 competitors. Any of these risks may prevent us from successfully building a successful *in vitro* business or entering into a strategic partnership or collaboration related to, or otherwise license or sell the assets or intellectual property associated with, our *in vitro* business on favorable terms, or at all. If we fail to do so, any strategic transaction we consummate may offer limited value for our business and proprietary technology and may not enhance stockholder value.

If we elect to resume the development and commercialization of our in vitro products, we would require access to a constant, steady, reliable supply of human cells to successfully develop and commercialize our in vitro products and services.

If we elect to resume the development and commercialization of our *in vitro* products, we would require a reliable supply of qualified human cells for our commercial products and services and for our research and product development activities. We typically purchased certain qualified human cells from selected third-party suppliers based on quality assurance, cost effectiveness, and regulatory requirements. We formed our wholly-owned subsidiary, Samsara, to eventually serve as a key source of the primary human cells we utilized in our business and we recently dissolved Samsara in connection with pursuing the proposed Merger with Tarveda, which was not successful. We have relied on a combination of third-party suppliers and Samsara to meet our demand for human cells for our *in vitro* business. We worked closely with Samsara and our third-party suppliers to assure adequate supply while maintaining high quality and reliability. Following any resumption of the development and commercialization of our *in vitro* products and services, if demand for our products and services were to grow significantly, we would most likely need to identify additional sources of qualified human cells and there can be no guarantee that we would be able to access the quantity and quality of raw materials needed at a cost-effective price. In this event, any failure to obtain a reliable supply of sufficient human cells or a supply at cost effective prices would harm our business and our results of operations and could cause us to be unable to comply with the associated contractual obligations we would owe to our customers and collaboration partners.

Risks Related to Government Regulation

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 products are used in the manufacturing or testing processes for customers 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 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. Failure to comply with these requirements could result in lost sales of our products and regulatory delays or objections and potential product liability claims. In addition, customers may require that services be conducted pursuant to the requirements of Good Laboratory Practice (“GLP”) in order to provide suitable data for their INDs and other regulatory filings. No regulatory review of data from our platform technology has yet been conducted and there is no guarantee that our technology will be acceptable under GLP, or that compliance with GLP requirements could be achieved on the timetable required by customers. As a result, the violation of government regulations or failure to comply with quality requirements could harm demand for these products or services, and the evolving nature of government regulations could have an adverse impact on our ability to commercialize our products or services or sell the assets or intellectual property associated with these products and services on favorable terms, or at all. If we fail to do so, any strategic transaction we consummate may offer limited value for our existing business and proprietary technology and may not enhance stockholder value.

In the past, we have used hazardous chemicals, biological materials and infectious agents in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our product manufacturing, research and development, and testing activities have involved the controlled use of hazardous materials, including chemicals, biological materials and infectious disease agents. We cannot eliminate the risks of accidental contamination or the accidental spread or discharge of these materials, or any resulting injury from such an event. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed our insurance coverage and our total assets. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials and specified waste products, as well as the discharge of pollutants into the environment and human health and safety matters. We were also subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, and the experimental use of animals. Our operations may have required that environmental permits and approvals be issued by applicable government agencies. If we failed to comply with these requirements, we could incur substantial costs, including civil or criminal fines and penalties, clean-up costs or capital expenditures for control equipment or operational changes necessary to achieve and maintain compliance.

Risks Related to Our Capital Requirements, Finances and Operations

Our board of directors may decide to pursue a dissolution and liquidation of the Company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

Given our inability to obtain stockholder approval for the proposed Merger with Tarveda, our board of directors may decide to pursue a dissolution and liquidation of the Company, which would also require stockholder approval. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations, and the costs that would be incurred to effect such liquidation or dissolution. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of the Company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provisions for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our remaining cash assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of the Company. If a dissolution and liquidation were pursued, our board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of our liquidation, dissolution or winding up.

We may be unable to continue as a going concern in the future.

We have had recurring losses from operations since inception and will likely not generate meaningful revenue for the foreseeable future. We believe that our existing cash, cash equivalents and marketable securities and interest thereon will be sufficient to fund our projected operating requirements under our current operating plan. However, if our operating plans change and our projected operating requirements increase, we may be unable to continue as a going concern. In this event, the perception that we may not be able to continue as a going concern may have an adverse impact on our business due to concerns about our ability to meet our future contractual obligations or pursue additional strategic transactions. Further, if we are unable to continue as a going concern, we may have to liquidate our assets, and the values we receive for our assets in liquidation and dissolution could be significantly lower than the values reflected in our financial statements and an investor could lose all or part of its investment in our equity.

If we were to resume our research and development activities and pursue development of any of our pipeline products, we would require substantial additional funding. Raising additional capital would cause dilution to our existing stockholders and may restrict our operations or require us to relinquish rights to our technologies or to a product candidate.

We currently do not have any committed external source of funds and do not expect to generate any meaningful revenue in the foreseeable future. We believe that our existing cash, cash equivalents and marketable securities and interest thereon will be sufficient to fund our projected operating requirements under our current operating plan. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect if our operating plans change. If our current operating plans change and we decide to pursue further research and development activities, we will require substantial additional funding to operate our business, including to expand our facilities and hire additional qualified personnel, and would expect to finance these cash needs through a combination of equity offerings, debt financings, government or other third-party funding and licensing or collaboration arrangements.

To the extent that we raise additional capital through the sale of equity or convertible debt, the ownership interests of our stockholders will be diluted. In addition, the terms of any equity or convertible debt we agree to issue may include liquidation or other preferences that adversely affect the rights of our stockholders. Convertible debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, and declaring dividends, and may impose limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to curtail or cease our operations.

Given our failure to obtain stockholder approval for the proposed Merger with Tarveda, raising additional funding through debt or equity financing will be difficult or not successful at all, would be dilutive and may cause the market price of our common stock to decline further. Raising additional funding through debt or equity financing is likely to be difficult or unavailable altogether given the early stage of our therapeutic candidates. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline further and existing stockholders may not agree with our financing plans or the terms of such financings.

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

We have generated operating losses each year since we began operations, including $21.5 million and $27.3 million for the years ended March 31, 2020 and 2019, respectively. As of March 31, 2020, we had incurred cumulative operating losses of $229.9 million and cumulative net losses totaling $279.5 million. We expect to incur substantial additional operating losses over the next several years. To achieve profitability, we must either generate sufficient revenue through our *in vitro* tissues business to offset the costs of operating our business, or we must successfully develop and obtain regulatory approval for one or more of our therapeutic candidates and effectively market and sell any products we develop. Even if we are successful in commercializing a therapeutic product that receives regulatory approval, we may not be able to realize revenues at a level that would allow us to achieve or sustain profitability. We may never generate significant revenue, and even if we do generate significant revenue, we may never achieve profitability.

Our quarterly operating results may vary, which could negatively affect the market price of our common stock.

Our results of operations in any quarter may vary from quarter to quarter and are influenced by such factors as expenses related to:

- evaluating and implementing strategic alternatives, technology licensing opportunities, potential collaborations, and other strategic transactions;
- responding to the SEC inquiry;
- responding to shareholder demand letters; and
- changes in costs related to the COVID-19 pandemic or the general global economy.

We believe that operating results for any particular quarter are not necessarily a meaningful indication of future results. Nonetheless, fluctuations in our quarterly operating results could negatively affect the market price of our common stock.

Our business will be adversely impacted if we are unable to retain our executive officers and other key personnel.

Our future success will depend to a significant degree upon the continued contributions of our key personnel, especially our executive officers. We do not currently have long-term employment agreements with our executive officers or our other key personnel, and there is no guarantee that our executive officers or key personnel will remain employed with us. Moreover, we have not obtained key man life insurance that would provide us with proceeds in the event of the death, disability or incapacity of any of our executive officers or other key personnel. Further, the process of attracting and retaining suitable replacements for any executive officers and other key personnel we lose in the future would result in transition costs and would divert the attention of other members of our senior management from our existing operations. Additionally, such a loss could be negatively perceived in the capital markets.

We may be subject to security breaches or other cybersecurity incidents that could compromise our information and expose us to liability.

We routinely collect and store sensitive data (such as intellectual property, proprietary business information and personally identifiable information) for the Company, its employees and its suppliers and customers. We make significant efforts to maintain the security and integrity of our computer systems and networks and to protect this information. However, like other companies in our industry, our networks and infrastructure may be vulnerable to cyber-attacks or intrusions, including by computer hackers, foreign governments, foreign companies or competitors, or may be breached by employee error, malfeasance or other disruption. Any such breach could result in unauthorized access to (or disclosure of) sensitive, proprietary or confidential information of ours, our employees or our suppliers or customers, and/or loss or damage to our data. Any such unauthorized access, disclosure, or loss of information could cause competitive harm, result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and/or cause reputational harm.

Risks Related to Our Common Stock and Liquidity Risks

We could fail to maintain the listing of our common stock on The Nasdaq Capital Market, which could seriously harm the liquidity of our stock and our ability to raise capital or complete a strategic transaction.

The Nasdaq Stock Market LLC (“Nasdaq”) has established continued listing requirements, including a requirement to maintain a minimum closing bid price of at least $1 per share. If a company trades for 30 consecutive business days below such minimum closing bid price, it will receive a deficiency notice from Nasdaq. Assuming it is in compliance with the other continued listing requirements, Nasdaq would provide such company a period of 180 calendar days in which to regain compliance by maintaining a closing bid price at least $1 per share for a minimum of ten consecutive business days.

On June 25, 2019, we received a notice letter from the Listing Qualifications Staff of Nasdaq indicating that, based upon the closing bid price of our common stock for the last 30 consecutive business days, we no longer met the requirement to maintain a minimum closing bid price of $1 per share, as set forth in Nasdaq Listing Rule 5450(a)(1). On December 26, 2019, we obtained an additional compliance period of 180 calendar days by electing to transfer to The Nasdaq Capital Market to take advantage of the additional compliance period offered on that market. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market. On March 26, 2020, we obtained shareholder approval to effect a reverse stock split in a range from 20:1 to 40:1, which is subject to the approval of our board of directors (such final ratio, as determined by our board of directors, the "Reverse Stock Split Ratio" such reverse stock split, the "Reverse Stock Split"). On April 17, 2020 we received an additional notice letter from Nasdaq indicating that based on extraordinary market conditions, Nasdaq has determined to toll the compliance periods for bid price and market value of publicly held shares requirements (collectively, the "Price-based Requirements") through June 30, 2020. Accordingly, since we had 66 calendar days remaining in, the compliance period as of April 16, 2020, we will, upon reinstatement of the Price-based Requirements, still have 66 calendar days from July 1, 2020, or until September 4, 2020, to regain compliance. We can regain compliance, either during the suspension or during the compliance period resuming after the suspension, by evidencing compliance with the Price-based Requirements for a minimum of 10 consecutive trading days. We intend to comply with the Price-based Requirements by effecting the Reverse Stock Split. However, there can be no assurance that we will be able to regain compliance with the minimum bid price requirement or maintain compliance with the other listing requirements necessary for us to maintain the listing of our common stock on The Nasdaq Capital Market. If we are unable to cure the deficiency or regain compliance, our common stock will be delisted from The Nasdaq Capital Market and begin trading on the OTC bulletin board.

A delisting from The Nasdaq Capital Market and commencement of trading on the OTC bulletin board would likely result in a reduction in some or all of the following, each of which could have a material adverse effect on stockholders:

- the liquidity of our common stock;
- the market price of our common stock (and the accompanying valuation of our Company);
- our ability to obtain financing or complete a strategic transaction;
- the number of institutional and other investors that will consider investing in shares of our common stock;
- the number of market markers or broker-dealers for our common stock; and
- the availability of information concerning the trading prices and volume of shares of our common stock.

The Reverse Stock Split that we intend to effect may not increase our stock price over the long-term.

The principal purpose of the Reverse Stock Split is to increase the per share market price of our common stock. It cannot be assured, however, that the Reverse Stock Split will accomplish the objective of increasing the per share market price of our common stock for any meaningful period of time. While it is expected that the reduction in the number of outstanding shares of our common stock will proportionally increase the market price of our common stock, it cannot be assured that the Reverse Stock Split will increase the market price of our common stock by a multiple of the Reverse Stock Split Ratio, as determined by our board of directors, or result in any permanent or sustained increase in the market price of our common stock, which is dependent upon many factors, including our business and financial performance, general market conditions and prospects for future success. Therefore, while price of our common stock might meet the continued listing requirements for The Nasdaq Capital Market initially, it cannot be assured that it will continue to do so.

The Reverse Stock Split may decrease the liquidity of our common stock.

Although our board of directors believes that the anticipated increase in the market price of our common stock could encourage interest in our common stock and possibly promote greater liquidity for our stockholders, such liquidity could also be adversely affected by the reduced number of shares outstanding after the Reverse Stock Split. The reduction in the number of outstanding shares may lead to reduced trading and a smaller number of market makers for our common stock.

The Reverse Stock Split may lead to a decrease in our overall market capitalization.

Should the market price of our common stock decline after the Reverse Stock Split, the percentage decline may be greater, due to the smaller number of shares outstanding, than it would have been prior to the Reverse Stock Split. A reverse stock split may be viewed negatively by the market and, consequently, can lead to a decrease in our market capitalization. If the per share market price does not increase in proportion to the Reverse Stock Split ratio, then the value of our Company, as measured by its stock capitalization, will be reduced. In some cases, the per share stock price of companies that have effected reverse stock splits subsequently declined back to pre-reverse split levels, and accordingly, it cannot be assured that the total market value of our common stock will remain the same after the Reverse Stock Split is effected, or that the Reverse Stock Split will not have an adverse effect on the stock price of our common stock due to the reduced number of shares outstanding after the Reverse Stock Split.

Our two largest shareholders have significant influence over key decision making as a result of their concentrated ownership of the voting power of our outstanding capital stock.

Our two largest shareholders, ARK Investment Management LLC ("ARK") and Nikko Asset Management Americas, Inc. ("Nikko"), collectively own approximately 30% of our outstanding stock and, as demonstrated by the unsuccessful proposed Merger with Tarveda, are able to exercise sufficient voting rights to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation, sale of all or substantially all of our assets, or liquidation or dissolution. This concentrated position could delay, defer, or prevent a change of control, merger, consolidation, or sale of all or substantially all of our assets, or liquidation or dissolution that a substantial portion of our other stockholders support, or conversely this significant influence could potentially result in the consummation of such a transaction or liquidation that a substantial portion of our other stockholders do not support. This significant influence could also discourage a potential investor from acquiring our common stock or a potential counterparty from entering into negotiations about a potential strategic transaction and might harm the trading price of our common stock. As stockholders, even with significant influence, ARK and Nikko are entitled to vote their shares in their own interests, which may not always be in the interests of our stockholders generally.

We have a limited trading history and there is no assurance that an active market in our common stock will continue at present levels or increase in the future.

There is limited trading history in our common stock, and although our common stock is now traded on The Nasdaq Capital Market, there is no assurance that an active market in our common stock will continue at present levels or increase in the future. As a result, an investor may find it difficult to dispose of our common stock on the timeline and at the volumes they desire. This factor limits the liquidity of our common stock and may have a material adverse effect on the market price of our common stock and on our ability to raise additional capital.

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

We are a public reporting company in the United States, and accordingly, subject to the information and reporting requirements of the Exchange Act and other federal securities laws, including the compliance obligations of the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley Act"). The costs of complying with the reporting requirements of the federal securities laws, including preparing and filing annual and quarterly reports and other information with the SEC and furnishing audited reports to stockholders, can be substantial.

If we fail to comply with the rules of Section 404 of the Sarbanes-Oxley Act related to accounting controls and procedures, or, if we discover material weaknesses and deficiencies in our internal control and accounting procedures, we may be subject to sanctions by regulatory authorities and our stock price could decline.

Section 404 of the Sarbanes-Oxley Act (the "Section 404") requires that we evaluate and determine the effectiveness of our internal control over financial reporting. We believe our system and process evaluation and testing comply with the management certification requirements of Section 404. We cannot be certain, however, that we will be able to satisfy the requirements in Section 404 in all future periods. If we are not able to continue to meet the requirements of Section 404 in a timely manner or with adequate compliance, we may be subject to sanctions or investigation by regulatory authorities, such as the SEC or Nasdaq. Any such action could adversely affect our financial results or investors' confidence in us and could cause our stock price to fall. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner, or if we identify deficiencies in our internal controls that are deemed to be material weaknesses, we may be required to incur significant additional financial and management resources to achieve compliance.

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

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

- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- continued macroeconomic conditions related to the COVID-19 pandemic;
- any announcement regarding the strategic transaction process;
- reduced government funding for research and development activities;
- actual or anticipated variations in our operating results;
- adoption of new accounting standards affecting our industry;
- additions or departures of key personnel;
- sales of our common stock or other securities in the open market;
- degree of coverage of securities analysts and reports and recommendations issued by securities analysts regarding our business;
- volume fluctuations in the trading of our common stock; and
- other events or factors, many of which are beyond our control.

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

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

We are authorized to issue 200,000,000 shares of common stock and 25,000,000 shares of preferred stock. As of March 31, 2020, there were an aggregate of 157,976,729 shares of our common stock issued and outstanding and available for issuance on a fully diluted basis and no shares of preferred stock outstanding. That total for our common stock includes 26,229,913 shares of our common stock that may be issued upon the exercise of outstanding stock options or is available for issuance under our equity incentive plans, and 1,188,718 shares of common stock that may be issued through our Employee Stock Purchase Plan ("ESPP").

In the future, we may issue additional authorized but previously unissued equity securities to raise funds to support our continued operations and to implement our business plan. We may also issue additional shares of our capital stock or other securities that are convertible into or exercisable for our capital stock in connection with hiring or retaining employees, future acquisitions, or for other business purposes. If we raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders may result. In addition, the future issuance of any such additional shares of capital stock may create downward pressure on the trading price of our common stock. There can be no assurance that we will not be required to issue additional shares, warrants or other convertible securities in the future in conjunction with any capital raising efforts, including at a price (or exercise prices) below the price at which shares of our common stock is currently traded on The Nasdaq Capital Market. Moreover, depending on market conditions, we cannot be sure that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or to our stockholders.

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

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

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

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

- authorize the issuance of preferred stock which can be created and issued by our board of directors without prior stockholder approval, with rights senior to those of the common stock;
- provide for a classified board of directors, with each director serving a staggered three-year term;
- prohibit our stockholders from filling board vacancies, calling special stockholder meetings, or taking action by written consent; and
- require advance written notice of stockholder proposals and director nominations.

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

Risks Related to Our Intellectual Property

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

Our success will depend to a significant extent on our ability to obtain patents and maintain adequate protection for our technologies, intellectual property and products and service offerings in the United States and other countries. If we do not protect our intellectual property adequately, competitors may be able to use our technologies and gain a competitive advantage.

To protect our products and technologies, we and our collaborators and licensors must prosecute and maintain existing patents, obtain new patents and pursue other intellectual property protection. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technologies or from developing competing products and technologies. Moreover, the patent positions of many biotechnology and pharmaceutical companies are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, we cannot guarantee that:

- any patent applications filed by us will issue as patents;
- third parties will not challenge our proprietary rights, and if challenged that a court or an administrative board of a patent office will hold that our patents are valid and enforceable;
- third parties will not independently develop similar or alternative technologies or duplicate any of our technologies by inventing around our claims;
- any patents issued to us will cover our technology and products as ultimately developed;
- we will develop additional proprietary technologies that are patentable;
- the patents of others will not have an adverse effect on our business; or
- as issued patents expire, we will not lose some competitive advantage.

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

Certain foreign jurisdictions have an absolute requirement of novelty that renders any public disclosure of an invention immediately fatal to patentability in such jurisdictions. Therefore, there is a risk that we may not be able to protect some of our intellectual property in the United States or abroad due to disclosures, which we may not be aware of, by our collaborators or licensors. Some foreign jurisdictions prohibit certain types of patent claims, such as "method-of-treatment/use-type" claims; thus, the scope of protection available to us in such jurisdictions is limited.

Moreover, filing, prosecuting and defending patents on all of our potential products and technologies throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not sought or obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our future products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

We may be involved in lawsuits or other proceedings to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our collaborators or licensors. Or, our licensors may breach or otherwise prematurely terminate the provisions of our license agreements with them. To counter infringement or unauthorized use, we may be required to file infringement claims or lawsuits, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our collaborators or licensors is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Additionally, our licensors may retain certain rights to use technologies licensed by us for research purposes. Patent disputes can take years to resolve, can be very costly and can result in loss of rights, injunctions and substantial penalties. Moreover, patent disputes and related proceedings can distract management's attention and interfere with running the business.

Furthermore, because of the potential for substantial discovery in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments which could harm our business.

As more companies file patents relating to bioprinters and bioprinted tissues, it is possible that patent claims relating to bioprinters or bioprinted human tissue may be asserted against us, and any such assertions could harm our business. Moreover, we may face claims from non-practicing entities, which have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect. Any such claims, with or without merit, could be time-consuming to defend, result in costly litigation and diversion of resources, cause product shipment or delays or require us to enter into royalty or license agreements. These licenses may not be available on acceptable terms, or at all. Even if we are successful in defending such claims, infringement and other intellectual property litigation can be expensive and time-consuming to litigate and divert management's attention from our core business. Any of these events could harm our business significantly.

Our current and future research, development and commercialization activities also must satisfy the obligations under our license agreements. Any disputes arising under our license agreements could be costly and distract our management from the conduct of our business. Moreover, premature termination of a license agreement could have an adverse impact on our business.

In addition to infringement claims against us, if third parties have prepared and filed patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the United States Patent and Trademark Office ("PTO") to determine the priority of invention. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party.

Third parties may also attempt to initiate reexamination, post grant review or *inter partes* review of our patents or those of our collaborators or licensors in the PTO. We may also become involved in similar opposition proceedings in the European Patent Office or similar offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology.

We depend on license agreements with University of Missouri, Clemson, and UniQuest for rights to use certain patents, pending applications, and know how. Failure to comply with obligations under these agreements and any related or other termination of these agreements could materially harm our business and prevent us from developing or commercializing new product candidates.

We are party to license agreements with University of Missouri, Clemson, and UniQuest PC under which we were granted exclusive rights to patents and patent applications that are important to our business and to our ability to develop and commercialize our NovoGen Bioprinters and 3D tissue products fabricated using our NovoGen Bioprinters. Our rights to use these patents and patent applications and employ the inventions claimed in these licensed patents are subject to the continuation of and our compliance with the terms of our license agreements. If we were to breach the terms of these license agreements and the agreements were terminated as a result, our ability to continue to develop and commercialize our NovoGen Bioprinters and 3D tissue products and to operate our business could be adversely impacted.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

From July 2012 to November 2019, we leased our main facilities at 6275 Nancy Ridge Drive, San Diego, California 92121. Since November 2019, we leased our main facilities at 440 Stevens Avenue, Solana Beach, California 92075. See “Note 6. Leases” of the Notes to the Consolidated Financial Statements contained within this Annual Report for a further discussion of properties.

We believe our facilities are adequate for our current and intermediate-term needs, and that we will be able to locate additional facilities as needed.

Item 3. Legal Proceedings.

We are not involved in any material legal proceedings or legal matters at this time. See “Note 7. Commitments and Contingencies” of the Notes to the Consolidated Financial Statements contained within this Annual Report for a further discussion of potential commitments and contingencies related to legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information for Common Stock

Our common stock is traded on The Nasdaq Capital Market under the symbol "ONVO."

Holders of Record

As of March 31, 2020, we had 130,558,098 outstanding shares of common stock and approximately 88 holders of record of our common stock. The number of beneficial owners is substantially greater than the number of record holders because a large portion of our common stock is held of record through brokerage firms in "street name."

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all future earnings, if any, for use in our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Performance Graph

This performance graph is furnished and shall not be deemed "filed" with the SEC or subject to Section 18 of the Exchange Act, nor shall it be deemed incorporated by reference in any of our filings under the Securities Act of 1933, as amended.

The graph set forth below compares the cumulative total stockholder return data on our common stock with the cumulative return data of (i) the Nasdaq Stock Market Composite Index, and (ii) the Nasdaq Biotechnology Index over the five-year period ending March 31, 2020. This graph assumes the investment of $100 on March 31, 2015 in our common stock and each of the comparative indices and assumes the reinvestment of dividends. No cash dividends have been declared or paid on our common stock.

The comparisons in the graph and related information is not intended to forecast or be indicative of possible future performance of our common stock, and we do not make or endorse any predictions as to future stockholder returns.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Among Organovo Holdings, Inc.,
the Nasdaq Composite Index, and the Nasdaq Biotechnology Index

* $100 invested on March 31, 2015 in stock or index, including reinvestment of dividends.

Securities Authorized for Issuance under Equity Compensation Plans

Information about securities authorized for issuance under equity compensation plans is set forth in Part III, Item 12. "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" of this Annual Report.

Item 6. Selected Financial Data (in thousands except per share data).

The following selected historical financial data reflects our consolidated statements of operations and consolidated balance sheets as of and for the years ended March 31, 2020, 2019, 2018, 2017, and 2016. The data below should be read in conjunction with, and is qualified by reference to, Item 7. “Management's Discussion and Analysis of Financial Condition and Results of Operations” and our audited financial statements and notes thereto contained elsewhere in this Annual Report. The following table is presented in thousands, except share and per share amounts.

	Year Ended March 31, 2020	Year Ended March 31, 2019	Year Ended March 31, 2018	Year Ended March 31, 2017	Year Ended March 31, 2016
Selected Consolidated Statement of Operations Data:					
Revenue	$ 2,196	$ 3,091	$ 4,603	$ 4,230	$ 1,483
Operating loss	$ (21,475)	$ (27,274)	$ (35,271)	$ (38,575)	$ (38,643)
Net loss	$ (18,710)	$ (26,635)	$ (34,803)	$ (38,447)	$ (38,575)
Loss per share, basic and diluted	$ (0.14)	$ (0.23)	$ (0.32)	$ (0.39)	$ (0.43)
Weighted average shares outstanding, basic and diluted	129,556,156	115,379,902	107,243,974	97,763,032	90,057,356

	March 31, 2020	March 31, 2019	March 31, 2018	March 31, 2017	March 31, 2016
Selected Consolidated Balance Sheet Data:					
Working capital	$ 26,508	$ 34,837	$ 42,102	$ 59,081	$ 59,162
Total assets	$ 28,441	$ 40,623	$ 49,827	$ 69,180	$ 67,576
Long-term liabilities	$ -	$ 588	$ 583	$ 807	$ 905
Stockholders’ equity	$ 26,631	$ 36,298	$ 44,586	$ 62,362	$ 62,181

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following management's discussion and analysis of financial condition and results of operations should be read in conjunction with our historical consolidated financial statements and the related notes. This management's discussion and analysis contains forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Any statements that are not statements of historical fact are forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause our actual results or events to differ materially from those expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in section Item 1A. "Risk Factors" in this Annual Report. Except as required by applicable law we do not undertake any obligation to update our forward-looking statements to reflect events or circumstances occurring after the date of this Annual Report.

Overview

We are an early-stage biotechnology company that has been focused on pioneering the development of bioprinted human tissues that emulate key aspects of human biology and disease. We have focused on developing our *in vivo* liver tissues to treat end-stage liver disease and a select group of life-threatening, orphan diseases, for which there are limited treatment options other than organ transplantation. We have also explored the development of other potential pipeline *in vivo* tissue constructs in-house and through collaborations with academic and government researchers. Our current limited operations comprise of managing certain collaborations with research institutions and universities with respect to our NovoGen Bioprinters® for research purposes. Our NovoGen Bioprinters® are automated devices that enable the fabrication of 3D living tissues comprised of mammalian cells. We believe that the use of our bioprinting platform by major research institutions may help to advance the capabilities of the platform and generate new applications for bioprinted tissues. In some instances, an academic institution or other third party has provided funding to support the academic collaborator's access to our technology platform. This funding is typically reflected as collaboration revenues in our financial statements; however, we are not currently generating any revenues from these collaborations. Our research collaborations typically involve both us and the academic partner contributing resources directly to projects, but also involves sponsored research agreements where we fund specific research programs. We also continue to retain certain key management, employees and consultants, our core intellectual property and licenses.

Strategic Alternatives Process

In August 2018, following a pre-pre-IND meeting with the FDA regarding our lead liver therapeutic candidate, we announced that we were concentrating our financial resources around supporting our healthy liver therapeutic tissue development, and that we would continue to opportunistically generate revenue to support our therapeutics program by leveraging our cell and *in vitro* tissue platform including providing funded access to our developmental *in vitro* liver tissue platform to clients for their own R&D programs.

In August 2019, after a rigorous assessment of our liver therapeutic tissue program, we concluded that the variability of biological performance and related duration of potential benefits no longer supported an attractive opportunity due to redevelopment challenges and lengthening timelines to compile sufficient data to support an IND filing. As a result, we suspended development of our lead program and all other related in-house pipeline development activities. Our board of directors also engaged a financial advisory firm to explore its available strategic alternatives, including evaluating a range of ways to generate value from our technology platform and intellectual property, our commercial and development capabilities, our listing on The Nasdaq Capital Market, and our remaining financial assets. These strategic alternatives included possible mergers and business combinations, sales of part or all of our assets, and licensing and partnering arrangements. We implemented various restructuring steps to manage our resources and extend our cash runway, including reducing commercial activities related to our liver tissues, except for sales of primary human cells out of inventory, negotiating an exit from our long-term facility lease, selling various assets, and reducing our workforce. Additionally, in November 2019, we sold certain inventory and equipment and related proprietary information held by our wholly-owned subsidiary, Samsara, and as a result of such sale, Samsara ceased its operations.

After conducting a diligent and extensive process of evaluating strategic alternatives and identifying and reviewing potential candidates for a strategic acquisition or other transaction, which included the receipt of more than twenty-seven non-binding indications of interest from interested parties and careful evaluation and consideration of those proposals, and following extensive negotiation with Tarveda, on December 13, 2019, we entered into the Merger Agreement and, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, our wholly owned merger subsidiary would merge into Tarveda, with Tarveda surviving the merger. The Merger Agreement included various conditions to the consummation of the merger, including approval by our stockholders at the Special Meeting.

On April 7, 2020 at the Special Meeting of Shareholders, the Merger was not approved by our stockholders. As a result, we are currently reconsidering our strategic alternatives and may pursue one of the following courses of action, which include but are not limited to the following actions:

- Pursue another strategic transaction similar to the Merger. We may resume our process of evaluating other candidate companies interested in pursuing a strategic transaction and, if a candidate is identified, focus our attention on negotiating and completing such strategic transaction with such candidate.

- Continue to operate and expand our business. We could elect to continue to operate and expand our business and pursue licensing or partnering transactions or utilize our intellectual property and platform technology to pursue the redevelopment of our liver tissues or the development of therapeutic tissues currently being studied by our collaborators. Due to the early development stage of our, and our collaborators', potential therapeutic tissues, any such redevelopment or development efforts would require a significant amount of time and financial resources, and would be subject to all the risk and uncertainties involved in the development of novel, early stage therapeutic products, research tools, and drug screening technologies. There is no assurance that we could raise sufficient capital to support these efforts, that our development efforts would be successful commercially in the case of research applications or that we could successfully obtain any required regulatory approvals to market any therapeutic product we pursue. We would also need to increase qualified scientific, sales and marketing, and administrative staffing, lease a suitable facility and make other expenditures necessary to support these efforts.

- Dissolve and liquidate our assets. If we are unable, or do not believe that we will be able, to find a suitable candidate for another strategic transaction or continue to operate our business, we may dissolve and liquidate our assets, subject to approval by our stockholders. In that event, we would be required to pay all of our debts and contractual obligations and to set aside certain reserves for potential future claims. If we dissolve and liquidate our assets, there can be no assurance as to the amount or timing of available cash that will remain for distribution to our stockholders after paying our debts and other obligations and setting aside funds for our contingent liabilities.

COVID-19

In December 2019 a respiratory illness caused by a novel strain of coronavirus, SARS-CoV-2, causing the Coronavirus Disease 2019, also known as COVID-19 or coronavirus emerged. While initially the outbreak was largely concentrated in China it has spread globally. Global health concerns relating to the COVID-19 pandemic have been weighing on the macroeconomic environment, and the pandemic has significantly increased economic volatility and uncertainty. The pandemic has resulted in government authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns.

The extent to which the coronavirus impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak and travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns. In particular, the continued COVID-19 pandemic could adversely impact our operations, including among others, the timing and ability to pursue strategic alternatives, given the impact it may have on the manufacturing and supply chain, sales and marketing and clinical trial operations of potential strategic partners and the ability, if we elect to do so, to advance our research and development activities and pursue development of any of our pipeline products each of which could have an adverse impact on our business and our financial results. However, our employees and consultants have been working remotely prior to the COVID-19 pandemic and we currently believe our operations have not otherwise been negatively impacted by the pandemic.

Critical Accounting Policies, Estimates, and Judgments

Our financial statements are prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We continually evaluate our estimates and judgments, the most critical of which are those related to revenue recognition, the measurement of operating lease right-of-use assets and lease liabilities, the valuation of stock-based compensation expense, the valuation of impairment of long-lived assets, and the valuation allowance on deferred tax assets. We base our estimates and judgments on historical experience and other factors that we believe to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known. Besides the estimates identified above that are considered critical, we make many other accounting estimates in preparing our financial statements and related disclosures. All estimates, whether or not deemed critical, affect reported amounts of assets, liabilities, revenues and expenses, as well as disclosures of contingent assets and liabilities. These estimates and judgments are also based on historical experience and other factors that are believed to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known, even for estimates and judgments that are not deemed critical.

There have been no significant changes to our critical accounting policies since March 31, 2019, with the exception of changes made upon adoption of Accounting Standards Update ("ASU") 2016-02, Leases ("ASC 842") and the related supplemental ASUs. Our significant accounting policies are set forth in "Note 1. Description of Business and Summary of Significant Accounting Policies" in the Notes to Consolidated Financial Statements contained within this Annual Report. Of those policies, we believe that the policies discussed below may involve a higher degree of judgment and may be more critical to an accurate reflection of our financial condition and results of operations.

Revenue recognition

We have generated revenues from payments received from research service agreements, product sales, collaborative agreements with partners including pharmaceutical and biotechnology companies and academic institutions, licenses, and grants from the National Institutes of Health ("NIH") and private not-for-profit organizations.

Billings to customers or payments received from customers are included in deferred revenue on the balance sheet until all revenue recognition criteria are met. As of March 31, 2020 and 2019, the Company had approximately $0 and $525,000, respectively, in deferred revenue related to its research service agreements, collaborative agreements, and licenses within the scope of ASU 2014-09, Revenue from Contracts with Customers ("Topic 606"). In the year ended March 31, 2020, we recognized revenue on approximately $525,000, of which $490,000 related to the expiration of an agreement with a non-refundable up-front fee, that had been recorded as deferred revenue at March 31, 2019.

Service revenues

The Company's service-based business, Organovo, Inc., utilized its NovoGen® bioprinting platform to provide customers access to its highly specialized tissues that model human biology and disease, and to *in vitro* testing services based on that technology. These contracts with customers contained multiple performance obligations including: (i) bioprinting tissues for the customer, (ii) reporting the results of tests performed on the printed tissues pursuant to the agreed upon work plan through exposure of the tissue to various factors (including the customer's proprietary compound), and (iii) delivering specific byproduct study materials, which were satisfied, respectively, at each of the following points in time: (i) upon completion of manufacturing of the bioprinted tissue for the customer, (ii) upon delivery of the report on tests performed on the tissue, and (iii) upon making certain study materials generated from the aforementioned testing process available to the customer. The customer did not have access or control of any performance obligation prior to the point in time of full completion of the corresponding performance satisfying event as defined above. Furthermore, although the service could be customized for each customer, it was not so highly customized as to not have an alternative use either to other customers or to the Company without significant economic consequences or rework. Accordingly, the Company's service-based business utilized point-in-time recognition under Topic 606.

For service contracts, the Company allocated the transaction price to each performance obligation based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. If the standalone selling price was not observable through past transactions, the Company estimated the standalone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations. The transaction price for service business contracts was a fixed consideration.

In connection with the Company's decision to pursue its strategic alternatives, the Company halted commercial activities related to its liver tissues. The Company expects to continue to maintain its external research collaborations and its intellectual property portfolio.

Product sales, net

The Company's product-based business, Samsara, produced high-quality cell-based products for use in Organovo's 3D tissue manufacturing and for use by life science customers. The Company recognizes product revenue when the performance obligation is satisfied, which is at the point in time the customer obtains control of the Company's product, typically upon delivery. Product revenues are recorded at the transaction price, net of any estimates for variable consideration under Topic 606. The Company's process for estimating variable consideration does not differ materially from its historical practices. Variable consideration is estimated using the expected value method which considers the sum of probability-weighted amounts in a range of possible amounts under the contract. Product revenue reflects the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the individual contracts. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results vary materially from the Company's estimates, the Company will adjust these estimates, which will affect revenue from product sales and earnings in the period such estimates are adjusted.

The Company provides no right of return to its customers except in cases where a customer obtains authorization from the Company for the return. To date, there have been no product returns.

On November 7, 2019, the Company entered into an agreement to sell substantially all of the Samsara inventory and associated assets for $1.5 million, which was recorded to other income. As a result, the Company will have no further product sales of cells nor tissues beyond what it sold prior to the November 2019 sale. In March 2020, the Company dissolved Samsara.

Collaborative research, development, and licenses

The Company has entered into collaborative agreements with partners that typically include one or more of the following: (i) non-exclusive license fees; (ii) non-refundable up-front fees; (iii) payments for reimbursement of research costs; (iv) payments associated with achieving specific development milestones; and (v) royalties based on specified percentages of net product sales, if any. At the initiation of an agreement, the Company has analyzed whether it results in a contract with a customer under Topic 606 or in an arrangement with a collaborator subject to guidance under ASC 808, *Collaborative Arrangements*.

The Company has considered a variety of factors in determining the appropriate estimates and assumptions under these arrangements, such as whether the elements are distinct performance obligations, whether there are determinable stand-alone prices, and whether any licenses are functional or symbolic. The Company has evaluated each performance obligation to determine if it can be satisfied and recognized as revenue at a point in time or over time. Typically, non-exclusive license fees, non-refundable upfront fees, and funding of research activities have been considered fixed, while milestone payments have been identified as variable consideration which must be evaluated to determine if it has been constrained and, therefore, excluded from the transaction price.

The Company's collaborative agreements that were not completed at the implementation of Topic 606 on April 1, 2018, consisted of research collaboration and limited technology access licenses. These agreements provide the licensee with a non-exclusive, non-transferable, limited, royalty-free technology license, including access to Organovo's proprietary bioprinter platform, training, and continued support by means of consumables and consultation throughout the duration of the contract. The Company has determined that the intellectual property license is not distinct from the continued support promised under the agreement and is therefore a single combined performance obligation. The Company recognized revenue for these combined performance obligations over time for the duration of the license period, as the combined performance obligation would not be fully satisfied until the end of the contract.

For the year ended March 31, 2020, all collaborations and licenses revenue was within the scope of Topic 606 and recognized accordingly. As of September 30, 2019, the Company completed its obligations under the existing agreements with respect to receipts of revenue and does not anticipate recording any further revenue. See "Note 4. Collaborative Research, Development, and License Agreements" in the Notes to Consolidated Financial Statements included in this Annual Report for more information on the Company's collaborative agreements.

Grant revenue

In July 2017, the NIH awarded the Company a "Research and Development" grant totaling approximately $1.7 million, of funding over three years. The Company has concluded this government grant is not within the scope of Topic 606, as government entities do not meet the definition of a "customer" as defined by Topic 606, as there is not considered to be a transfer of control of goods or services to the government entity funding the grant. Additionally, the Company has concluded this government grant does meet the definition of a contribution and is a non-reciprocal transaction, however, Subtopic 958-605, *Not-for-Profit-Entities-Revenue Recognition* does not apply, as the Company is a business entity and the grant is with a governmental agency.

Revenues from this grant have been based upon internal costs incurred that are specifically covered by the grant, plus an additional rate that provides funding for overhead expenses. Revenue has been recognized as the Company incurs expenses that are related to the grant. The Company believes this policy is consistent with the overarching premise in Topic 606, to ensure that it recognizes revenues to reflect the transfer of promised goods or services to customers in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services, even though there is no "exchange" as defined in the FASB Accounting Standards Codification ("ASC"). The Company believes the recognition of revenue as costs are incurred and amounts become earned/realizable is analogous to the concept of transfer of control of a service over time under Topic 606.

Revenue recognized under this grant was approximately $52,000 and $587,000 for the year ended March 31, 2020 and 2019, respectively.

In connection to the Company's decision to pursue its strategic alternatives, specific to the NIH grant, all internal research activities have been halted and transferred to the University of California, San Diego, leaving a remaining available balance of approximately $0.5 million that will not be utilized by the Company.

Cost of revenues

We reported approximately $0.3 million and $0.5 million in cost of revenues for the year ended March 31, 2020 and 2019, respectively, which includes an inventory write-off during the current year fiscal second quarter of approximately $0.2 million consisting of raw materials related to the Company's bioprinting and testing services and is a result of the Company's decision to pursue its strategic alternatives. Cost of revenues consists of our costs related to manufacturing and delivering our product and service revenue.

Stock-based compensation

For purposes of calculating stock-based compensation, we estimate the fair value of stock options and shares acquirable under our 2016 Employee Stock Purchase Plan (the "ESPP") using a Black-Scholes option-pricing model. The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by our stock price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. For stock options, prior to fiscal year 2020, the Company used a blend of historical volatility and implied volatility of comparable companies. As of April 1, 2019, the Company is using the Company-specific historical volatility rate as it is more reflective of market conditions and a better indicator of expected volatility. For shares acquirable under our ESPP, during the first full year of ESPP offering periods, beginning September 1, 2016, the expected volatility incorporates the historical and implied volatility of comparable companies whose share prices are publicly available due to our limited historical data as an early-stage commercial business. As of September 1, 2017, we are using our Company-specific volatility rate. The expected life of the stock options is based on historical and other economic data trended into the future. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected terms of our stock options. The dividend yield assumption is based on our history and expectation of no dividend payouts. If factors change and we employ different assumptions, our stock-based compensation expense may differ significantly from what we have recorded in the past. If there is a difference between the assumptions used in determining our stock-based compensation expense and the actual factors that become known over time, specifically with respect to anticipated forfeitures, we may change the input factors used in determining stock-based compensation costs for future grants. These changes, if any, may materially impact our results of operations in the period such changes are made.

For purposes of calculating stock-based compensation, we estimate the fair value of restricted stock units ("RSUs") and performance-based restricted stock units ("PBRSUs") with pre-defined performance criteria, is based on the closing stock price on the date of grant. No exercise price or other monetary payment is required for receipt of the shares issued in settlement of the respective award; instead, consideration is furnished in the form of the participant's service to the Company. The expense for PBRSUs with pre-defined performance criteria is adjusted with the probability of achievement of such performance criteria at each period end.

Results of Operations

Comparison of the Years Ended March 31, 2020 and 2019

The following table summarizes our results of operations for the years ended March 31, 2020 and 2019 (in thousands):

	Year Ended March 31,		Increase (decrease)	
	2020	2019	$	%
Revenues	$ 2,196	$ 3,091	$ (895)	(29%)
Cost of revenues	$ 328	$ 482	$ (154)	(32%)
Research and development	$ 5,284	$ 14,752	$ (9,468)	(64%)
Selling, general and administrative	$ 18,059	$ 15,131	$ 2,928	19%
Other income	$ 2,767	$ 642	$ 2,125	331%

Revenues

Revenues of $2.2 million for the year ended March 31, 2020 decreased approximately $0.9 million, or approximately 29%, over revenues of $3.1 million for the year ended March 31, 2019. This change reflects decreases of $0.5 million and $0.3 million in grant revenue and product and service revenue, respectively, over the year ended March 31, 2019, as we reduced our activities and streamlined expenses during the year to pursue strategic alternatives.

Costs and Expenses

Cost of Revenues

Cost of product and service revenues, which reflects expenses related to manufacturing our products and delivering services, was $0.3 million and $0.5 million for the years ended March 31, 2020 and 2019, respectively. The decrease was primarily due to the wind-down of certain commercial activities related to our liver tissues during the year ended March 31, 2020.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended March 31, 2020 and 2019 (in thousands):

	Year ended March 31,		Increase (decrease)	
	2020	2019	$	%
Research and development	$ 4,940	$ 13,290	$ (8,350)	(63%)
Non-cash stock-based compensation	111	911	(800)	(88%)
Depreciation and amortization	233	551	(318)	(58%)
Total research and development expenses	$ 5,284	$ 14,752	$ (9,468)	(64%)

Research and development expenses decreased $9.5 million, or 64%, from approximately $14.8 million for the year ended March 31, 2019 to approximately $5.3 million for the year ended March 31, 2020 as we materially reduced research and development activities following our decision to pursue our strategic alternatives during the second quarter of fiscal 2020. This action caused a $4.2 million reduction of personnel related costs, a $2.4 million reduction in lab supply costs, a $1.6 million reduction in facilities costs, and a $1.3 million reduction in all other costs. The Company's average full-time research and development staff decreased from an average of forty-seven full-time employees for the year ended March 31, 2019 to an average of fourteen full-time employees for the year ended March 31, 2020. Going forward, we do not currently expect to incur any further research and development expenses.

Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses for the years ended March 31, 2020 and 2019 (in thousands):

	Year ended March 31,		Increase (decrease)	
	2020	2019	$	%
Selling, general and administrative	$ 13,153	$ 10,420	$ 2,733	26%
Non-cash stock-based compensation	3,997	4,282	(285)	(7%)
Depreciation and amortization	909	429	480	112%
Total selling, general and administrative expenses	$ 18,059	$ 15,131	$ 2,928	19%

Selling, general and administrative expenses increased approximately $2.9 million, or 19%, from $15.1 million for the year ended March 31, 2019 to approximately $18.1 million for the year ended March 31, 2020 as we incurred approximately $2.1 million of legal, accounting, financial printing, and shareholder solicitation costs related to our proposed Merger with Tarveda and $0.2 million of costs related to settling various stockholder actions. In addition, we also incurred approximately $0.9 million of depreciation and amortization costs related to leasehold improvement write-offs in connection with the early termination of our lease and $2.7 million of severance related costs in connection with restructuring the business following our decision to pursue our strategic alternatives. These actions caused a $2.2 million increase in corporate costs, a $0.7 million increase in allocated facilities costs, and a $0.5 million increase in depreciation and amortization costs, which were offset by a $0.5 million decrease in personnel and other costs. Our average selling, general and administrative headcount was twelve full-time employees for the year ended March 31, 2020 compared to twenty-two full-time employees in the prior year period.

Other Income (Expense)

Other income was approximately $2.8 million for the year ended March 31, 2020, consisting of a $1.2 million gain from the sale of Samsara assets, a $0.5 million of gain on our lease termination, $0.5 million of income from the sale of other assets, and $0.6 million of interest income. For the year ended March 31, 2019, other income was approximately $0.6 million for the year ended March 31, 2019 and consisted of $0.7 million of interest income, offset by a $0.1 million loss on disposal of assets. Interest income decreased year over year due to lower average yields and investment balances.

Financial Condition, Liquidity and Capital Resources

We have primarily devoted our efforts to developing a platform technology to produce and study living tissues that emulate key aspects of human biology and disease, raising capital and building infrastructure. Following the decision to explore strategic alternatives, we have taken steps to manage our resources and extend our cash runway, including reducing all commercial and research and development laboratory activities related to our liver tissues, negotiating an exit from our long-term facility lease, selling lab equipment and inventory, and reducing our workforce We have retained certain key management, employees and consultants, our core intellectual property, licenses, collaborations with research institutions and universities, and proprietary equipment, and will continue our operations as we explore strategic alternatives.

As of March 31, 2020, we had cash and cash equivalents of approximately $27.4 million and an accumulated deficit of $279.5 million. As of March 31, 2019, we had cash and cash equivalents of $36.5 million and an accumulated deficit of $260.8 million. We also had negative cash flows from operations of $14.9 million and $20.4 million for the years ended March 31, 2020 and 2019, respectively.

As of March 31, 2020, we had total current assets of approximately $28.3 million and current liabilities of approximately $1.8 million, resulting in working capital of $26.5 million. At March 31, 2019, we had total current assets of approximately $38.6 million and current liabilities of approximately $3.8 million, resulting in working capital of $34.8 million.

The following table sets forth a summary of the primary sources and uses of cash for the years ended March 31, 2020 and 2019 (in thousands):

	Year ended March 31,	
	2020	2019
Net cash (used in) provided by:		
Operating activities	$ (14,882)	$ (20,375)
Investing activities	747	(76)
Financing activities	4,935	13,154
Net decrease in cash, cash equivalents, and restricted cash	$ (9,200)	$ (7,297)

Operating activities

Net cash used by operating activities was approximately $14.9 million and $20.4 million for the years ended March 31, 2020 and 2019, respectively. This $5.5 million decrease, for the year ended March 31, 2020, is a result of a $6.5 million improvement in our cash net loss resulting from streamlining our research and administrative activities, which was offset by a $1.0 million increase in working capital requirements.

Investing activities

Net cash provided by investing activities was $0.7 million versus net cash used by investing activities of less than $0.1 million for the years ended March 31, 2020 and 2019, respectively. The net cash provided by investing activities was related to proceeds from the disposal of fixed assets associated with the streamlining of our operations.

Financing activities

Net cash provided by financing activities was approximately $4.9 million and $13.2 million for the years ended March 31, 2020 and 2019, respectively. The results in both years are primarily driven by “at-the-market” share offerings.

Operations funding requirements

During the year ended March 31, 2020, we raised net proceeds of approximately $5.0 million through the sale of 6,087,382 shares of our common stock through “at-the-market” offerings, which were offset by less than $0.1 million of payroll taxes paid by the Company related to the vesting of restricted stock units where vested shares were withheld by us to satisfy employee withholding tax obligations.

During the year ended March 31, 2019, we raised net proceeds of approximately $13.2 million through the sale of 11,631,803 shares of our common stock through “at-the-market” offerings, $0.1 million through the sale of shares through the ESPP, and less than $0.1 million through stock option exercises, which were offset by $0.2 million of payroll taxes paid by the Company related to the vesting of restricted stock units where vested shares were withheld by us to satisfy employee withholding tax obligations.

Through March 31, 2020, we have financed our operations primarily through the sale of common stock in public offerings, the private placement of equity securities, from revenue derived from products and research-based services, grants, and collaborative research agreements, and from the sale of convertible notes. Based on our current operating plan and available cash resources, we have sufficient resources to fund our business for at least the next twelve months.

Aside from the maintenance of our intellectual property portfolio, license and collaboration agreements, remaining assets, and listing on The Nasdaq Capital Market, our ongoing cash requirements are expected to consist primarily of fees associated with pursuing strategic alternatives, including fees payable to financial advisors, consulting fees, legal and accounting support, insurance premiums, key employee retention, severance and change of control benefits and ongoing compensation obligations for the six general and administrative personnel that remain with us.

We have an effective shelf registration statement on Form S-3 (File No. 333-222929) ("the 2018 Shelf") that registered $100,000,000 of common stock, preferred stock, warrants and units, or any combination of the foregoing, which expires on February 22, 2021. On March 16, 2018, we filed a prospectus supplement to the 2018 Shelf to register the sale of up to $50.0 million of shares of our common stock that may be issued in at-the-market offerings pursuant to an equity offering sales agreement we entered into with two investment banking firms as of the same date. During the year ended March 31, 2020, we sold 6,087,382 shares of common stock in at-the-market offerings, with net proceeds of approximately $5.0 million under the 2018 Shelf.

Based on our use of the 2018 Shelf through March 31, 2020, we cannot raise more than $81.3 million in future offerings under the 2018 Shelf, including through our at-the-market program.

Having insufficient funds may require us to relinquish rights to our technology on less favorable terms than we would otherwise choose. Failure to obtain adequate financing could eventually adversely affect our ability to operate as a going concern. If we raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

On June 25, 2019, we received a notice letter from the Listing Qualifications Staff of Nasdaq indicating that, based upon the closing bid price of our common stock for the last 30 consecutive business days, we no longer meet the requirement to maintain a minimum closing bid price of $1 per share, as set forth in Nasdaq Listing Rule 5450(a)(1). On December 26, 2019, we obtained an additional compliance period of 180 calendar days by electing to transfer to The Nasdaq Capital Market to take advantage of the additional compliance period offered on that market. On April 17, 2020 we received an additional notice letter from Nasdaq indicating that based on extraordinary market conditions, Nasdaq has determined to toll the compliance periods for bid price and market value of publicly held shares requirements (collectively, the "Price-based Requirements") through June 30, 2020. Accordingly, since we had 66 calendar days remaining in the compliance period as of April 16, 2020, we will, upon reinstatement of the Price-based Requirements, still have 66 calendar days from July 1, 2020, or until September 4, 2020, to regain compliance. We can regain compliance, either during the suspension or during the compliance period resuming after the suspension, by evidencing compliance with the Price-based Requirements for a minimum of 10 consecutive trading days. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market.

As of March 31, 2020, we had 130,558,098 total issued and outstanding shares of common stock and no warrants were outstanding.

In addition, our 2008 Equity Incentive Plan provided for the issuance of up to 1,521,584 shares of common stock upon the exercise of outstanding stock options, of which 896,256 shares were issued. The 2008 Equity Incentive Plan terminated on July 1, 2018. The 2012 Equity Incentive Plan, as amended, provides for the issuance of up to 28,553,986 shares of our common stock, of which 14,158,654 shares remain available for issuance as of March 31, 2020, to executive officers, directors, advisory board members, employees and consultants. Additionally, 1,500,000 shares of common stock have been reserved for issuance under the 2016 ESPP, of which 1,188,718 shares remain available for future issuance as of March 31, 2020. Lastly, 2,246,918 shares of common stock have been reserved for issuances under Inducement Award Agreements. In aggregate, issued and outstanding common stock, shares underlying outstanding warrants, and shares issuable under outstanding equity awards or reserved for future issuance under the 2008 and 2012 Equity Incentive Plans, the Inducement Award Agreements, and the 2016 ESPP total 157,976,729 shares of common stock as of March 31, 2020.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements, including unrecorded derivative instruments that have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources. We have certain warrants and options outstanding, but we do not expect to receive sufficient proceeds from the exercise of these instruments unless and until the underlying securities are registered, and/or all restrictions on trading, if any, are removed, and in either case the trading price of our common stock is significantly greater than the applicable exercise prices of the options and warrants.

Effect of Inflation and Changes in Prices

Management does not believe that inflation and changes in price will have a material effect on our operations.

Recent Accounting Pronouncements

For information regarding recently adopted and issued accounting pronouncements, see “Note 12. Recent Accounting Pronouncements” in the Notes to Consolidated Financial Statements contained in this Annual Report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

The primary objective of our investment activities is to preserve our capital for the purpose of funding our operations. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash, cash equivalents, and short-term investments in a variety of securities, including money market funds. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are comprised of cash and cash equivalents. We currently do not hedge interest rate exposure. Due to the nature of our short-term investments, we believe that we are not subject to any material market risk exposure. We have limited foreign currency risk exposure as our business operates primarily in U.S. dollars. We do not have significant foreign currency nor any other derivative financial instruments.

Item 8. Consolidated Financial Statements.

Organovo Holdings, Inc.
Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of:
Organovo Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of **Organovo Holdings, Inc.** (the "Company") as of March 31, 2020 and 2019, and the related consolidated statements of operations and other comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended March 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of March 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended March 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Adoption of New Accounting Standard

As discussed in Note 6 to the financial statements, the Company has changed its method of accounting for leases due to the adoption of Accounting Standards Codification Topic 842, *Leases*, effective April 1, 2019, under the retrospective method.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Mayer Hoffman McCann P.C.

We have served as the Company's auditor since 2011.

San Diego, California
May 28, 2020

ORGANOVO HOLDINGS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands except for share and per share data)

	March 31, 2020	March 31, 2019
Assets		
Current Assets		
Cash and cash equivalents	$ 27,356	$ 36,477
Accounts receivable	111	503
Grant receivable	—	55
Inventory, net	—	490
Prepaid expenses and other current assets	851	1,049
Total current assets	28,318	38,574
Fixed assets, net	—	1,832
Restricted cash	—	79
Other assets, net	123	138
Total assets	$ 28,441	$ 40,623
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 720	$ 628
Accrued expenses	1,090	2,549
Deferred revenue	—	525
Deferred rent	—	35
Total current liabilities	1,810	3,737
Deferred rent, net of current portion	—	588
Total liabilities	1,810	4,325
Commitments and Contingencies		
Stockholders' Equity		
Common stock, $0.001 par value; 200,000,000 shares authorized, 130,558,098 and 124,015,429 shares issued and outstanding at March 31, 2020 and March 31, 2019, respectively	131	124
Additional paid-in capital	305,965	296,929
Accumulated deficit	(279,465)	(260,755)
Total stockholders' equity	26,631	36,298
Total Liabilities and Stockholders' Equity	$ 28,441	$ 40,623

The accompanying notes are an integral part of these consolidated financial statements.

ORGANOVO HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND OTHER COMPREHENSIVE LOSS

(in thousands except for share and per share data)

	Year Ended March 31, 2020	Year Ended March 31, 2019
Revenues		
Products and services	$ 2,055	$ 2,333
Collaborations and licenses	89	171
Grants	52	587
Total Revenues	2,196	3,091
Cost of revenues	328	482
Research and development expenses	5,284	14,752
Selling, general, and administrative expenses	18,059	15,131
Total costs and expenses	23,671	30,365
Loss from Operations	(21,475)	(27,274)
Other Income (Expense)		
Gain (loss) on fixed asset disposals	113	(63)
Gain on lease termination	525	—
Interest income	594	705
Other income (expense)	1,535	—
Total Other Income (Expense)	2,767	642
Income Tax Expense	(2)	(3)
Net Loss	$ (18,710)	$ (26,635)
Net loss per common share—basic and diluted	$ (0.14)	$ (0.23)
Weighted average shares used in computing net loss per common share—basic and diluted	129,556,156	115,379,902
Comprehensive Loss:		
Net Loss	$ (18,710)	$ (26,635)
Comprehensive Loss	$ (18,710)	$ (26,635)

The accompanying notes are an integral part of these consolidated financial statements.

ORGANOVO HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (in thousands)

	Common Stock		Additional Paid-in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance at March 31, 2018	**111,033**	**$ 111**	**$ 278,595**	**$ (234,120)**	**$ 44,586**
Stock option exercises	622	1	49	—	50
Issuance of common stock under employee and director stock option, RSU and purchase plans	728	1	(140)	—	(139)
Stock-based compensation expense	—	—	5,193	—	5,193
Issuance of common stock from public offering, net	11,632	11	13,232	—	13,243
Net loss	—	—	—	(26,635)	(26,635)
Balance at March 31, 2019	**124,015**	**$ 124**	**$ 296,929**	**$ (260,755)**	**$ 36,298**
Issuance of common stock under employee and director stock option, RSU and purchase plans	456	1	(62)	—	(61)
Stock-based compensation expense	—	—	4,108	—	4,108
Issuance of common stock from public offering, net	6,087	6	4,990	—	4,996
Net loss	—	—	—	(18,710)	(18,710)
Balance at March 31, 2020	**130,558**	**$ 131**	**$ 305,965**	**$ (279,465)**	**$ 26,631**

The accompanying notes are an integral part of these consolidated financial statements.

ORGANOVO HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS (in thousands)

	Year Ended March 31, 2020	Year Ended March 31, 2019
Cash Flows From Operating Activities		
Net loss	$ (18,710)	$ (26,635)
Adjustments to reconcile net loss to net cash used in operating activities:		
(Gain) loss on disposal of fixed assets	(113)	63
(Gain) loss on lease termination	(525)	—
Depreciation and amortization	1,142	980
Stock-based compensation	4,108	5,193
Inventory write-off	214	—
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	392	380
Grants receivable	55	90
Inventory	276	352
Prepaid expenses and other assets	269	118
Accounts payable	92	164
Accrued expenses	(1,459)	(792)
Deferred revenue	(525)	(162)
Deferred rent	—	(126)
Operating Right-of-use asset and lease liability, net	(98)	—
Net cash used in operating activities	(14,882)	(20,375)
Cash Flows From Investing Activities		
Purchases of fixed assets	—	(79)
Proceeds from disposals of fixed assets	747	3
Net cash provided by (used in) investing activities	747	(76)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock	4,996	13,327
Employee taxes paid related to net share settlement of equity awards	(61)	(223)
Proceeds from exercise of stock options	—	50
Net cash provided by financing activities	4,935	13,154
Net Decrease in Cash, Cash Equivalents, and Restricted Cash	(9,200)	(7,297)
Cash, cash equivalents, and restricted cash at beginning of period	36,556	43,853
Cash, cash equivalents, and restricted cash at end of period	$ 27,356	$ 36,556
Reconciliation of cash, cash equivalents, and restricted cash to the consolidated balance sheets		
Cash and cash equivalents	$ 27,356	$ 36,477
Restricted cash	—	79
Total cash, cash equivalent and restricted cash	$ 27,356	$ 36,556
Supplemental Disclosure of Cash Flow Information:		
Restricted cash released	$ 79	$ —
Tenant improvements funded by landlord	$ 37	$ —
Assets held for sale	$ 33	$ —
Income taxes paid	$ 2	$ 3

The accompanying notes are an integral part of these consolidated financial statements.

Organovo Holdings, Inc.

Notes to Consolidated Financial Statements

Note 1. Description of Business and Summary of Significant Accounting Policies

Nature of operations and basis of presentation

Organovo Holdings, Inc. ("Organovo Holdings," "Organovo," and "the Company") is an early-stage biotechnology company that has historically been focused on pioneering the development of bioprinted human tissues that emulate key aspects of human biology and disease. Organovo has focused on developing its *in vivo* liver tissues to treat end-stage liver disease and a select group of life-threatening, orphan diseases, for which there are limited treatment options other than organ transplantation. Organovo has also explored the development of other potential pipeline *in vivo* tissue constructs in-house and through collaborations with academic and government researchers. The Company's current limited operations include managing certain collaborations with research institutions and universities with respect to its NovoGen Bioprinters® for research purposes. Organovo's NovoGen Bioprinters® are automated devices that enable the fabrication of 3D living tissues comprised of mammalian cells. The Company believes that the use of its bioprinting platform by major research institutions may help to advance the capabilities of the platform and generate new applications for bioprinted tissues. In some instances, an academic institution or other third party has provided funding to support the academic collaborator's access to the Company's technology platform. This funding is typically reflected as collaboration revenues in its financial statements; however, the Company is not currently generating any revenues from these collaborations. The Company's research collaborations typically involve both the Company and the academic partner contributing resources directly to projects, but also involves sponsored research agreements where the Company funds specific research programs. The Company also continues to retain certain key management, employees and consultants, its core intellectual property and licenses, and proprietary equipment.

Strategic Alternatives Process

In August 2018, following a pre-pre-Investigational New Drug application ("IND") meeting with the Food and Drug Administration (the "FDA") regarding its lead liver therapeutic candidate, Organovo announced that it was concentrating its financial resources around supporting its healthy liver therapeutic tissue development, and that it would continue to opportunistically generate revenue to support its therapeutics program by leveraging its cell and *in vitro* tissue platform including providing funded access to its developmental *in vitro* liver tissue platform to clients for their own R&D programs.

In August 2019, after a rigorous assessment of its liver therapeutic tissue program, Organovo concluded that the variability of biological performance and related duration of potential benefits no longer supported an attractive opportunity due to redevelopment challenges and lengthening timelines to compile sufficient data to support an IND filing. As a result, Organovo suspended development of its lead program and all other related in-house pipeline development activities. The Organovo board of directors also engaged a financial advisory firm to explore its available strategic alternatives, including evaluating a range of ways to generate value from its technology platform and intellectual property, its commercial and development capabilities, its listing on The Nasdaq Capital Market, and its remaining financial assets. These strategic alternatives included possible mergers and business combinations, sales of part or all of Organovo's assets, and licensing and partnering arrangements. Organovo implemented various restructuring steps to manage its resources and extend its cash runway, including reducing commercial activities related to its liver tissues, except for sales of primary human cells out of inventory, negotiating an exit from its long-term facility lease, selling various assets, and reducing its workforce. Additionally, in November 2019, Organovo sold certain inventory and equipment and related proprietary information held by its wholly owned subsidiary, Samsara Sciences, Inc. ("Samsara"), and as a result of such sale, Samsara ceased its operations in March 2020.

After conducting a diligent and extensive process of evaluating strategic alternatives for Organovo and identifying and reviewing potential candidates for a strategic acquisition or other transaction, which included the receipt of more than 27 non-binding indications of interest from interested parties and careful evaluation and consideration of those proposals, and following extensive negotiation with Tarveda Therapeutics, Inc. ("Tarveda"), on December 13, 2019, Organovo and Tarveda entered into an agreement and plan of merger agreement (the "Merger Agreement"). Pursuant to the Merger Agreement, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, a wholly-owned merger subsidiary of Organovo would merge (the "Merger") into Tarveda, with Tarveda surviving the Merger. The Merger Agreement included various conditions to the consummation of the Merger, including approval by Organovo's stockholders at a special meeting of stockholders (the "Special Meeting").

On April 7, 2020 at the Special Meeting, the Merger was not approved by Organovo stockholders. As a result, Organovo is currently reconsidering its strategic alternatives and may pursue one of the following courses of action, which include but are not limited to the following actions:

- Pursue another strategic transaction similar to the Merger. Organovo may resume its process of evaluating other candidate companies interested in pursuing a strategic transaction and, if a candidate is identified, focus its attention on negotiating and completing such strategic transaction with such candidate.

- Continue to operate and expand its business. Organovo could elect to continue to operate and expand its business and pursue licensing or partnering transactions or utilize its intellectual property and platform technology to pursue the redevelopment of its liver tissues or the development of therapeutic tissues currently being studied by its collaborators. Due to the early development stage of Organovo's, and its collaborators', potential therapeutic tissues, any such redevelopment or development efforts would require a significant amount of time and financial resources, and would be subject to all the risk and uncertainties involved in the development of novel, early stage therapeutic products, research tools, and drug screening technologies. There is no assurance that Organovo could raise sufficient capital to support these efforts, that its development efforts would be successful commercially in the case of research applications or that it could successfully obtain any required regulatory approvals required to market any therapeutic product it pursued. The Company would also need to increase qualified scientific, sales and marketing, and administrative staffing, lease a suitable facility and make other expenditures necessary to support these efforts.

- Dissolve and liquidate its assets. If Organovo is unable, or does not believe that it will be able, to find a suitable candidate for another strategic transaction or continue to operate its business, Organovo may dissolve and liquidate its assets, subject to approval by Organovo's stockholders. In that event, Organovo would be required to pay all of its debts and contractual obligations and to set aside certain reserves for potential future claims. If Organovo dissolves and liquidates its assets, there can be no assurance as to the amount or timing of available cash that will remain for distribution to Organovo's stockholders after paying Organovo's debts and other obligations and setting aside funds for its contingent liabilities.

Except where specifically noted or the context otherwise requires, references to "Organovo Holdings," "the Company," and "Organovo" in these notes to the consolidated financial statements refers to Organovo Holdings, Inc. and its wholly owned subsidiaries, Organovo, Inc., Samsara Sciences, Inc, and Opal Merger Sub, Inc.

COVID-19

In December 2019 a respiratory illness caused by a novel strain of coronavirus, SARS-CoV-2, causing the Coronavirus Disease 2019, also known as COVID-19 or coronavirus emerged. While initially the outbreak was largely concentrated in China it has spread globally. Global health concerns relating to the COVID-19 pandemic have been weighing on the macroeconomic environment, and the pandemic has significantly increased economic volatility and uncertainty. The pandemic has resulted in government authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns.

The extent to which the coronavirus impacts the Company's operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak and travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns. In particular, the continued coronavirus pandemic could adversely impact the Company's operations, including among others, the timing and ability to pursue strategic alternatives, given the impact it may have on the manufacturing and supply chain, sales and marketing and clinical trial operations of potential strategic partners, and the ability, if we elect to do so, to advance our research and development activities and pursue development of any of our pipeline products, each of which could have an adverse impact on the Company's business and financial results.

Nasdaq listing

On June 25, 2019, the Company received a notice letter from the Listing Qualifications Staff of the Nasdaq Stock Market LLC ("Nasdaq") indicating that, based upon the closing bid price of our common stock for the last 30 consecutive business days, the Company no longer met the requirement to maintain a minimum closing bid price of $1 per share, as set forth in Nasdaq Listing Rule 5450(a)(1). On December 26, 2019, the Company obtained an additional compliance period of 180 calendar days by electing to transfer to The Nasdaq Capital Market to take advantage of the additional compliance period offered on that market. On March 26, 2020, the Company obtained shareholder approval to effect a reverse stock split in a range from 20:1 to 40:1, which remains subject to the approval of the Company's board of directors (such final ratio, as determined by our board of directors, the "Reverse Stock Split Ratio" such reverse stock split, the "Reverse Stock Split"). On April 17, 2020, the Company received an additional notice letter from

Nasdaq indicating that based on extraordinary market conditions, Nasdaq has determined to toll the compliance periods for bid price and market value of publicly held shares requirements (collectively, the "Price-based Requirements") through June 30, 2020. Accordingly, since the Company had 66 calendar days remaining in the compliance period as of April 16, 2020, the Company will, upon reinstatement of the Price-based Requirements, still have 66 calendar days from July 1, 2020, or until September 4, 2020, to regain compliance. The Company can regain compliance, either during the suspension or during the compliance period resuming after the suspension, by evidencing compliance with the Price-based Requirements for a minimum of 10 consecutive trading days. The Company intends to comply with the Price-based Requirements by effecting the Reverse Stock Split. To qualify, the Company would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market.

Liquidity

As of March 31, 2020, the Company had cash and cash equivalents of approximately $27.4 million and no restricted cash. The Company had an accumulated deficit of approximately $279.5 million. The Company also had negative cash flows from operations of approximately $14.9 million during the year ended March 31, 2020.

Through March 31, 2020, the Company has financed its operations primarily through the sale of convertible notes, warrants, the private placement of equity securities, the sale of common stock through public and at-the-market ("ATM") offerings, and through revenue derived from product and research service-based agreements, collaborative agreements, licenses, and grants. During the year ended March 31, 2020, the Company issued 6,087,382 shares of its common stock through its ATM facility and received net proceeds of approximately $5.0 million.

Throughout the strategic alternatives assessment process, the Company has taken steps to manage its resources and extend its cash runway including reducing commercial activities related to its liver tissues, except for sales of primary human cells out of inventory, negotiating an exit from its long-term facility lease, selling various assets, and reducing its workforce to the minimum level necessary to explore and support these strategic alternatives as well as to support the remainder of the Company's on-going business activities and assets, including its intellectual property platform and collaborations with research institutions and universities. As a result, the Company terminated the employment of 52 employees, or 90% of its workforce and recorded a restructuring charge during the year ended March 31, 2020 of approximately $2.7 million, related to employee severance and benefits costs, of which $1.7 million was paid out during the fiscal second quarter, $0.9 million was paid out during the fiscal third quarter, and $0.1 million was paid out during the fiscal fourth quarter.

While the Company believes that it can maintain its current operations for at least the next 12 months, based on its current plans and available resources, the assessment by the Company discussed above with respect to its strategic alternatives raises uncertainty over the Company's ability to successfully finance itself on a long-term basis. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Use of estimates

The preparation of the financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ from those estimates. Significant estimates used in preparing the consolidated financial statements include those assumed in revenue recognition, the measurement of operating lease right-of-use assets and lease liabilities, the valuation of stock-based compensation expense, the valuation of impairment of long-lived assets, our assessment of contingent liabilities that would require the establishment of a reserve, and the valuation allowance on deferred tax assets. On an ongoing basis, management reviews these estimates and assumptions. Though the impact of the COVID-19 pandemic to our business and operating results presents additional uncertainty, we continue to use the best information available to inform our critical accounting estimates.

Financial instruments

For certain of the Company's financial instruments, including cash and cash equivalents, inventory, prepaid expenses and other assets, accounts payable, accrued expenses, deferred revenue, and capital lease obligations, the carrying amounts are generally considered to be representative of their respective fair values because of the short-term nature of those instruments.

Cash and cash equivalents

The Company considers all highly liquid investments with original maturities of 90 days or less to be cash equivalents.

Restricted cash

As of March 31, 2020 and 2019, the Company had approximately $0 and $79,000 of restricted cash, respectively, deposited with a financial institution. The entire amount was held in certificates of deposit to support a letter of credit agreement related to the Company's facility lease, which was terminated in November 2019.

Inventory

Inventories are stated at the lower of the cost or net realizable value (first-in, first-out). The Company had no inventory at March 31, 2020. Inventory at March 31, 2019 consists of approximately $361,000 in raw materials, no work-in-process inventory, and approximately $129,000 in finished goods net of reserve.

Fixed assets and depreciation

Property and equipment are carried at cost. Expenditures that extend the life of the asset are capitalized and depreciated. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the related assets or, in the case of leasehold improvements, over the lesser of the useful life of the related asset or the remaining lease term. The estimated useful lives of the fixed assets range between one and seven years.

Impairment of long-lived assets

In accordance with ASC 360-10, the Company records an impairment loss on long-lived assets used in operations when events and circumstances indicate that long-lived assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets (i.e. not able to be recovered). During the second quarter of fiscal 2020, the Company announced the restructuring of its operations. This event required the reevaluation of the recoverability of the gross carrying value of its long-lived assets. Upon the Company's announcement and at each quarter-end, the Company performed an asset impairment analysis on its long-lived asset group, consisting primarily of licensed intangible assets, computer equipment, and software following the completion of various asset sales prior to March 31, 2020, which concluded that the carrying amount is not recoverable. However, the Company's analysis indicated that carrying amount of the asset group did not exceed its fair value. As such, no impairment loss is required to be recognized. Nonetheless, it is reasonably possible that the impairment analysis may change in the near term resulting in the need to write down those assets to fair value. The Company will continue to monitor assets for impairment.

Assets held for sale

The Company classifies assets held for sale if all held for sale criteria is met pursuant to ASC 360-10. Assets classified as held for sale are not depreciated and are measured at the lower of their carrying amount or fair value less cost to sell. Further, assets held for sale are presented as current assets on the consolidated balance sheet.

Research and development

Research and development expenses, including direct and allocated expenses, consist of independent research and development costs, as well as costs associated with sponsored research and development. Research and development costs are expensed as incurred.

Income taxes

Deferred income taxes are recognized for the tax consequences in future years for differences between the tax basis of assets and liabilities and their financial reporting amounts at each year end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense is the combination of the tax payable for the year and the change during the year in deferred tax assets and liabilities. The Company's policy regarding uncertainty in income taxes is pursuant to ASC 740-10. Interest and penalties that would be assessed in relation to the settlement value of unrecognized tax benefits is recognized as a component of income tax expense.

Revenue recognition

The Company has generated revenues from payments received from research service agreements, product sales, collaborative agreements with partners including pharmaceutical and biotechnology companies and academic institutions, licenses, and grants from the National Institutes of Health ("NIH") and private not-for-profit organizations.

Billings to customers or payments received from customers are included in deferred revenue on the consolidated balance sheet until all revenue recognition criteria are met. As of March 31, 2020 and 2019, the Company had approximately $0 and $525,000, respectively, in deferred revenue related to its research service agreements, collaborative agreements, and licenses within the scope of Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers ("Topic 606"). In the year ended March 31, 2020, the Company recognized revenue on approximately $525,000, of which $490,000 related to the expiration of an agreement with a non-refundable up-front fee, that had been recorded as deferred revenue at March 31, 2019.

Service revenues

The Company's service-based business, Organovo, Inc., utilized its NovoGen® bioprinting platform to provide customers access to its highly specialized tissues that model human biology and disease, and to *in vitro* testing services based on that technology. These contracts with customers contained multiple performance obligations including: (i) bioprinting tissues for the customer, (ii) reporting the results of tests performed on the printed tissues pursuant to the agreed upon work plan through exposure of the tissue to various factors (including the customer's proprietary compound), and (iii) delivering specific byproduct study materials, which were satisfied, respectively, at each of the following points in time: (i) upon completion of manufacturing of the bioprinted tissue for the customer, (ii) upon delivery of the report on tests performed on the tissue, and (iii) upon making certain study materials generated from the aforementioned testing process available to the customer. The customer did not have access or control of any performance obligation prior to the point in time of full completion of the corresponding performance satisfying event as defined above. Furthermore, although the service could be customized for each customer, it was not so highly customized as to not have an alternative use either to other customers or to the Company without significant economic consequences or rework. Accordingly, the Company's service-based business utilized point-in-time recognition under Topic 606.

For service contracts, the Company allocates the transaction price to each performance obligation based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. If the standalone selling price is not observable through past transactions, the Company estimates the standalone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations. The transaction price for service business contracts is a fixed consideration.

In connection to the Company's decision to pursue its strategic alternatives, the Company halted commercial activities related to its liver tissues. The Company is expected to continue to maintain its external research collaborations and its intellectual property portfolio.

Product sales, net

The Company's product-based business, Samsara, produced high-quality cell-based products for use in Organovo's 3D tissue manufacturing and for use by life science customers. The Company recognizes product revenue when the performance obligation is satisfied, which is at the point in time the customer obtains control of the Company's product, typically upon delivery. Product revenues are recorded at the transaction price, net of any estimates for variable consideration under Topic 606. The Company's process for estimating variable consideration does not differ materially from its historical practices. Variable consideration is estimated using the expected value method which considers the sum of probability-weighted amounts in a range of possible amounts under the contract. Product revenue reflects the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the individual contracts. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results vary materially from the Company's estimates, the Company will adjust these estimates, which will affect revenue from product sales and earnings in the period such estimates are adjusted.

The Company provides no right of return to its customers except in cases where a customer obtains authorization from the Company for the return. To date, there have been no product returns.

On November 7, 2019, the Company entered into an agreement to sell substantially all of the Samsara inventory and associated assets for $1.5 million, which was recorded to other income. As a result, the Company will have no further product sales of cells nor tissues beyond what it sold prior to the November 2019 sale. In March 2020, the Company dissolved Samsara.

Collaborative research, development, and licenses

The Company has entered into collaborative agreements with partners that typically include one or more of the following: (i) non-exclusive license fees; (ii) non-refundable up-front fees; (iii) payments for reimbursement of research costs; (iv) payments associated with achieving specific development milestones; and (v) royalties based on specified percentages of net product sales, if any. At the initiation of an agreement, the Company has analyzed whether it results in a contract with a customer under Topic 606 or in an arrangement with a collaborator subject to guidance under ASC 808, *Collaborative Arrangements* ("Topic 808").

The Company has considered a variety of factors in determining the appropriate estimates and assumptions under these arrangements, such as whether the elements are distinct performance obligations, whether there are determinable stand-alone prices, and whether any licenses are functional or symbolic. The Company has evaluated each performance obligation to determine if it can be satisfied and recognized as revenue at a point in time or over time. Typically, non-exclusive license fees, non-refundable upfront fees, and funding of research activities have been considered fixed, while milestone payments have been identified as variable consideration which must be evaluated to determine if it has been constrained and, therefore, excluded from the transaction price.

The Company's collaborative agreements that were not completed at the implementation of Topic 606 on April 1, 2018, consisted of research collaboration and limited technology access licenses. These agreements provide the licensee with a non-exclusive, non-transferable, limited, royalty-free technology license, including access to Organovo's proprietary bioprinter platform, training, and continued support by means of consumables and consultation throughout the duration of the contract. The Company has determined that the intellectual property license is not distinct from the continued support promised under the agreement and is therefore a single combined performance obligation. The Company recognized revenue for these combined performance obligations over time for the duration of the license period, as the combined performance obligation would not be fully satisfied until the end of the contract.

For the year ended March 31, 2020, all collaborations and licenses revenue was within the scope of Topic 606 and recognized accordingly. As of September 30, 2019, the Company completed its obligations under the existing agreements with respect to receipts of revenue and does not anticipate recording any further revenue. See "Note 4. Collaborative Research, Development, and License Agreements" for more information on the Company's collaborative agreements.

Grant revenues

In July 2017, the NIH awarded the Company a "Research and Development" grant totaling approximately $1,657,000 of funding over three years. The Company has concluded this government grant is not within the scope of Topic 606, as government entities do not meet the definition of a "customer" as defined by Topic 606, as there is not considered to be a transfer of control of goods or services to the government entity funding the grant. Additionally, the Company has concluded this government grant does meet the definition of a contribution and is a non-reciprocal transaction, however, Subtopic 958-605, *Not-for-Profit-Entities-Revenue Recognition* does not apply, as the Company is a business entity and the grant is with a governmental agency.

Revenues from this grant have been based upon internal costs incurred that are specifically covered by the grant, plus an additional rate that provides funding for overhead expenses. Revenue has been recognized as the Company incurs expenses that are related to the grant. The Company believes this policy is consistent with the overarching premise in Topic 606, to ensure that it recognizes revenues to reflect the transfer of promised goods or services to customers in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services, even though there is no "exchange" as defined in the Financial Accounting Standards Board's Accounting Standards Codification ("ASC"). The Company believes the recognition of revenue as costs are incurred and amounts become earned/realizable is analogous to the concept of transfer of control of a service over time under Topic 606.

Revenue recognized under this grant was approximately $52,000 and $587,000 during the years ended March 31, 2020 and 2019, respectively.

In connection to the Company's decision to pursue its strategic alternatives, specific to the NIH grant, all internal research activities have been halted and transferred to the University of California, San Diego, leaving a remaining available balance of approximately $0.5 million that will not be utilized by the Company.

Cost of revenue

The Company reported $0.3 million and $0.5 million in cost of revenue for the years ended March 31, 2020 and 2019, respectively, which includes an inventory write-off during the current year fiscal second quarter of approximately $0.2 million consisting of raw materials related to the Company's bioprinting and testing services and is a result of the Company's decision to pursue its strategic alternatives. Cost of revenues consists of our costs related to manufacturing and delivering our product and service revenue.

Stock-based compensation

The Company accounts for stock-based compensation in accordance with the ASC Topic 718, *Compensation — Stock Compensation*, which establishes accounting for equity instruments exchanged for employee services. Under such provisions, stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense, under the straight-line method, over the employee's requisite service period (generally the vesting period of the equity grant).

The Company accounts for equity instruments, including restricted stock or stock options, issued to non-employees in accordance with authoritative guidance for equity-based payments to non-employees. Stock options issued to non-employees are accounted for at their estimated fair value determined using the Black-Scholes option-pricing model. As of April 1, 2019, the fair value of options granted to non-employees is consistent with the measurement and classification of share-based payment to employees. Restricted stock issued to non-employees is accounted for at its estimated fair value as it vests.

Comprehensive income (loss)

Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company is required to record all components of comprehensive income (loss) in the financial statements in the period in which they are recognized. Net income (loss) and other comprehensive income (loss), including unrealized gains and losses on investments, are reported, net of their related tax effect, to arrive at comprehensive income (loss). For the years ended March 31, 2020 and 2019, the comprehensive loss was equal to the net loss.

Net loss per share

Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. The weighted-average number of shares used to compute diluted loss per share excludes any assumed exercise of stock options and warrants, shares reserved for purchase under the Company's 2016 Employee Stock Purchase Plan ("ESPP"), the assumed release of restriction of restricted stock units, and shares subject to repurchase as the effect would be anti-dilutive. No dilutive effect was calculated for the years ended March 31, 2020 and 2019 as the Company reported a net loss for each respective period and the effect would have been anti-dilutive.

Common stock equivalents excluded from computing diluted net loss per share were approximately 12.1 million shares and 14.4 million shares for the years ended March 31, 2020 and 2019, respectively.

Note 2. Fixed Assets

Fixed assets consisted of the following (in thousands):

	March 31, 2020	March 31, 2019
Construction in Progress	$ —	$ 47
Laboratory equipment	$ —	$ 3,690
Leasehold improvements	—	1,809
Computer software and equipment	415	645
Furniture and fixtures	—	213
Vehicles	—	9
Fixed Assets, gross	415	6,413
Less accumulated depreciation	(415)	(4,581)
Fixed Assets, net	$ —	$ 1,832

Depreciation expense for the years ended March 31, 2020 and 2019 was approximately $1,128,000 and $969,000, respectively.

Assets held for sale consisted of the following (in thousands):

	March 31, 2020	March 31, 2019
Laboratory equipment	$ 683	$ —
Vehicles	9	—
Assets held for sale, gross	692	—
Less accumulated depreciation	(659)	—
Assets held for sale, net	$ 33	$ —

Assets held for sale are reflected on the consolidated balance sheet at March 31, 2020 as other current assets.

Note 3. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2020	March 31, 2019
Accrued compensation	$ 829	$ 2,160
Accrued legal and professional fees	240	152
Other accrued expenses	21	237
	$ 1,090	$ 2,549

Note 4. Collaborative Research, Development, and License Agreements

Collaboration Agreements

In December 2016, the Company signed a collaborative non-exclusive research affiliation with a university medical school and a non-profit medical charity, under which the Company received a one-time grant from the charity towards the placement of a NovoGen® Bioprinter at the university for the purpose of developing a kidney organoid for potential therapeutic applications. The Company received up-front payments in January and March 2017, which has been recorded as deferred revenue. Revenue of $19,000 and $39,000 was recorded under this agreement for the years ended March 31, 2020 and 2019, respectively. The Company completed its obligations under this agreement and does not anticipate recording any further revenue.

In April 2017, the Company signed a collaborative non-exclusive research affiliation with a university, under which the Company received a one-time non-refundable payment toward the placement of a NovoGen® Bioprinter at the university for the purpose of specific research projects mutually agreed upon by the university and the Company in the field of volumetric muscle loss. The Company received an up-front payment in May 2017, which was recorded as deferred revenue. Revenue of approximately $0 and $57,000 has been recorded under this agreement for the years ended March 31, 2020 and 2019, respectively. In addition, during April 2017, the Company signed a non-exclusive patent license agreement with the university including an annual fee of $75,000 for each of the two years for the license to the Company patents for research use limited to the field of volumetric muscle loss. The Company received the first annual payment of $75,000 in April 2017 and the second annual payment of $75,000 in May 2018, which were initially recorded as deferred revenue. Revenue of $0 and $75,000 was recorded under this agreement for the years ended March 31, 2020 and 2019, respectively. The Company completed its obligations under these agreements with respect to receipts of revenue and does not anticipate recording any further revenue.

In November 2019, the Company signed a non-exclusive patent license agreement with Viscient Biosciences, a related party, including a one-time, non-refundable fee of $70,000 for a license to certain Company patents for *in vitro* research limited to certain fields of use. The Company received the one-time payment in November 2019, which was recorded as revenue. The Company completed its obligations under these agreements with respect to receipts of revenue and does not anticipate recording any further revenue. See “Note. 10 Related Parties” for more information.

University of Missouri

In March 2009, the Company entered into a license agreement with the Curators of the University of Missouri to in-license certain technology and intellectual property relating to self-assembling cell aggregates and to intermediate cellular units. The Company received the exclusive worldwide rights to commercialize products comprising this technology for all fields of use. The Company is required to pay the University of Missouri royalties ranging from 1% to 3% of net sales of covered tissue products, and of the fair market value of covered tissues transferred internally for use in the Company’s commercial service business, depending on the level of net sales achieved by the Company each year. The Company paid minimum annual royalties of $25,000 in January 2020 and January 2019 for their respective calendar years, which is credited against royalties due during the subsequent twelve months. No payments have been made in excess of the minimum annual royalties in the years ended March 31, 2020 and 2019.The license agreement terminates upon expiration of the patents licensed and is subject to certain conditions as defined in the license agreement, which are expected to expire after 2029.

In March 2010, the Company entered into a license agreement with the Curators of the University of Missouri to in-license certain technology and intellectual property relating to engineered biological nerve grafts. The Company received the exclusive worldwide rights to commercialize products comprising this technology for all fields of use. The Company is required to pay the University of Missouri royalties ranging from 1% to 3% of net sales of covered tissue products depending on the level of net sales achieved by the Company each year. The license agreement terminates upon expiration of the patents licensed and is subject to certain conditions as defined in the license agreement. No payments have been made in the years ended March 31, 2020 and 2019.

Clemson University

In May 2011, the Company entered into a license agreement with Clemson University Research Foundation to in-license certain technology and intellectual property relating to ink-jet printing of viable cells. The Company received the exclusive worldwide rights to commercialize products comprising this technology for all fields of use. The Company is required to pay the University royalties ranging from 1.5% to 3% of net sales of covered tissue products and the fair market value of covered tissues transferred internally for use in the Company's commercial service business, depending on the level of net sales reached each year. The license agreement terminates upon expiration of the patents licensed, which is expected to expire in May 2024, and is subject to certain conditions as defined in the license agreement. Minimum annual royalty payments of $20,000 were due for each of the two years beginning with calendar 2014, and $40,000 per year beginning with calendar 2016. The annual minimum royalty is creditable against royalties owed during the same calendar year.

UniQuest

In August 2015, the Company entered into a license agreement with UniQuest Pty Limited to in-license certain technology and intellectual property relating to technologies for *in vitro* applications with the exclusion of individual cell types isolated and purified from the organoids or induced pluripotent stem-derived kidney structures. The Company received the exclusive worldwide rights to commercialize products comprising this technology for all fields of use. The Company is required to pay UniQuest certain royalties based on net sales of licensed products, depending on the level of net sales reached each year, and certain royalties for any consideration invoiced or received by the Licensee in return for the grant of sub-licenses, options, marketing, or distribution rights, arising from the licensed intellectual property. In addition, the Company is required to pay certain milestone payments. As of March 31, 2020, the Company has made two milestone payments of $20,000. The license agreement terminates upon expiration of the patents licensed, which is expected to expire in August 2025, and is subject to certain conditions as defined in the license agreement. The Company paid an initial fee of $35,000 in September 2015, as well as minimum annual royalty payments of $15,000 AUD, which are due annually following the third anniversary of the agreement (i.e. August 2018).

In December 2016, the Company entered into a license agreement with UniQuest Pty Limited to in-license certain technology and intellectual property relating to technologies for generation of organoids or cells in a 3D configuration via a bioprinter or other device for additive cellular manufacturing and use in *in vivo* applications. The Company received the exclusive worldwide rights to commercialize products comprising this technology for all fields of use. The Company is required to pay UniQuest certain royalties based on net sales of licensed products, depending on the level of net sales reached each year, and certain royalties for any consideration invoiced or received by the Licensee in return for the grant of sub-licenses, options, marketing, or distribution rights, arising from the licensed intellectual property. In addition, the Company is required to pay certain milestone payments. As of March 31, 2020, the Company has not made any milestone payments. The license agreement terminates upon expiration of the patents licensed, which is expected to expire in December 2026, and is subject to certain conditions as defined in the license agreement. The Company paid an initial fee of $35,000 for each of the two licenses in June 2017. Minimum annual royalty payments of $25,000 are due annually following the third anniversary of the agreement (i.e. December 2019).

Capitalized license fees consisted of the following (in thousands):

	March 31, 2020	March 31, 2019
License fees	$ 218	$ 218
Less accumulated amortization	(95)	(81)
License fees, net	$ 123	$ 137

The above license fees, net of accumulated amortization, are included in Other Assets in the accompanying consolidated balance sheets and are being amortized over the life of the related patents. Amortization expense of licenses was approximately $14,000 for the years ended March 31, 2020 and 2019. At March 31, 2020, the weighted average remaining amortization period for all licenses was approximately 10 years. The annual amortization expense of licenses for the next five years is estimated to be approximately $14,000 per year.

Note 5. Stockholders' Equity

Stock-based compensation expense and valuation information

Stock-based awards include stock options and restricted stock units under the 2012 Equity Incentive Plan, as amended ("2012 Plan") and Inducement Awards, performance-based restricted stock units under an Incentive Award Performance-Based Restricted Stock Unit Agreement, and rights to purchase stock under the ESPP. The Company calculates the grant date fair value of all stock-based awards in determining the stock-based compensation expense.

Stock-based compensation expense for all stock awards consists of the following (in thousands):

	Year Ended March 31, 2020	Year Ended March 31, 2019
Research and development	$ 111	$ 911
General and administrative	$ 3,997	$ 4,282
Total	$ 4,108	$ 5,193

The total unrecognized compensation cost related to unvested stock option grants as of March 31, 2020 was approximately $3,184,000 and the weighted average period over which these grants are expected to vest is 1.76 years.

The total unrecognized stock-based compensation cost related to unvested restricted stock units (not including performance-based restricted stock units) as of March 31, 2020 was approximately $854,000, which will be recognized over a weighted average period of 1.63 years.

The total unrecognized stock-based compensation cost related to unvested performance-based restricted stock units as of March 31, 2020 was approximately $1,278,000, which will be recognized over a weighted average period of 1.42 years.

As of March 31, 2020, there are no participants enrolled into the employee stock purchase plan for the current purchase period, beginning March 1, 2020.

The Company uses the Black-Scholes valuation model to calculate the fair value of stock options. Stock-based compensation expense is recognized over the vesting period using the straight-line method. The fair value of stock options was estimated at the grant date using the following weighted average assumptions:

	Year Ended March 31, 2020	Year Ended March 31, 2019
Dividend yield	—	—
Volatility	84.36%	72.99%
Risk-free interest rate	1.53%	2.75%
Expected life of options	6.00 years	6.00 years
Weighted average grant date fair value	$ 0.23	$ 0.84

The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. Prior to fiscal year 2020, the Company used a blend of historical volatility and implied volatility of comparable companies. As of April 1, 2019, the Company is using the Company-specific historical volatility rate as it is more reflective of market conditions and a better indicator of expected volatility. The risk-free interest rate assumption was based on U.S. Treasury rates. The weighted average expected life of options was estimated using the average of the contractual term and the weighted average vesting term of the options. Prior to fiscal year 2020, certain options granted to consultants were subject to variable accounting treatment and were required to be revalued until vested. As of April 1, 2019, the measurement and classification of share-based payment to non-employees is consistent with the measurement and classification of share-based payment to employees.

The fair value of each restricted stock unit is recognized as stock-based compensation expense over the vesting term of the award. The fair value is based on the closing stock price on the date of the grant.

The Company uses the Black-Scholes valuation model to calculate the fair value of shares issued pursuant to the Company's ESPP. Stock-based compensation expense is recognized over the purchase period using the straight-line method. The fair value of ESPP shares was estimated at the purchase period commencement date using the following weighted average assumptions:

	Year Ended March 31, 2020*	Year Ended March 31, 2019
Dividend yield	—	—
Volatility	43.69%	43.7 - 80.2%
Risk-free interest rate	2.52%	1.85 - 2.52%
Expected term	6 months	6 months
Grant date fair value	$ 0.29	$ 0.29 - $0.45

*There were no participants in the ESPP for the purchase period September 1, 2019 – February 29, 2020 nor any participants in the ESPP for the current purchase period (beginning March 1, 2020).

The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. The Company uses the Company-specific historical volatility rate as the indicator of expected volatility. The risk-free interest rate assumption was based on U.S. Treasury rates. The expected life is the 6-month purchase period.

Preferred stock

The Company is authorized to issue 25,000,000 shares of preferred stock. There are no shares of preferred stock currently outstanding, and the Company has no present plans to issue shares of preferred stock.

Common stock

In May of 2008, the Board of Directors of the Company approved the 2008 Equity Incentive Plan (the "2008 Plan"). The 2008 Plan authorized the issuance of up to 1,521,584 common shares for awards of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock award units, and stock appreciation rights. The 2008 Plan terminated on July 1, 2018. As of March 31, 2019, 896,256 shares under the 2008 Plan have been issued.

In January 2012, the Board of Directors of the Company approved the 2012 Plan. The 2012 Plan authorized the issuance of up to 6,553,986 shares of common stock for awards of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, performance units, performance shares, and other stock or cash awards. The Board of Directors and stockholders of the Company approved an amendment to the 2012 Plan in August 2013 to increase the number of shares of common stock that may be issued under the 2012 Plan by 5,000,000 shares. In August 2015, the Board of Directors and stockholders of the Company approved an amendment to the 2012 Plan in August 2015 to further increase the number of shares of common stock that may be issued under the 2012 Plan by 6,000,000 shares. In July 2018, the Board of Directors and stockholders of the Company approved an amendment to the 2012 Plan to further increase the number of shares of common stock that may be issued under the 2012 Plan by 11,000,000 shares, bringing the aggregate shares issuable under the 2012 Plan to 28,553,986. The 2012 Plan as amended and restated became effective on July 26, 2018 and terminates ten years after such date. As of March 31, 2020, 14,158,654 shares remain available for issuance under the 2012 Plan.

On April 24, 2017 the Company filed a Registration Statement on Form S-8 with the SEC authorizing the issuance of 2,297,034 shares of the Company's Common Stock, pursuant to the terms of an Inducement Award Stock Option Agreement and an Inducement Award Performance-Based Restricted Stock Unit Agreement (collectively, the "Inducement Award Agreements").

On August 14, 2018 the Company filed a Registration Statement on Form S-8 with the SEC authorizing the issuance of 1,135,408 shares of the Company's Common Stock, pursuant to the terms of an Inducement Award Stock Option Agreement and an Inducement Award Restricted Stock Unit Agreement (collectively, the "Inducement Award Agreements").

The Company has an effective shelf registration statement on Form S-3 (File No. 333-222929) and the related prospectus previously declared effective by the Securities and Exchange Commission (the "SEC") on February 22, 2018, as supplemented by a prospectus supplement, dated March 16, 2018 (the "2018 Shelf"), that expires on February 22, 2021. This replaces the 2015 Shelf which expired on March 17, 2018.

On March 16, 2018, the Company entered into a Sales Agreement ("2018 Sales Agreement") with H.C. Wainwright & Co., LLC and Jones Trading Institutional Services LLC (each an "Agent" and together, the "Agents") and filed a prospectus supplement to the 2018 Shelf, pursuant to which the Company may offer and sell, from time to time through the Agents, shares of its common stock in at-the-market sales transactions having an aggregate offering price of up to $50,000,000. Any shares offered and sold will be issued pursuant to the Company's 2018 Shelf. During the years ended March 31, 2020 and 2019, the Company issued 6,087,382 shares and 11,631,803 shares of common stock, respectively, for net proceeds of $5.0 million and $13.2 million in at-the-market offerings under the 2018 Sales Agreement. As of March 31, 2020, the Company has sold an aggregate of 17,719,185 shares of common stock in at-the-market offerings under the 2018 Sales Agreement, with gross proceeds of approximately $18.7 million. Based on these sales, the Company cannot raise more than an aggregate of $81.3 million in future offerings under the 2018 Shelf, including the $31.3 million remaining available for future issuance through its at-the-market program under the 2018 Sales Agreement. On July 26, 2018, the Company filed an amendment to its certificate of incorporation to increase the number of authorized shares of common stock to 200,000,000 shares.

During the years ended March 31, 2020 and 2019, the Company issued 0 and 622,192 shares of common stock upon exercise of 0 and 622,192 stock options, respectively.

On June 25, 2019, the Company received a notice letter from the Listing Qualifications Staff of Nasdaq indicating that, based upon the closing bid price of the Company's common stock for the last 30 consecutive business days, the Company no longer met the requirement to maintain a minimum closing bid price of $1 per share, as set forth in Nasdaq Listing Rule 5450(a)(1). On December 26, 2019, the Company obtained an additional compliance period of 180 calendar days by electing to transfer to The Nasdaq Capital Market. On March 26, 2020, the Company obtained shareholder approval to effect a reverse stock split in a range from 20:1 to 40:1, which remains subject to the approval of the Company's board of directors, in order to meet the minimum closing bid price per share requirement under the Nasdaq Listing Rules. On April 17, 2020 the Company received an additional notice letter from Nasdaq indicating that based on extraordinary market conditions, Nasdaq has determined to toll the compliance periods for bid price and market value of publicly held shares requirements (collectively, the "Price-based Requirements") through June 30, 2020. Accordingly, since the Company had 66 calendar days remaining in its compliance period as of April 16, 2020, the Company will, upon reinstatement of the Price-based Requirements, still have 66 calendar days from July 1, 2020, or until September 4, 2020, to regain compliance. The Company can regain compliance, either during the suspension or during the compliance period resuming after the suspension, by evidencing compliance with the Price-based Requirements for a minimum of 10 consecutive trading days. The Company intends to comply with the Price-based Requirements by effecting the Reverse Stock Split. To qualify, the Company would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market. There can be no assurance that the Company will be able to regain compliance with the minimum bid price requirement or maintain compliance with the other listing requirements necessary to maintain the listing of its common stock on The Nasdaq Capital Market. The Company's failure to regain compliance during this second compliance period could result in delisting.

Restricted stock units

During the year ended March 31, 2020, the Company issued restricted stock units for an aggregate of 585,926 shares of common stock to its employees. These shares of common stock will be issued upon vesting of the restricted stock units.

On August 14, 2018, in connection with the appointment of a new Chief Medical Officer ("CMO"), the Company allocated 160,714 Restricted Stock Units ("RSUs") outside of the 2012 Plan. The Company intends for these to be "inducement awards" within the meaning of Nasdaq Marketplace Rule 5635(c)(4). While outside the Company's 2012 Plan, the terms and conditions of these awards are consistent with awards granted to the Company's executive officers pursuant to the 2012 Plan. These RSUs vest over a four-year period, with a quarter of the option shares vesting on the one-year anniversary of the vesting commencement date and the remaining options shares vesting in equal quarterly installments over the 12 quarterly periods thereafter. The CMO was terminated in August 2019.

The following table summarizes the Company's restricted stock unit (not including performance-based restricted stock units) activity for the year ended March 31, 2020:

	Number of Shares	Weighted Average Price
Unvested at March 31, 2019	2,080,723	$ 1.80
Granted	585,926	$ 0.97
Vested	(563,271)	$ 2.29
Canceled / forfeited	(1,623,122)	$ 1.29
Unvested at March 31, 2020	480,256	$ 1.95

Performance-based restricted stock units

On April 24, 2017, the Company issued a Performance-Based Restricted Stock Unit Award for 208,822 shares of common stock (the "PBRSU") to its newly hired Chief Executive Officer ("CEO"). The PBRSU was issued outside of the 2012 Plan, in the Inducement Award Agreement, as an "inducement award" within the meaning of Nasdaq Marketplace Rule 5635(c)(4). While outside the Company's 2012 Plan, the terms and conditions of this award are consistent with awards granted to the Company's executive officers pursuant to the 2012 Plan. On August 23, 2017, the Board of Directors formally approved the vesting criteria for the PBRSU. The vesting of the PBRSU was divided into five separate tranches each with independent vesting criteria. The first four tranches had performance criteria related to annual revenue goals with measurement at the end of fiscal year 2018 (20 percent), fiscal year 2019 (20 percent), fiscal year 2020 (20 percent), and fiscal year 2021 (20 percent). The fifth tranche has a performance metric related to a path to profitability goal measured as Negative Adjusted Earnings Before Interest, Taxes, Depreciation and Amortization ("EBITDA") achievable at any point between the grant date and the end of fiscal year 2020 (20 percent). The number of units that could ultimately vest for each tranche ranged from 0 percent to 120 percent of the target amount, not to exceed 208,822 in aggregate. On December 12, 2018, the Board of Directors formally approved an amendment to the vesting criteria for the PBRSUs. As of March 31, 2020, 100% of the Negative Adjusted EBITDA tranche, or 41,764 shares had vested and 8,352 units had been forfeited. Based on the amendment to the vesting criteria, the remaining 158,706 units eligible to vest upon future performance were divided into three separate but equal tranches with independent vesting criteria based on the achievement of certain regulatory milestones. As of March 31, 2020, none of the amended tranches had vested.

Based on the amended PBRSU vesting terms, a Type III modification, the modified grant date fair value of the PBRSUs is $165,000 of which one-third is being recognized over the expected service period of each tranche ending April 23, 2023. The Company began recording stock-based compensation expense for the initial performance tranches after the August 23, 2017 grant date when the initial financial performance goals were established and approved and has modified its recording of compensation expense in accordance with the amended performance tranches beginning on December 12, 2018.

On July 2, 2019, the Company issued Performance-Based Restricted Stock Unit Awards (the "PBRSU Retention Awards") for an aggregate of 6,027,899 shares of common stock to its management team. The PBRSUs were issued pursuant to the 2012 Plan. The PBRSU Retention Awards will vest in full upon the earlier of the Company's engagement in a pre-IND meeting with the FDA, twenty-four months from the grant date, or a change in control. As of March 31, 2020, all PBRSUs are expected to vest twenty-four months from the grant date.

The following table summarizes the Company's performance-based restricted stock unit activity for the year ended March 31, 2020:

	Number of Shares	Weighted Average Price
Unvested at March 31, 2019	158,706	$ 1.04
Granted	6,027,899	$ 0.49
Vested	—	$ —
Canceled / forfeited	(2,233,678)	$ 0.49
Unvested at March 31, 2020	3,952,927	$ 0.51

Stock options

During the year ended March 31, 2020 under the 2012 Equity Incentive Plan, 342,500 stock options were issued at various exercise prices.

On April 24, 2017, in connection with the appointment of a new CEO, the Company granted 2,088,212 stock options outside of the 2012 Plan. The Company intends for these to be "inducement awards" within the meaning of Nasdaq Marketplace Rule 5635(c)(4). While granted outside the Company's 2012 Plan, the terms and conditions of this stock option award are consistent with awards granted to the Company's executive officers pursuant to the 2012 Plan. On August 14, 2018, in connection with the appointment of a new CMO, the Company allocated 974,694 stock options outside of the 2012 Plan. The Company intends for these to be "inducement awards" within the meaning of Nasdaq Marketplace Rule 5635(c)(4). While outside the Company's 2012 Plan, the terms and conditions of these awards are consistent with awards granted to the Company's executive officers pursuant to the 2012 Plan. These stock options vest over a four-year period, with a quarter of the option shares vesting on the one-year anniversary of the vesting commencement date and the remaining options shares vesting in equal quarterly installments over the next 12 quarterly periods. The CMO was terminated in August 2019.

The following table summarizes stock option activity for the year ended March 31, 2020:

	Options Outstanding	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at March 31, 2019	12,039,264	$ 2.24	$ —
Options granted	342,500	$ 0.32	$ —
Options canceled	(4,743,688)	$ 2.35	$ —
Options exercised	—	$ —	$ —
Outstanding at March 31, 2020	7,638,076	$ 2.08	$ 37,440
Vested and Exercisable at March 31, 2020	4,184,674	$ 2.53	$ —

The weighted-average remaining contractual term of stock options exercisable and outstanding at March 31, 2020 was approximately 7.34 years.

Employee Stock Purchase Plan

In June 2016, the Company's board of directors adopted, and in August 2016 stockholders subsequently approved, the 2016 Employee Stock Purchase Plan ("ESPP"). The Company reserved 1,500,000 shares of common stock for issuance thereunder. The ESPP permits employees after five months of service to purchase common stock through payroll deductions, limited to 15 percent of each employee's compensation up to $25,000 per employee per year or 10,000 shares per employee per six-month purchase period. Shares under the ESPP are purchased at 85 percent of the fair market value at the lower of (i) the closing price on the first trading day of the six-month purchase period or (ii) the closing price on the last trading day of the six-month purchase period. The initial offering period commenced in September 2016. During the year ended March 31, 2020, no shares were issued under the ESPP. At March 31, 2020, there were 1,188,718 shares remaining available for the purchase under the ESPP.

Warrants

The following table summarizes warrant activity for the year ended March 31, 2020:

	Warrants	Weighted-Average Exercise Price
Balance at March 31, 2019	145,000	$ 7.11
Granted	—	$ —
Expired / Canceled	(145,000)	$ 7.11
Exercised	—	$ —
Balance at March 31, 2020	—	$ —

There were no warrants outstanding at March 31, 2020.

Common stock reserved for future issuance

Common stock reserved for future issuance consisted of the following at March 31, 2020:

Common stock options outstanding and reserved under the 2012 Plan	5,549,864
Common stock reserved under the 2012 Plan	14,158,654
Common stock reserved under the 2016 Employee Stock Purchase Plan	1,188,718
Restricted stock units outstanding under the 2012 Plan	480,256
Performance-based restricted stock units outstanding under the 2012 Plan	3,794,221
Common stock options outstanding and reserved under the Incentive Award Agreement	2,088,212
Performance-based restricted stock units outstanding under the Incentive Award Agreement	158,706
Total at March 31, 2020	27,418,631

Note 6. Leases

Adoption of ASC 842

As of April 1, 2019, the Company adopted ASC 842, which requires lessees to recognize a right-of-use asset ("ROU asset") and lease liability for leases with terms of greater than twelve months. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. The Company implemented this new accounting standard using the modified retrospective method for its existing leases, which did not cause any adjustments to prior year financial statements. The Company elected the package of practical expedients available for existing contracts, which allowed it to carry forward its historical assessments of whether contracts are or contain leases and the classification of its existing operating leases. Additionally, the Company elected the practical expedient to treat lease and non-lease components as a single lease component.

At the time of adoption, the Company leased property and equipment under operating leases, specifically its office building and various copier machines. The Company also had a short-term lease (lease term is less than 12 months), which is not required to be recorded on the balance sheet under ASC 842. Instead, under ASC 842, the Company elected the accounting policy for short term leases to recognize lease payments as an expense on a straight-line basis over the lease term. Upon adoption of ASC 842, the Company recognized ROU assets and corresponding lease liabilities based on the present value of remaining lease payments over the lease terms. ROU assets were measured as lease liabilities plus prepaid rent less any deferred rent. As interest rates were not implicitly stated in the respective lease agreements, nor were they readily determinable, the Company used its incremental borrowing rate as the discount rate when measuring lease liabilities. As a result, the Company recorded ROU assets and lease liabilities of $4.5 million and $5.0 million, respectively. The Company also classified deferred rent of $0.6 million as an offset to the Company's ROU asset upon adoption.

The impact of the adoption of ASC 842 on the consolidated balance sheet as of April 1, 2019 is as follows (in thousands):

	ASC 840 March 31, 2019	Impact of Adoption	ASC 842 April 1, 2019
Deferred Rent	$ 35	$ (35)	$ —
Deferred Rent, net of current portion	$ 588	$ (588)	$ —
Prepaid Rent	$ 88	$ (88)	$ —
Operating right-of-use assets	$ —	$ 4,451	$ 4,451
Operating lease liability	$ —	$ 1,038	$ 1,038
Operating lease liability, net of current portion	$ —	$ 3,948	$ 3,948

After the initial adoption of ASC 842, on an on-going basis, the Company evaluates all contracts upon inception and determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of identified asset in exchange for consideration over a period of time. If a lease is identified, the Company will apply the guidance from ASC 842 to properly account for the lease.

Operating Leases

From July 2012 to November 2019, the Company leased its main facilities at 6275 Nancy Ridge Drive, San Diego, California 92121. The lease, as amended in 2013, 2015, 2016, 2018, and 2019, consisted of approximately 45,580 rentable square feet containing laboratory, clean room and office space. Monthly rental payments are approximately $87,000 with 3% annual escalators. The lease for 14,685 of the total rentable square footage was amended to accelerate the expiration date from December 15, 2018 to October 31, 2018. On November 30, 2018, the Company agreed to extend the term for the remainder of the total rentable square footage under the lease from August 31, 2021 to August 31, 2024 in exchange for $500,000 of landlord funded tenant improvements and a rescission of its option to terminate the lease on or after September 1, 2019 with 9 months prior written notice. On October 11, 2019, the Company entered into an agreement to accelerate the expiration date of the term of the lease for its main facilities on 6275 Nancy Ridge Drive from August 31, 2024 to November 15, 2019. Under this agreement, the Landlord and Tenant agreed that the other is excused as of the termination date from any further obligations. As such, the Company wrote-off its associated right-of-use asset of approximately $4.1 million and lease liabilities of approximately $4.6 million in fiscal 2020, which resulted in a $0.5 million gain on lease termination.

In addition to the Company's main facility lease, on March 21, 2019, the Company entered into an agreement to lease several copy machines for a term of 36 months. The lease contained fixed monthly payments through the entire term of the lease, and it did not contain an option to extend the term or a bargain purchase option. This lease was also carried forward as an operating lease through the adoption of Topic 842. On October 9, 2019, the Company entered into an agreement to assume its leased copy machines, which terminates future obligations. As such, the Company wrote-off its associated right-of-use asset of approximately $26,000 and lease liabilities of approximately $26,000 in the third quarter of fiscal 2020.

On October 2, 2019, the Company entered into an agreement to rent office space at 440 Stevens Avenue, Suite 200, Solana Beach, California 92075. This agreement is a month-to-month contract and can be terminated at-will by either party at any time. As such, the Company has concluded that this agreement does not contain a lease and will be expensed as incurred. Monthly rental payments are approximately $4,000 per month.

The Company recorded operating lease expense on a straight-line basis over the life of the leases. This is consistent with the Company's historical treatment of the lease costs included in operating expenses (referred to as "Rent Expense" prior to adoption of Topic 842). For the year ended March 31, 2020, the Company recorded operating lease expense of approximately $568,000. In addition, the Company recorded rent expense for the office space of approximately $19,000 for the year ended March 31, 2020. For the year ended March 31, 2019, the Company recorded rent expense of approximately $1,173,000. Variable lease costs associated with the Company's leases, such as payments for additional monthly fees to cover the Company's share of certain facility expenses (common area maintenance, or CAM) are not included in operating lease right-of-use assets and lease liabilities, but rather expensed as incurred. Variable lease expense was approximately $305,000 for the year ended March 31, 2020, respectively. Short-term lease cost for the year ended March 31, 2020 was approximately $37,000. The short-term lease was terminated in the fiscal 2020 second quarter.

The table below is a summary of the cash flows associated with the Company's leases for the year ended March 31, 2020 (in thousands):

	For the Year Ended March 31, 2020
Cash paid for amount included in measurement of liabilities:	
Operating cash flows from operating leases	$ 579

Note 7. Commitments and Contingencies

Legal matters

In addition to commitments and obligations in the ordinary course of business, the Company may be subject, from time to time, to various claims and pending and potential legal actions arising out of the normal conduct of its business. On October 10, 2019, a putative class action lawsuit was filed in the U.S. District Court for the District of Delaware against the Company and its board of directors in connection with the annual proxy statement filed by the Company on July 26, 2019. The case was captioned Rianhard v. Crouch., et al., Case No. 19-cv-1922 (D. Del. Oct. 10, 2019) (the "Action"). The complaint alleged that the Schedule 14A proxy statement contained material misrepresentations in connection with the reverse stock split proposal recommended therein and asserted claims for violations of Section 14(a) of the Securities Exchange Act of 1934 and Rule 14a-9 promulgated thereunder, as well as claims for breach of fiduciary duty. On November 25, 2019, the Action was voluntarily dismissed.

On December 31, 2019, the Company received a demand pursuant to Delaware General Corporation Law Section 220 for certain books and records of the Company (the “Demand”). The Company has objected to the Demand and made a limited production of certain records to the demanding stockholder.

On January 30, 2020, the Company received a demand letter (the “Letter”) from a purported stockholder alleging that the disclosures in the Form S-4 filed with the SEC on December 23, 2019 violated federal securities laws by failing to disclose certain allegedly material information. The Letter demands, among other things, that the Company make corrective disclosures and reserves the right to pursue legal action. The Company believes the assertions in the Letter are without merit.

On March 4, 2020, the Company received a letter from the SEC regarding an inquiry into certain of the Company’s prior disclosures and related operations. The Company is cooperating with the SEC in response to a subpoena.

The Company assesses contingencies to determine the degree of probability and range of possible loss for potential accrual in its financial statements. Because litigation is inherently unpredictable and unfavorable resolutions could occur, assessing litigation contingencies is subjective and requires judgments about future events. When evaluating contingencies, the Company 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 it may be unsupported, exaggerated or unrelated to possible outcomes, and as such are not meaningful indicators of its potential liability.

The Company regularly reviews contingencies to determine the adequacy of its accruals and related disclosures. During the period presented, the Company has not recorded any accrual for loss contingencies associated with any claims or legal proceedings; determined that an unfavorable outcome is probable or reasonably possible; or determined that the amount or range of any possible loss is reasonably estimable. However, the outcome of legal proceedings and claims brought against the Company is subject to significant uncertainty. Therefore, although management considers the likelihood of such an outcome to be remote, if one or more of these legal matters were resolved against the Company in a reporting period, the Company’s consolidated financial statements for that reporting period could be materially adversely affected.

Note 8. Income Taxes

A reconciliation of the statutory federal rate and the effective rate, for operations, is as follows for the years ended March 31, 2020 and March 31, 2019 (in thousands):

	March 31, 2020		March 31, 2019	
Tax computed at federal statutory rate	$ (3,929)	21%	$ (5,593)	21.0%
State income tax, net of federal benefit	(714)	3.8%	(884)	3.3%
Executive compensation	—	0.0%	—	0.0%
Stock based compensation	893	-4.8%	871	-3.3%
Research credits	(421)	2.2%	(1,033)	3.9%
Change in tax rate	(193)	1.0%	(380)	1.4%
Removal of net operating losses and research development credits	5,091	-27.2%	4,171	-15.7%
Rate adjustment - tax law	—	0.0%	14	-0.1%
Other	70	-0.3%	2,795	-10.5%
Valuation allowance	(797)	4.2%	39	-0.1%
Provision (benefit) for income taxes	$ —	0.0%	$ —	0.0%

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's net deferred tax assets are as follows as of March 31, 2020 and March 31, 2019 (in thousands):

	March 31, 2020	March 31, 2019
Deferred tax assets:		
Net operating loss carry forwards	$ —	$ —
Research and development credits	—	—
Depreciation and amortization	5	28
Accrued expenses and reserves	173	886
Stock compensation	3,899	3,941
Other, net	1	20
Total deferred tax assets	4,078	4,875
Valuation allowance	(4,078)	(4,875)
	$ —	$ —

A full valuation allowance has been established to offset the deferred tax assets as management cannot conclude that realization of such assets is more likely than not. Under the Internal Revenue Code ("IRC") Sections 382 and 383, annual use of our net operating loss and research tax credit carryforwards to offset taxable income may be limited based on cumulative changes in ownership. We have not completed an analysis to determine whether any such limitations have been triggered as of March 31, 2020. Until this analysis is completed, we have removed the deferred tax assets related to net operating losses and research credits from our deferred tax asset schedule. Further, until a study is completed and any limitation known, no amounts are being considered as an uncertain tax position or disclosed as an unrecognized tax benefit. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact its effective tax rate. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance. The valuation allowance decreased by approximately $798,000 and increased by approximately $39,000 for the years ended March 31, 2020 and 2019, respectively.

The Company had federal and state net operating loss carryforwards of approximately $183.8 million and $33.4 million, respectively, as of March 31, 2020. Federal net operating loss carryforwards of approximately $40.2 million will carryforward indefinitely and be available to offset up to 80% of future taxable income each year subject to revisions made by the CARES Act. The remaining federal net operating losses will begin to expire in 2028, unless previously utilized. The state net operating loss carryforwards ("NOLs") will begin to expire in 2028, unless previously utilized.

The Company had federal and state research tax credit carryforwards of approximately $4.2 million and $3.7 million at March 31, 2020, respectively. The federal research tax credit carryforwards begin expiring in 2028. The state research tax credit carryforwards do not expire.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was enacted in response to the COVID-19 pandemic. The CARES Act contains temporary taxpayer favorable provisions related to the use of net operating losses and the deductibility of interest expense, charitable contributions, and qualified improvement property. Due to the generation of losses, the Company does not expect to be materially impacted by the CARES Act.

On April 1, 2019, the Company adopted ASU 2016-02, Leases ("Topic 842"). There was no net tax impact recorded as a result of the adoption.

The Company did not record any accruals for income tax accounting uncertainties for the year ended March 31, 2020.

The Company did not accrue either interest or penalties from inception through March 31, 2020.

The Company does not expect its unrecognized tax benefits to significantly increase or decrease within the next 12 months.

The Company is subject to tax in the United States and in various state jurisdictions. As of March 31, 2020, the Company's tax years from inception are subject to examination by the tax authorities due to the generation of net operating losses. The Company is not currently under examination by any jurisdiction.

Note 9. Concentrations

Credit risk and significant customers

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of temporary cash investments. The Company maintains cash balances at various financial institutions located within the United States. Accounts at these institutions are secured by the Federal Deposit Insurance Corporation. Balances may exceed federally insured limits. The Company has not experienced losses in such accounts, and management believes that the Company is not exposed to any significant credit risk with respect to its cash and cash equivalents.

The Company is also potentially subject to concentrations of credit risk in its revenues and accounts receivable. Because it is in the early commercial stage, the Company's revenues to date have been derived from a relatively small number of customers and collaborators. However, the Company has not historically experienced any accounts receivable write-downs and management does not believe significant credit risk exists as of March 31, 2020.

Note 10. Related Parties

From time to time, the Company will enter into an agreement with a related party in the ordinary course of its business and on terms and conditions it believes are as fair as those it offers and receives from independent third parties. These agreements are ratified by the Company's Board of Directors or a committee thereof pursuant to its related party transaction policy.

In August 2017, the Company entered into a research services agreement with Cirius Therapeutics, Inc. ("Cirius"), an entity for which Robert Baltera, Jr., a former director of the Company, serves as Chief Executive Officer and President. Under this agreement, the Company is providing standard research services to Cirius utilizing its ExVive™ Liver Tissue platform. The Company has provided and recognized revenue for ExVive™ Liver Tissue Services for Cirius in the amount of $281,000 to date. Organovo completed its obligations as of December 2018. No further revenues are expected.

In November 2018, the Company entered into a research services Quote with Viscient Biosciences ("Viscient"), an entity for which Keith Murphy, the Company's former director, Chief Executive Officer, and President, serves as the Chief Executive Officer and President. Under this Quote, the Company provided research services in the amount of $142,000, amended in April 2019 to include an additional $7,000 of services. As of March 31, 2019, the Company recognized revenue of $42,000 for services provided and the remaining amount of $107,000 was recognized as revenue in the year ended March 31, 2020. In November 2019, the Company entered into an agreement with Viscient to sell certain bioprinting equipment and a non-exclusive license to certain intellectual property for approximately $171,000, of which $101,000 was recognized as other income and $70,000 was recognized as revenue in the year ended March 31, 2020. In addition to the services provided by Organovo, Viscient has purchased primary human cell-based products from our subsidiary, Samsara. Pursuant to the terms of multiple Quotes, $128,000 and $96,000 was recognized as revenue in the year ended March 31, 2020 and 2019, respectively. There is approximately $111,000 of accounts receivable outstanding as of March 31, 2020 and $39,000 of accounts receivable outstanding as of March 31, 2019. The balance owing at March 31, 2020 is several months past due (as of that date) and the Company is currently attempting to secure an informal resolution of these outstanding invoices, but if unable to do so, the Company intends to pursue a formal collection action. Since there has been no history of bad debt with Viscient and the customer indicated a willingness to settle the debt, the Company deemed that a reserve against the receivable was not necessary.

Note 11. Defined Contribution Plan

The Company has a defined contribution 401(k) plan covering substantially all employees. During the year ended March 31, 2015, the 401(k) plan was amended (the "Amended Plan") to include an employer matching provision. Under the terms of the Amended Plan, the Company will make matching contributions on up to the first 6% of compensation contributed by its employees. Amounts expensed under the Company's 401(k) plan for the years ended March 31, 2020 and 2019 were approximately $152,000 and $240,000, respectively.

Note 12. Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies. Unless otherwise stated, the Company believes that the impact of the recently issued accounting pronouncements that are not yet effective will not have a material impact on its consolidated financial position or results of operations upon adoption.

Adoption of New Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, Leases ("ASC 842"), which supersedes the lease guidance under ASC 840, Leases. The new accounting standard requires an entity to recognize right-of-use assets and corresponding lease liabilities on the balance sheet for all leases with terms of more than 12 months and to disclose key information about leasing arrangements. This new guidance became effective for the Company on April 1, 2019. The Company adopted ASC 842 on April 1, 2019 and elected the optional transition method that allows for a cumulative-effect adjustment in the period of adoption, which was not applicable, and did not require restatement of prior periods. The Company elected the package of practical expedients permitted under the transition guidance, but not the hindsight practical expedient. Please refer to "Note 6. Leases" for more information regarding the Company's adoption of the new lease standard.

In February 2018, the FASB issued ASU No. 2018-02, *Income Statement – Reporting Comprehensive Income* ("Topic 220"), which allows stranded tax effects resulting from the Tax Cuts and Jobs Act to be reclassified from accumulated other comprehensive income to retained earnings. The amendment only relates to the reclassification of the income tax effects of the Tax Cuts and Jobs Act; thus, the underlying guidance relating to the effect of a change in tax laws be included in income from continuing operations is not affected. The amendments in Topic 220 are effective for all entities for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. This new guidance became effective for the Company on April 1, 2019. The requirements of Topic 220 did not have a significant impact on the Company's consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, which provides guidance on whether certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606. The amendments in this update provide more comparability in the presentation of revenue for certain transactions between collaborative arrangement participants. The key improvements to GAAP for collaborative arrangements resulting from this amendment are to (i) clarify that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit-of-account, (ii) add unit-of-account guidance in Topic 808 to align with the guidance in Topic 606, and (iii) require that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 is precluded if the collaborative arrangement participant is not a customer. The amendments in this ASU are effective for all entities for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years with early adoption permitted. This new guidance is effective for us on April 1, 2020. The Company does not expect this guidance to have an impact on its consolidated financial statements.

Note 13. Restructuring

In August 2019, after a rigorous assessment of the Company's lead liver therapeutic tissue program following completion of various preclinical studies, the Company's board of directors concluded that the variability of biological performance and related duration of potential benefits presented development challenges and lengthy redevelopment timelines that no longer supported an attractive opportunity for the Company and its stockholders. Furthermore, the Company's board of directors deemed the stage of development of the Company's other therapeutic pipeline assets, including stem cell based tissue programs, to be too premature to potentially reach IND filing status within an acceptable investment horizon and with the Company's available resources. As a result, the Company suspended all development of its lead program and all other related pipeline development activity and engaged a financial advisory firm to explore its strategic alternatives, including evaluating a range of ways to generate value from the Company's technology platform and intellectual property, its commercial and development capabilities, its listing on The Nasdaq Capital Market, and its remaining financial assets. Under the restructuring plan, the Company terminated the employment of 52 employees, or 90% of its workforce and recorded a restructuring charge during the year ended March 31, 2020 of approximately $2.7 million, related to employee severance and benefits costs, of which $1.7 million was paid out during the fiscal second quarter, $0.9 million was paid out during the fiscal third quarter, and $0.1 million was paid out during the fiscal fourth quarter.

Restructuring charges were recorded in selling, general and administrative expenses and were comprised of the following (in thousands):

	Year Ended March 31, 2020	Year Ended March 31, 2019
Severance for Involuntary Employee Terminations	$ 2,727	$ 441
Total Restructuring Expense	$ 2,727	$ 441

The following table summarizes the activity and balances of the restructuring reserve (in thousands):

	Severance for Involuntary Employee Terminations
Balance at March 31, 2019	$ -
Reserve established	2,456
Increase to reserve	$ 271
Utilization of reserve:	
Payments	$ (2,706)
Balance at March 31, 2020	$ 21

The restructuring accrual is reflected on the consolidated balance sheet at March 31, 2020 as accrued expenses.

Note 14. Subsequent Events

On April 7, 2020 at the Special Meeting of Shareholders, the Merger was not approved by our stockholders.

On April 17, 2020, the Company received a notice letter from Nasdaq indicating that based on extraordinary market conditions, Nasdaq has determined to toll the compliance periods for bid price and market value of publicly held shares (“MVPHS”) requirements (collectively, the “Price-based Requirements”) through June 30, 2020. Accordingly, since the Company had 66 calendar days remaining in its Bid, compliance period as of April 16, 2020, it will, upon reinstatement of the Price-based Requirements, still have 66 calendar days from July 1, 2020, or until September 4, 2020, to regain compliance.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed pursuant to the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and our principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosure.

Under the supervision of our Chief Executive Officer and our Chief Financial Officer, and with the participation of all members of management, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Exchange Act. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were designed and operating effectively as of the end of the period covered by this Annual Report.

Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our management's annual report on internal control over financial reporting is set forth below.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our system of internal control over financial reporting is designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of our consolidated financial statements for external purposes in accordance with generally accepted accounting principles.

Our management, under the supervision of our Chief Executive Officer and our Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of March 31, 2020. In making this assessment, we used the framework included in *Internal Control — Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the criteria set forth in *Internal Control — Integrated Framework* (2013), our management concluded that our internal control over financial reporting was effective as of March 31, 2020.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during the fourth quarter of the fiscal year ended March 31, 2020 to which this report relates that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and our Chief Financial Officer, do not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information relating to our directors, executive officers and corporate governance, including our Code of Business Conduct, will be included in the proxy statement for the 2020 annual meeting of the Company's stockholders, expected to be filed within 120 days of the end of our fiscal year, which is incorporated herein by reference. The full text of our Code of Business Conduct, which is the code of ethics that applies to all of our officers, directors and employees, can be found in the "Investors" section of our website accessible to the public at www.organovo.com.

Item 11. Executive Compensation.

Information relating to executive compensation will be included in the proxy statement for the 2020 annual meeting of the Company's stockholders, expected to be filed within 120 days of the end of our fiscal year, which is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table summarizes information about the Company's equity compensation plans by type as of March 31, 2020:

Plan category	(A) Number of securities to be issued upon exercise/vesting of outstanding options, warrants, units and rights (2)	(B) Weighted-average exercise price of outstanding options, warrants, units and rights	(C) Number of securities available for future issuance under Equity Compensation Plans (excluding securities reflected in column (A)) (3)
Equity compensation plans approved by security holders (1)	9,824,341	$ 1.69	15,347,372
Equity compensation plans not approved by security holders (4)	2,246,918	$ 2.54	—

(1) Includes the 2008 Equity Incentive Plan, the Amended and Restated 2012 Equity Incentive Plan (the "2012 Plan"), and the 2016 Employee Stock Purchase Plan (the "ESPP").

(2) Includes stock options to purchase 5,549,864 shares of common stock with a per share weighted-average exercise price of $1.84. Also includes 480,256 restricted stock units and 3,794,221 performance-based restricted stock units with no exercise price.

(3) Includes 1,188,718 shares of common stock available for purchase under the ESPP as of March 31, 2020.

(4) Includes 2,088,212 stock options with a per share exercise price of $2.73 and 158,706 performance-based restricted stock units with no exercise price, collectively, the "Inducement Award Agreements," granted to the Chief Executive Officer upon commencement of his employment. While outside the Company's 2012 Plan, the terms and conditions of these awards are consistent with awards granted to the Company's executive officers pursuant to the 2012 Plan.

Information relating to the beneficial ownership of our common stock will be included in the proxy statement for the 2020 annual meeting of the Company's stockholders, expected to be filed within 120 days of the end of our fiscal year, which is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information relating to certain relationships and related transactions and director independence will be included in the proxy statement for the 2020 annual meeting of the Company's stockholders, expected to be filed within 120 days of the end of our fiscal year, which is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

Information relating to principal accountant fees and services will be included in the proxy statement for the 2020 annual meeting of the Company's stockholders, expected to be filed within 120 days of the end of our fiscal year, which is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a). The following documents have been filed as part of this Annual Report:

1. Consolidated Financial Statements: The information required by this item is included in Item 8 of Part II of this annual report.

2. Financial Statement Schedules: Financial statement schedules required under the related instructions are not applicable for the years ended March 31, 2020 and 2019 and have therefore been omitted.

3. Exhibits: The exhibits listed in the Exhibit Index attached to this report are filed or incorporated by reference as part of this annual report.

(b). The exhibits listed in the accompanying Exhibit Index are filed or incorporated by reference as part of this Annual Report.

EXHIBIT INDEX

Exhibit No.	Description
2.1	Agreement and Plan of merger and Reorganization, dated as of December 13, 2019, by and among the Company, Opal Merger Sub, Inc. and Tarveda Therapeutics, Inc. (incorporated by reference from Exhibit 2.1 to the Company's Current Report on Form 8-K, as filed with the SEC on December 16, 2019).
2.2	First Amendment to Merger Agreement, dated as of January 26, 2020, by and among the Company, Opal Merger Sub, Inc. and Tarveda Therapeutics, Inc. (incorporated by reference from Exhibit 2.1 to the Company's Current Report on Form 8-K, as filed with the SEC on January 29, 2020).
3.1	Certificate of Incorporation of Organovo Holdings, Inc. (Delaware) (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on February 3, 2012).
3.2	Certificate of Amendment of Certificate of Incorporation of Organovo Holdings, Inc. (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on July 27, 2018).
3.3	Bylaws of Organovo Holdings, Inc. (Delaware) (incorporated by reference from Exhibit 3.2 to the Company's Current Report on Form 8-K, as filed with the SEC on February 3, 2012).
3.4	Amendment to Bylaws of Organovo Holdings, Inc., dated October 10, 2019 (incorporated by reference from Exhibit 99.1 to the Company's Current Report on Form 8-K, as filed with the SEC on October 11, 2019).
4.1	Description of Securities.*
10.1+	Organovo, Inc. 2008 Equity Incentive Plan (incorporated by reference from Exhibit 10.14 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012).
10.2+	Organovo Holdings, Inc. 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.15 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012).
10.3+	Form of Stock Option Award Agreement under the 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.16 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012).
10.4+	Form of Indemnification Agreement (incorporated by reference from Exhibit 10.17 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012).
10.5†	License Agreement dated as of March 24, 2009, by and between Organovo, Inc. and the Curators of the University of Missouri (incorporated by reference from Exhibit 10.23 to the Company's Current Report on Form 8-K, as filed with the SEC on May 11, 2012).
10.6†	License Agreement dated as of March 12, 2010 by and between the Company and the Curators of the University of Missouri (incorporated by reference from Exhibit 10.24 to the Company's Current Report on Form 8-K, as filed with the SEC on May 11, 2012).
10.7†	License Agreement dated as of May 2, 2011, by and between the Company and Clemson University Research Foundation (incorporated by reference from Exhibit 10.25 to the Company's Current Report on Form 8-K, as filed with the SEC on May 11, 2012).
10.8	First Amendment to Lease, dated December 4, 2013, by and between Organovo, Inc. and ARE-SD Region No. 25, LLC. (incorporated by reference from Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on February 6, 2014).
10.9+	Form of Non-Employee Director Stock Option Award Agreement under the 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K, as filed with the SEC on June 9, 2015).
10.10+	Form of Executive Stock Option Award Agreement under the 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K, as filed with the SEC on June 9, 2015).
10.11+	Organovo Holdings, Inc. Severance and Change in Control Plan (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on November 9, 2015).
10.12+	Amendment to the Organovo Holdings, Inc. Severance and Change in Control Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on May 20, 2020).

Exhibit No.	Description
10.13+	Form of Organovo Holdings, Inc. Severance and Change in Control Plan Participation Agreement (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on November 9, 2015).
10.14+	Offer Letter, between Craig Kussman and Organovo Holdings, Inc., dated July 29, 2016 (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, as filed with the SEC on August 2, 2016).
10.15+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement (Retention Form) under the 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on August 4, 2016).
10.16+	Form of Employee Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under the 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on August 4, 2016).
10.17+	Form of Non-Employee Director Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under the 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on August 4, 2016).
10.18+	Organovo Holdings, Inc. 2016 Employee Stock Purchase Plan (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on August 18, 2016).
10.19+	Offer Letter, dated April 11, 2017, by and between Organovo Holdings, Inc. and Taylor Crouch (incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on April 11, 2017).
10.20+	Organovo Holdings, Inc. Inducement Award Stock Option Agreement, dated April 24, 2017 (incorporated by reference from Exhibit 99.1 to the Company's Registration Statement on Form S-8 (File No. 333-217437), as filed with the SEC on April 24, 2017).
10.21+	Organovo Holdings, Inc. Inducement Award Performance-Based Restricted Stock Unit Agreement, dated April 24, 2017 (incorporated by reference from Exhibit 99.2 to the Company's Registration Statement on Form S-8 (File No. 333-217437), as filed with the SEC on April 24, 2017).
10.22+	Organovo Holdings, Inc. Amended and Restated 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on July 27, 2018).
10.23+	Organovo Holdings, Inc. Inducement Award Stock Option Agreement, dated August 14, 2018 (incorporated by reference from Exhibit 99.1 to the Company's Registration Statement on Form S-8 (File No. 333-226837), as filed with the SEC on August 14, 2018).
10.24+	Organovo Holdings, Inc. Inducement Award Restricted Stock Unit Agreement, dated August 14, 2018 (incorporated by reference from Exhibit 99.2 to the Company's Registration Statement on Form S-8 (File No. 333-226837), as filed with the SEC on August 14, 2018).
21.1	Subsidiaries of Organovo Holdings, Inc.*
23.1	Consent of Independent Registered Public Accounting Firm.*
24.1	Power of Attorney (included on signature page hereto).*
31.1	Certification of Chief Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.*
31.2	Certification of Chief Financial Officer a Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.*
32.1	Certifications Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and to 18 U.S.C. Section 1350.*
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase*

Exhibit No.	Description
101.DEF	XBRL Taxonomy Extension Definition Linkbase*
101.LAB	XBRL Taxonomy Extension Label Linkbase*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase*

* Filed herewith.
\+ Designates management contracts and compensation plans.
† This Exhibit has been filed separately with the Secretary of the Securities and Exchange Commission without the redaction pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

ORGANOVO HOLDINGS, INC.

By: /s/ Taylor Crouch
Taylor Crouch
Chief Executive Officer and President

Date: May 28, 2020

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Taylor Crouch and Jennifer Bush, and each of them individually, as the undersigned's true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign any and all amendments to this Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their respective substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Taylor Crouch Taylor Crouch	Chief Executive Officer and President (Principal Executive Officer)	May 28, 2020
/s/ Craig Kussman Craig Kussman	Chief Financial Officer (Principal Financial Officer)	May 28, 2020
/s/ Kirk Malloy Kirk Malloy	Chairman of the Board	May 28, 2020
/s/ Mark Kessel Mark Kessel	Director	May 28, 2020
/s/ Richard Maroun Richard Maroun	Director	May 28, 2020
/s/ David Shapiro David Shapiro	Director	May 28, 2020
/s/ Carolyn D. Beaver Carolyn D. Beaver	Director	May 28, 2020

Exhibit 4.1

DESCRIPTION OF ORGANOVO HOLDINGS, INC.'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description of the common stock, par value $0.001 per share, of Organovo Holdings, Inc. ("us," "our," "we," or the "Company"), which is the only security of the Company registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), summarizes certain information regarding the common stock in our certificate of incorporation, as amended, our by-laws, as amended, and applicable provisions of Delaware general corporate law (the "DGCL"), and is qualified by reference to our certificate of incorporation, our certificate of amendment of certificate of incorporation, our by-laws and our amendment to bylaws, which are incorporated by reference as Exhibit 3.1, 3.2, 3.3 and 3.4, respectively, to the Annual Report on Form 10-K for the fiscal year ending March 31, 2020.

Our authorized capital stock consists of 200,000,000 shares of common stock, par value $0.001 per share and 25,000,000 shares of preferred stock, par value $0.001 per share.

General

As of March 31, 2020, our certificate of incorporation, as amended (the "certificate of amendment"), authorizes us to issue up to (i) 200,000,000 shares of common stock, par value $0.001 per share, and (ii) 25,000,000 shares of preferred stock, par value $0.001 per share.

The following is a summary of the material provisions of the common stock and preferred stock provided for in our certificate of incorporation and bylaws, as amended (the "bylaws"). For additional detail about our capital stock, please refer to our certificate of incorporation and bylaws.

Common Stock

Our common stock is listed on the Nasdaq Capital Market under the symbol "ONVO".

Voting: Holders of our common stock are entitled to one vote for each share on all matters submitted to a stockholder vote, except matters that relate only to a series of our preferred stock.

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

Dividends: Subject to limitations under Delaware law and preferences that may apply to any then-outstanding shares of preferred stock, holders of common stock are entitled to share ratably in dividends, if any, as may be declared from time to time by our board of directors in its discretion from funds legally available therefor.

Dividends, if any, will be contingent upon our revenues and earnings, if any, and capital requirements and financial conditions. The payment of dividends, if any, will be within the discretion of our board of directors. We presently intend to retain all earnings, if any, and accordingly our board of directors does not anticipate declaring any dividends prior to a business combination.

Liquidation: In the event of a liquidation, dissolution or winding up, the holders of common stock are entitled to share pro rata all assets remaining after payment in full of all liabilities and after providing for each class of stock, if any, having preference over the common stock, subject to the liquidation preference of any then outstanding shares of preferred stock.

Miscellaneous: Holders of our common stock have no pre-emptive rights, no conversion rights and there are no redemption provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Preferred Stock

Under the terms of our certificate of incorporation, our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock. There are no restrictions presently on the repurchase or redemption of any shares of our preferred stock.

The issuance of preferred stock will affect, and may adversely affect, the rights of holders of common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of common stock until the board of directors determines the specific rights attached to that preferred stock. The effects of issuing preferred stock could include one or more of the following:

- restricting dividends on the common stock;
- diluting the voting power of the common stock;
- impairing the liquidation rights of the common stock; or
- delaying or preventing changes in control or management of our company.

We have no present plans to issue any shares of preferred stock nor are any shares of our preferred stock presently outstanding.

Effect of Certain Provisions of our Certificate of Incorporation and Bylaws

Provisions of our certificate of incorporation and our bylaws could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, may have the effect of discouraging takeover bids. These provisions are also designed, in part, to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Classified Board. Our certificate of incorporation and our bylaws provide that our board of directors is divided into three classes, consisting of three Class I directors, two Class II directors and two Class III directors. The directors designated as Class I directors have a term expiring at our annual meeting of stockholders in 2021. The directors designated as Class II directors have a term expiring at our annual meeting of stockholders in 2022, and the directors designated as a Class III directors have a term expiring at our annual meeting of stockholders in 2020. Directors for each class will be elected at the annual meeting of stockholders held in the year in which the term for that class expires and thereafter will serve for a term of three years. At any meeting of stockholders for the election of directors at which a quorum is present, the election will be determined by a plurality of the votes cast by the stockholders entitled to vote at the election. Under the classified board provisions, it will take at least two elections of directors for any individual or group to gain control of our board. Accordingly, these provisions could discourage a third party from initiating a proxy contest, making a tender offer or otherwise attempting to gain control of us.

Undesignated preferred stock. The authority of our board of directors to issue preferred stock could potentially be used to discourage attempts by third parties to obtain control of our company through a merger, tender offer, proxy contest, or otherwise by making it more difficult or more costly to obtain control of our company. Our board of directors may issue preferred stock with voting rights or conversion rights that, if exercised, could adversely affect the voting power of the holders of common stock.

Advanced Notice Requirement. Stockholder nominations of individuals for election to our board of directors and stockholder proposals of other matters to be brought before an annual meeting of our stockholders must comply with the advance notice procedures set forth in our bylaws. Generally, to be timely, such notice must be received at our principal executive offices no later than the date specified in our proxy statement released to stockholders in connection with the preceding year's annual meeting of stockholders, which date shall be not earlier than the 75th day, nor later than the close of business on the 45th day, prior to the one-year anniversary of the date on which we first mailed our proxy materials or a notice of availability of proxy materials (whichever is earlier) for the preceding year's annual meeting.

Special Meeting Requirements. Our bylaws provide that special meetings of our stockholders may only be called at the request of a majority of the authorized number of members of the board of directors, chairperson of the board of directors, chief executive officer, president or secretary. Only such business shall be considered at a special meeting as shall have been stated in the notice for such meeting.

No Cumulative Voting. Our certificate of incorporation does not include a provision for cumulative voting for directors.

Removal of Directors. Our certificate of incorporation and bylaws provide that the holders of our voting stock may only remove our directors for cause.

Authorized but Unissued Shares. Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without stockholder approval. We may use additional shares for a variety of purposes, including future public offerings to raise additional capital, to fund acquisitions and as employee compensation. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Size of Board and Vacancies. Our bylaws provide that the number of directors on our board of directors is fixed exclusively by our board of directors. Vacancies and newly created directorships resulting from any increase in our authorized number of directors will be filled by a majority of our board of directors then in office, although less than a quorum, or by a sole remaining director.

Indemnification. Our certificate of incorporation and our bylaws provide that we will indemnify our officers and directors against losses as they incur in investigations and legal proceedings resulting from their services to us, which may include service in connection with takeover defense measures.

Delaware Anti-Takeover Statute

We are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. In general, Section 203 generally prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date on which the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least $66^{2}/_{3}$% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, lease, exchange, mortgage, transfer, pledge or other disposition of 10% or more of either the assets or outstanding stock of the corporation involving the interested stockholder;

- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines interested stockholder as an entity or person who, together with affiliates and associates, beneficially owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

The provisions of Delaware law and our certificate of incorporation and our bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions may make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Exhibit 21.1

Subsidiaries of Organovo Holdings, Inc.

I. Organovo, Inc., a Delaware corporation

II. Opal Merger Sub, Inc., a Delaware corporation

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in Registration Statement Nos. 333-226839, 333-226837, 333-217437, 333-213345, 333-209395, 333-192248 and 333-181324 on Form S-8 and Registration Statement No. 333-222929 on Form S-3, of our report dated May 28, 2020, relating to the consolidated financial statements of Organovo Holdings, Inc. as of March 31, 2020 and 2019, and for the two years in the period ended March 31, 2020, included in this Annual Report on Form 10-K for the year ended March 31, 2020 (which includes an explanatory paragraph related to the change in method of accounting for leases).

/s/ Mayer Hoffman McCann P.C.

San Diego, California
May 28, 2020

Exhibit 31.1

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Taylor Crouch, Chief Executive Officer and President of Organovo Holdings, Inc., certify that:

1. I have reviewed this annual report on Form 10-K of Organovo Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 28, 2020

/s/ Taylor Crouch
Taylor Crouch
Chief Executive Officer and President (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Craig Kussman, Chief Financial Officer of Organovo Holdings, Inc., certify that:

1. I have reviewed this annual report on Form 10-K of Organovo Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 28, 2020

/s/ Craig Kussman
Craig Kussman
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Organovo Holdings, Inc. (the "Company") for the year ended March 31, 2020, as filed with the Securities and Exchange Commission (the "Report"), Taylor Crouch, Chief Executive Officer and President of the Company, and Craig Kussman, Chief Financial Officer of the Company, do hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- The information in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 28, 2020

/s/ Taylor Crouch
Taylor Crouch
Chief Executive Officer and President (Principal Executive Officer)

/s/ Craig Kussman
Craig Kussman
Chief Financial Officer (Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to Organovo Holdings, Inc. and will be retained by Organovo Holdings, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission, and is not to be incorporated by reference into any filing of Organovo Holdings, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.