

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549**

**Form 10-Q**

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

For the quarterly period ended September 30, 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 Number 001-35996

**Organovo Holdings, Inc.**  
(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**440 Stevens Ave, Suite 200,  
Solana Beach, CA 92075**

(Address of principal executive offices and zip code)

**27-1488943**

(I.R.S. Employer  
Identification No.)

**(858) 224-1000**

(Registrant's telephone number, including area code)

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

Title of each class  
**Common Stock, \$0.001 par value**

Trading symbol  
**ONVO**

Name of Each Exchange on which registered  
**The Nasdaq Stock Market LLC**

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 "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer   
Non-accelerated filer

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of November 1, 2020, a total of 6,732,090 shares of the registrant's Common Stock, \$0.001 par value, were outstanding.

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## PART I—FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

**Organovo Holdings, Inc.**  
**Condensed Consolidated Balance Sheets**  
(in thousands except for share and per share data)

	<u>September 30, 2020</u>	<u>March 31, 2020</u>
	(Unaudited)	
<b>Assets</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 17,656	\$ 27,356
Accounts receivable	19	111
Prepaid expenses and other current assets	1,810	851
Total current assets	<u>19,485</u>	<u>28,318</u>
Fixed assets, net	22	—
Prepaid expenses and other assets, net	1,137	123
<b>Total assets</b>	<u>\$ 20,644</u>	<u>\$ 28,441</u>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 201	\$ 720
Accrued expenses	457	1,090
Total current liabilities	<u>658</u>	<u>1,810</u>
<b>Commitments and Contingencies</b>		
<b>Stockholders' Equity</b>		
Common stock, \$0.001 par value; 200,000,000 shares authorized, 6,732,090 and 6,527,900 shares issued and outstanding at September 30, 2020 and March 31, 2020, respectively	7	7
Additional paid-in capital	311,164	306,089
Accumulated deficit	(291,184)	(279,465)
Treasury stock	(1)	—
Total stockholders' equity	<u>19,986</u>	<u>26,631</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 20,644</u>	<u>\$ 28,441</u>

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

**Organovo Holdings, Inc.**  
**Unaudited Condensed Consolidated Statements of Operations and Other Comprehensive Loss**  
(in thousands except share and per share data)

	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Six Months Ended September 30, 2020	Six Months Ended September 30, 2019
<b>Revenues</b>				
Products and services	\$ —	\$ 1,221	\$ —	\$ 1,827
Collaborations and licenses	—	9	—	19
Grants	—	—	—	52
<b>Total Revenues</b>	<b>—</b>	<b>1,230</b>	<b>—</b>	<b>1,898</b>
Cost of revenues	—	264	—	315
Research and development expenses	28	1,445	28	5,268
Selling, general and administrative expenses	8,922	6,348	11,708	9,663
Total costs and expenses	8,950	8,057	11,736	15,246
<b>Loss from Operations</b>	<b>(8,950)</b>	<b>(6,827)</b>	<b>(11,736)</b>	<b>(13,348)</b>
<b>Other Income (Expense)</b>				
Gain (loss) on fixed asset disposals	(5)	85	1	86
Interest income	4	183	12	380
Other income	1	267	6	267
<b>Total Other Income</b>	<b>—</b>	<b>535</b>	<b>19</b>	<b>733</b>
<b>Income Tax Expense</b>	<b>—</b>	<b>(2)</b>	<b>(2)</b>	<b>(2)</b>
<b>Net Loss</b>	<b>\$ (8,950)</b>	<b>\$ (6,294)</b>	<b>\$ (11,719)</b>	<b>\$ (12,617)</b>
Net loss per common share—basic and diluted	\$ (1.36)	\$ (1.00)	\$ (1.79)	\$ (2.00)
Weighted average shares used in computing net loss per common share—basic and diluted	6,565,245	6,517,859	6,547,430	6,430,781
<b>Comprehensive Loss:</b>				
Net loss	\$ (8,950)	\$ (6,294)	\$ (11,719)	\$ (12,617)
Comprehensive loss	\$ (8,950)	\$ (6,294)	\$ (11,719)	\$ (12,617)

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

**Organovo Holdings, Inc.**  
**Unaudited Condensed Consolidated Statements of Stockholders' Equity**  
(in thousands)

	Three and Six Months Ended September 30, 2019						
	Common Stock		Additional Paid-in Capital	Treasury Stock		Accumulated Deficit	Total
	Shares	Amount		Shares	Amount		
<b>Balance at March 31, 2019</b>	<b>6,201</b>	<b>\$ 6</b>	<b>\$ 297,047</b>	—	\$ —	<b>\$ (260,755)</b>	<b>\$ 36,298</b>
Issuance of common stock under employee and director stock option, RSU, and purchase plans	9	—	(52)	—	—	—	(52)
Issuance of common stock from public offering, net	304	—	4,996	—	—	—	4,996
Stock-based compensation expense	—	—	1,220	—	—	—	1,220
Net loss	—	—	—	—	—	(6,323)	(6,323)
<b>Balance at June 30, 2019 (Unaudited)</b>	<b>6,514</b>	<b>\$ 6</b>	<b>\$ 303,211</b>	—	\$ —	<b>\$ (267,078)</b>	<b>\$ 36,139</b>
Issuance of common stock under employee and director stock option, RSU, and purchase plans	8	—	(8)	—	—	—	(8)
Stock-based compensation expense	—	—	1,236	—	—	—	1,236
Net loss	—	—	—	—	—	(6,294)	(6,294)
<b>Balance at September 30, 2019 (Unaudited)</b>	<b>6,522</b>	<b>\$ 6</b>	<b>\$ 304,439</b>	—	\$ —	<b>\$ (273,372)</b>	<b>\$ 31,073</b>

	Three and Six Months Ended September 30, 2020						
	Common Stock		Additional Paid-in Capital	Treasury Stock		Accumulated Deficit	Total
	Shares	Amount		Shares	Amount		
<b>Balance at March 31, 2020</b>	<b>6,528</b>	<b>\$ 7</b>	<b>\$ 306,089</b>	—	\$ —	<b>\$ (279,465)</b>	<b>\$ 26,631</b>
Issuance of common stock under employee and director stock option, RSU, and purchase plans	3	—	(1)	—	—	—	(1)
Stock-based compensation	—	—	925	—	—	—	925
Net loss	—	—	—	—	—	(2,769)	(2,769)
<b>Balance at June 30, 2020 (Unaudited)</b>	<b>6,531</b>	<b>\$ 7</b>	<b>\$ 307,013</b>	—	\$ —	<b>\$ (282,234)</b>	<b>\$ 24,786</b>
Stock option exercises	3	—	14	—	—	—	14
Issuance of common stock under employee and director stock option, RSU, and purchase plans	198	—	(1)	—	—	—	(1)
Stock-based compensation	—	—	4,138	—	—	—	4,138
Treasury stock	—	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	—	(8,950)	(8,950)
<b>Balance at September 30, 2020 (Unaudited)</b>	<b>6,732</b>	<b>\$ 7</b>	<b>\$ 311,164</b>	—	<b>\$ (1)</b>	<b>\$ (291,184)</b>	<b>\$ 19,986</b>

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

**Organovo Holdings, Inc.**  
**Unaudited Condensed Consolidated Statements of Cash Flows**  
(in thousands)

	Six Months Ended September 30, 2020	Six Months Ended September 30, 2019
<b>Cash Flows From Operating Activities</b>		
Net loss	\$ (11,719)	\$ (12,617)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain (loss) on disposal of fixed assets	1	(85)
Depreciation and amortization	8	379
Stock-based compensation	5,063	2,456
Inventory write-off	—	214
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	92	(116)
Grants receivable	—	55
Inventory	—	(75)
Prepaid expenses and other assets	(2,011)	415
Accounts payable	(519)	(476)
Accrued expenses	(633)	(617)
Deferred revenue	—	(525)
Operating lease right-of-use assets and liabilities, net	—	(98)
<b>Net cash used in operating activities</b>	<b>(9,718)</b>	<b>(11,090)</b>
<b>Cash Flows From Investing Activities</b>		
Proceeds from disposals of fixed assets	7	27
<b>Net cash provided by investing activities</b>	<b>7</b>	<b>27</b>
<b>Cash Flows From Financing Activities</b>		
Proceeds from issuance of common stock, net	—	4,996
Employee taxes paid related to net share settlement of equity awards	(2)	(60)
Proceeds from exercise of stock options	14	—
Purchase of treasury stock	(1)	—
<b>Net cash provided by financing activities</b>	<b>11</b>	<b>4,936</b>
<b>Net decrease in cash, cash equivalents, and restricted cash</b>	<b>(9,700)</b>	<b>(6,127)</b>
<b>Cash, cash equivalents, and restricted cash at beginning of period</b>	<b>27,356</b>	<b>36,556</b>
<b>Cash, cash equivalents, and restricted cash at end of period</b>	<b>\$ 17,656</b>	<b>\$ 30,429</b>
<b>Reconciliation of cash, cash equivalents, and restricted cash to the condensed consolidated balance sheets</b>		
Cash and cash equivalents	\$ 17,656	\$ 30,350
Restricted cash	—	79
<b>Total cash, cash equivalent and restricted cash</b>	<b>\$ 17,656</b>	<b>\$ 30,429</b>
<b>Supplemental Disclosure of Cash Flow Information:</b>		
Fixed asset reclass	\$ 31	\$ —
Income taxes paid	\$ 2	\$ 2

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

Notes to Unaudited Condensed Consolidated Financial Statements

**Note 1. Description of Business**

*Nature of operations*

Organovo Holdings, Inc. (“Organovo,” and “the Company”) is an early-stage biotechnology company that develops highly customized 3D human tissues as living, dynamic models of healthy and diseased human biology for drug development. The Company’s proprietary technology is being used to build functional 3D human tissues that mimic key aspects of native human tissue composition, architecture, function and disease. The Company’s advances include cell type-specific compartments, prevalent intercellular tight junctions, and the formation of microvascular structures. The Company believes these attributes can enable critical complex, multicellular disease models that the Company will use to develop clinically effective drugs for selected therapeutic areas. Except where specifically noted or the context otherwise requires, references to “the Company,” and “Organovo” in these notes to the unaudited condensed consolidated financial statements refers to Organovo Holdings, Inc. and its wholly owned subsidiaries, Organovo, Inc. and Opal Merger Sub, Inc.

*Historical Operations and Strategic Alternatives Process*

Prior to August 2019, the Company has focused its efforts 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. The Company also explored the development of other potential pipeline *in vivo* tissue constructs in-house and through collaborations with academic and government researchers. In the past, the Company also explored the development of *in vitro* tissues, including proof of concept models of diseased tissues, for use in drug discovery and development.

In August 2019, after a rigorous assessment of its *in vitro* liver therapeutic tissue program, the Company 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 investigational new drug (“IND”) filing. As a result, the Company suspended development of its lead program and all other related in-house pipeline development activities.

The Company’s Board of Directors (the “Board”) also engaged a financial advisory firm to explore the Company’s 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 the Company’s remaining financial assets. These strategic alternatives included possible mergers and business combinations, sales of part or all of its assets, and licensing and partnering arrangements. The Company 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, the Company 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.

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, the Company 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, the Company’s wholly-owned merger subsidiary would merge with and into Tarveda (the “Merger”), with Tarveda becoming a wholly-owned subsidiary of Organovo and the surviving corporation of the Merger. The Merger Agreement included various conditions to the consummation of the Merger, including approval by the Company’s stockholders at a Special Meeting of Stockholders to be held on April 7, 2020 (the “Special Meeting”).

At the Special Meeting, the Merger was not approved by the Company’s stockholders. As a result, the Company terminated the Merger Agreement with Tarveda. Pursuant to the terms of the Merger Agreement, the Company was obligated to reimburse certain of Tarveda’s merger-related expenses not to exceed \$300,000, which was offset by Tarveda’s portion of shared expenses incurred by Organovo in fiscal 2020.

### ***The Cooperation Agreement and Advisory Nominees Proposal***

Following the Special Meeting and the termination of the Merger Agreement, the Board continued to solicit stockholder feedback regarding the Company's strategic alternatives and how to maximize stockholder value. In response to feedback from its largest stockholder regarding its desire for the Board to consider opportunities in the 3D bioprinting field and suggestion that the Board should speak with Keith Murphy, the Company's founder, stockholder and former Chief Executive Officer and Chairman, for potential business ideas, the Board initiated discussions with Mr. Murphy. Based on these discussions, the Company entered into a Cooperation Agreement with Mr. Murphy on July 14, 2020 (the "Cooperation Agreement"). Under the terms of the Cooperation Agreement, the Board appointed Mr. Murphy and Adam K. Stern to the Board as Class III directors, and two of the Company's existing directors, Richard Maroun and David Shapiro, resigned from the Board and all Board committees. The Board also agreed to nominate, recommend, support and solicit proxies for the re-election of Messrs. Murphy and Stern at the Company's 2020 Annual Meeting of Stockholders (the "2020 Annual Meeting"). The Board also agreed to nominate, recommend, support and solicit proxies for an advisory stockholder vote (the "Advisory Nominees Proposal") at the 2020 Annual Meeting to appoint three individuals, Douglas Jay Cohen, David Gobel and Alison Tjosvold Milhous (collectively, the "Advisory Nominees"), to the Board. Mr. Murphy identified each of the Advisory Nominees. The Board approved the appointment of the Advisory Nominees, to be automatically effective immediately following the final adjournment of the 2020 Annual Meeting if the final vote tabulation for the Advisory Nominees Proposal received more votes cast "FOR" than "AGAINST" its approval. In addition, each of the Company's then-current directors (other than Messrs. Murphy and Stern) agreed to resign from the Board immediately following the appointment of the Advisory Nominees. At the 2020 Annual Meeting held on September 15, 2020, the Company's stockholders approved the re-election of Messrs. Murphy and Stern to the Board as Class III directors with votes "For" of 59,229,909 (98.9%) and 59,147,657 (98.8%), respectively, to hold office until the 2023 Annual Meeting of Stockholders. The final vote tabulation for the Advisory Nominees Proposal received more votes cast "FOR" than "AGAINST" its approval, with votes "For" of 54,368,360 (91.4%) and, accordingly, effective upon the final adjournment of the 2020 Annual Meeting, Ms. Milhous was appointed as a Class I director to hold office until the 2021 Annual Meeting of Stockholders and Messrs. Cohen and Gobel were appointed as Class II directors to hold office until the 2022 Annual Meeting (collectively, the "New Director Slate") and Carolyn Beaver, Taylor Crouch, Mark Kessel and Kirk Malloy, Ph.D. each resigned as directors.

### ***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 since spread globally and been declared a pandemic by the World Health Organization. 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 its strategy, 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 to advance its research and development activities and pursue development of its pipeline products, each of which could have an adverse impact on the Company's business and financial results.

### **Note 2. Summary of Significant Accounting Policies**

#### ***Basis of presentation and principles of consolidation***

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not necessarily include all information and notes required by GAAP for complete financial statements. The condensed consolidated balance sheet at March 31, 2020 is derived from the Company's audited consolidated balance sheet at that date.

The unaudited condensed consolidated financial statements include the accounts of Organovo and its wholly owned subsidiaries. All material intercompany accounts and transactions have been eliminated in consolidation. In the opinion of management, the unaudited financial information for the interim periods presented reflects all adjustments, which are only normal and recurring, necessary for a fair statement of the Company's financial position, results of operations, stockholders' equity and cash flows. These unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes included in the Company's Annual Report on Form 10-K for the year ended March 31, 2020, as filed with the Securities and Exchange Commission ("SEC"). Operating results for interim periods are not necessarily indicative of operating results for the Company's fiscal year ending March 31, 2021 (see "Note 1. Description of Business").



On August 18, 2020, the Company effected a 1-for-20 reverse stock split of its common stock (the “Reverse Stock Split”). Unless otherwise indicated, all share amounts, per share data, share prices, exercise prices and conversion rates set forth in these notes and the accompanying condensed consolidated financial statements have, where applicable, been adjusted retroactively to reflect the Reverse Stock Split.

### ***Liquidity***

As of September 30, 2020, the Company had cash and cash equivalents of approximately \$17.7 million and an accumulated deficit of approximately \$291.2 million. The Company also had negative cash flows from operations of approximately \$9.7 million during the six months ended September 30, 2020.

Through September 30, 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 three and six months ended September 30, 2020, the Company issued no shares of its common stock through its ATM facility.

Throughout the strategic alternatives assessment process, the Company has taken steps to manage its resources and extend its cash runway including 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.

The Company believes its cash and cash equivalents on hand will be sufficient to meet its financial obligations for at least the next 12 months of operations. The approval of the Advisory Nominees Proposal triggered a “Change of Control” under the Company’s severance plan, as well as its Directors and Officers (“D&O”) liability insurance policies, which required the following cash outlays: i) approximately \$2.8 million for severance obligations; ii) approximately \$2.0 million (or \$1.7 million net of returned premium) for a six year D&O tail insurance policy; and iii) a new D&O policy premium at approximately \$0.8 million. The cash outlays for severance obligations and D&O tail insurance policies were one-time non-recurring expenses that occurred in September 2020 and therefore are reflected in the ending cash balance. In addition, as the Company recommences its operations and is focusing its efforts on drug discovery and development, the Company will need to raise additional capital to implement this new business plan. The Company cannot predict with certainty the exact amount or timing for any future capital raises. If required, the Company may seek to raise additional capital through debt or equity financings, or through some other financing arrangement. However, the Company cannot be sure that additional financing will be available if and when needed, or that, if available, it can obtain financing on terms favorable to its stockholders. Any failure to obtain financing when required will have a material adverse effect on the Company’s business, operating results, financial condition and ability to continue as a going concern.

### ***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 unaudited condensed consolidated financial statements include those assumed in the valuation of stock-based compensation expense 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 its business and operating results presents additional uncertainty, the Company continues to use the best information available to inform its critical accounting estimates.

### ***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.

The Company recognized revenue under Accounting Standards Codification (“ASC”) Topic 606, *Revenue from Contracts with Customers* (“Topic 606”) when (or as) the promised services were transferred to customers in an amount that reflects the consideration to which it expected to be entitled in exchange for those services. To determine revenue recognition for arrangements the Company concluded were within the scope of Topic 606, the Company performed the following five steps: (i) identified the contract(s) with a customer; (ii) identified the performance obligation(s) in the contract; (iii) determined the transaction price; (iv) allocated the transaction price to the performance obligation(s) in the contract; and (v) recognized revenue when (or as) the performance obligation(s) were satisfied. At contract inception, the Company assessed the goods or services promised within each contract, assessed whether each promised good or service was distinct and identified those that were performance obligations. The Company recognized as revenue the amount of the transaction price that was allocated to the respective performance obligation when (or as) the performance obligation was satisfied.

Billings to customers or payments received from customers were included in deferred revenue on the consolidated balance sheet until all revenue recognition criteria were met. As of September 30, 2020 and March 31, 2020, the Company had no deferred revenue.

#### *Service revenues*

The Company's service-based business, Organovo, Inc., previously 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 former product-based business, Samsara Sciences, Inc., produced high-quality cell-based products for use in Organovo's 3D tissue manufacturing and for use by life science customers. The Company recognized product revenue when the performance obligation was satisfied, which was at the point in time the customer obtained control of the Company's product, typically upon delivery. Product revenues were recorded at the transaction price, net of any estimates for variable consideration under Topic 606. The Company's process for estimating variable consideration did not differ materially from its historical practices. Variable consideration was 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 reflected the Company's best estimates of the amount of consideration to which it was entitled based on the terms of the individual contracts. Actual amounts of consideration ultimately received may have differed from the Company's estimates. If actual results varied materially from the Company's estimates, the Company would have adjusted these estimates, which would have affected revenue from product sales and earnings in the period such estimates were adjusted.

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

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 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 Topic 808, *Collaborative Arrangements* ("Topic 808").

The Company considered a variety of factors in determining the appropriate estimates and assumptions under these arrangements, such as whether the elements were distinct performance obligations, whether there were determinable stand-alone prices, and whether any licenses were functional or symbolic. The Company evaluated each performance obligation to determine if it could 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 were considered fixed, while milestone payments were identified as variable consideration which must be evaluated to determine if it was 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 provided 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 determined that the intellectual property license was not distinct from the continued support promised under the agreement and was 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.

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 revenue*

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 concluded this government grant was 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 concluded this government grant did meet the definition of a contribution and is a non-reciprocal transaction, however, Subtopic 958-605, *Not-for-Profit-Entities-Revenue Recognition* did not apply, as the Company is a business entity and the grant was with a governmental agency.

Revenues from this grant were based upon internal costs incurred that are specifically covered by the grant, plus an additional rate that provides funding for overhead expenses. Revenue was recognized as the Company incurred expenses that were related to the grant. The Company believes this policy was consistent with the overarching premise in Topic 606, to ensure that it recognized revenues to reflect the transfer of promised goods or services to customers in an amount that reflected the consideration to which it expected to be entitled in exchange for those goods or services, even though there was no "exchange" as defined in the ASC. The Company believed the recognition of revenue as costs were incurred and amounts became earned/realizable was analogous to the concept of transfer of control of a service over time under Topic 606.

In connection with the Company's decision to pursue its strategic alternatives, specific to the NIH NASH 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*

The Company reported no cost of revenues for the three and six months ended September 30, 2020 and approximately \$0.3 million in cost of revenues for the three and six months ended September 30, 2019, respectively. Cost of revenues consisted of costs related to manufacturing and delivering product and service revenue.

#### *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, 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 three and six months ended September 30, 2020 or 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 due to their anti-dilutive effect were approximately 0.9 million at September 30, 2020 and 1.0 million at September 30, 2019.

#### *Recent Accounting Pronouncements*

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("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 November 2018, the FASB issued Accounting Standard Update (“ASU”) 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606 (“ASU 2018-18”), which provides guidance on whether certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606. ASU 2018-18 provides more comparability in the presentation of revenue for certain transactions between collaborative arrangement participants. The key improvements to GAAP for collaborative arrangements resulting from ASU 2018-18 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. ASU 2018-18 is 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 became effective for the Company on April 1, 2020 and did not have a significant impact on the Company’s unaudited condensed consolidated financial statements.

### Note 3. 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-based awards consists of the following (in thousands):

	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Six Months Ended September 30, 2020	Six Months Ended September 30, 2019
Research and development	\$ 7	\$ 10	\$ 7	\$ 174
General and administrative	\$ 4,131	\$ 1,226	\$ 5,056	\$ 2,282
Total	\$ 4,138	\$ 1,236	\$ 5,063	\$ 2,456

The total unrecognized compensation cost related to unvested stock option grants as of September 30, 2020 was approximately \$2,866,000 and the weighted average period over which these grants are expected to vest is 3.59 years.

The total unrecognized compensation cost related to unvested restricted stock units (not including performance-based restricted stock units) as of September 30, 2020 was approximately \$35,000, which will be recognized over a weighted average period of 2.14 years.

The total unrecognized compensation cost related to unvested performance-based restricted stock units as of September 30, 2020 was approximately \$45,000, which will be recognized over a weighted average period of 0.75 years.

As of September 30, 2020, there are no participants enrolled in the employee stock purchase plan for the current purchase period, beginning September 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:

	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Six Months Ended September 30, 2020	Six Months Ended September 30, 2019
Dividend yield	—	—	—	—
Volatility	108.39%	84.36%	108.39%	84.36%
Risk-free interest rate	0.27%	1.53%	0.27%	1.53%
Expected life of options	6.00 years	6.00 years	6.00 years	6.00 years
Weighted average grant date fair value	\$ 6.22	\$ 4.60	\$ 6.22	\$ 4.60

The assumed dividend yield is 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 weighted average expected life of options was estimated using the average of the contractual term and the weighted average vesting term of the options. The measurement and classification of share-based payments to non-employees is consistent with the measurement and classification of share-based payments to employees.

The fair value of each restricted stock unit and performance-based 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 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 assumptions:

	Three Months Ended September 30, 2020*	Three Months Ended September 30, 2019	Six Months Ended September 30, 2020*	Six Months Ended September 30, 2019
Dividend yield	—	—	—	—
Volatility	0.00%	43.69%	0.00%	43.69%
Risk-free interest rate	0.00%	2.52	0.00%	2.52
Expected term	0 months	6 months	0 months	6 months
Grant date fair value	\$ -	\$ 5.80	\$ -	\$ 5.80

\*There were no participants in the ESPP for the purchase period beginning March 1, 2020 and the current purchase period (beginning September 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 current plans to issue shares of preferred stock.

### ***Common stock***

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 the Company's common stock for the last 30 consecutive business days, the Company no longer meets 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 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 had until September 4, 2020 to regain compliance. On August 18, 2020, the Company effected the Reverse Stock Split with a ratio of 20:1, and on September 2, 2020, the Company received notification from Nasdaq that the closing bid price of its common stock had been at \$1.00 per share or greater for ten consecutive business days and that Nasdaq had closed the matter. There can be no assurance that the Company will be able to maintain compliance with the Price-based Requirements or other listing requirements necessary to maintain the listing of its common stock on the Nasdaq Capital Market.

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 (the "2018 Shelf"), that expires on February 22, 2021, which registered \$100,000,000 of common stock, preferred stock, warrants and units, or any combination of the foregoing.

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 (the “Shares”). Any shares offered and sold will be issued pursuant to the Company’s 2018 Shelf.

During the six months ended September 30, 2020 and 2019, the Company issued 0 and 304,369 shares of common stock, respectively, for net proceeds of \$0 and \$5.0 million in at-the-market offerings under the 2018 Sales Agreement.

As of September 30, 2020, the Company has sold an aggregate of 885,959 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.

During the three and six months ended September 30, 2020 and 2019, the Company issued 2,600 and 0 shares of common stock upon the exercise of stock options, respectively.

#### **Restricted stock units**

The following table summarizes the Company’s restricted stock units (not including performance-based restricted stock units) activity from March 31, 2020 through September 30, 2020:

	Number of Shares	Weighted Average Price
Unvested at March 31, 2020	18,116	\$ 43.49
Granted	—	\$ —
Vested	(16,377)	\$ 45.83
Cancelled / forfeited	—	\$ —
Unvested at September 30, 2020	<u>1,739</u>	<u>\$ 21.46</u>

#### **Performance-based restricted stock units**

On April 24, 2017, the Company issued a Performance-Based Restricted Stock Unit Award for 10,441 shares of common stock (the “PBRSU”) to its then newly hired Chief Executive Officer. 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 the awards are consistent with awards granted to the Company’s executive officers pursuant to the 2012 Plan. On August 23, 2017, the Board formally approved the vesting criteria for the PBRSU. The vesting of the PBRSU is 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 had 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 ultimately vest for each tranche will range from 0 percent to 120 percent of the target amount, not to exceed 10,441 in aggregate. On December 12, 2018, the Board formally approved an amendment to the vesting criteria for the PBRSU. As of December 12, 2018, 100 percent of the Negative Adjusted EBITDA tranche, or 2,088 shares had vested and 418 units had been forfeited. Based on the amendment to the vesting criteria, the remaining 7,935 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.

Based on the amended PBRSU vesting terms, a Type III modification, the modified grant date fair value of the PBRSU is \$165,000 of which one-third is being recognized over the expected service period of each tranche ending on 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. As of September 30, 2020, all tranches accelerated vesting due to a change in control.

On July 2, 2019, the Company issued Performance-Based Restricted Stock Unit Awards (the “PBRSU Retention Awards”) for an aggregate of 301,391 shares of common stock to its management team. The PBRSU 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 September 30, 2020, 111,682 shares forfeited due to terminations and 177,480 shares accelerated vesting due to a change in control. The remaining 12,229 shares are expected to vest twenty-four months from the grant date as these particular shares require two of the conditions to be met in order to vest.

The following table summarizes the Company's performance-based restricted stock unit activity from March 31, 2020 through September 30, 2020:

	Number of Shares	Weighted Average Price
Unvested at March 31, 2020	197,644	\$ 10.24
Granted	—	\$ —
Vested	(185,415)	\$ 10.27
Cancelled / forfeited	—	\$ —
Unvested at September 30, 2020	<u>12,229</u>	<u>\$ 9.80</u>

### **Stock options**

The following table summarizes the Company's stock option activity from March 31, 2020 to September 30, 2020:

	Options Outstanding	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at March 31, 2020	377,980	\$ 41.81	\$ 37,440
Options granted	466,875	\$ 7.61	\$ —
Options cancelled / forfeited	—	\$ —	\$ —
Options exercised	(2,600)	\$ 5.32	\$ 8,580
Outstanding at September 30, 2020	<u>842,255</u>	<u>\$ 22.96</u>	<u>\$ 168,742</u>
Vested and Exercisable at September 30, 2020	<u>375,380</u>	<u>\$ 42.06</u>	<u>\$ 26,936</u>

The weighted average remaining contractual term of options exercisable and outstanding at September 30, 2020 was approximately 0.88 years.

### **Employee Stock Purchase Plan**

In June 2016, the Board adopted, and in August 2016, the Company's stockholders subsequently approved, the ESPP. The Company reserved 75,000 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 500 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. At September 30, 2020, there were 59,435 shares available for purchase under the ESPP.

### **Common stock reserved for future issuance**

Common stock reserved for future issuance consisted of the following at September 30, 2020:

Common stock options outstanding and reserved under the 2012 Plan	737,845
Common stock reserved under the 2012 Plan	251,026
Common stock reserved under the ESPP	59,435
Restricted stock units outstanding under the 2012 Plan	1,739
Performance-based restricted stock units outstanding under the 2012 Plan	12,229
Common stock options outstanding and reserved under the Inducement Award Agreement	104,410
Total at September 30, 2020	<u>1,166,684</u>

### **Treasury stock**

Repurchased shares of common stock are recorded as treasury stock, at cost, but may from time to time be retired. Following the Reverse Stock Split in August 2020, the Company purchased 46 shares of treasury stock at cost of less than \$0.1 million related to the funding of cash payments in lieu of the issuance of fractional shares.

#### **Note 4. Collaborative Research, Development, and License 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 \$0 and \$9,000 was recorded under this agreement for the three months ended September 30, 2020 and 2019, respectively. Revenue of \$0 and \$19,000 was recorded under this agreement for the six months ended September 30, 2020 and 2019, respectively. The Company completed its obligations under this agreement and does not anticipate recording any further revenue.

#### **Note 5. 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 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 U.S. Securities and Exchange Commission ("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 and now moot.

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 has cooperated with the SEC in response to this subpoena. On October 5, 2020, the Company received a letter from the SEC with the following response: "We have concluded the investigation as to Organovo Holdings, Inc. ("Organovo"). Based on the information we have as of this date, we do not intend to recommend an enforcement action by the Commission against Organovo."

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 6. Leases**

##### ***Operating Leases***

In October 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 for its former facilities on 6275 Nancy Ridge Drive, San Diego, California 92121 and its copy machines on a straight-line basis over the life of the leases, which were terminated in the third quarter of fiscal 2019. For the three months ended September 30, 2020 and 2019, the Company recorded operating lease expense of approximately \$0 and \$262,000, respectively. For the six months ended September 30, 2020 and 2019, the Company recorded operating lease expense of approximately \$0 and \$524,000, respectively. In addition, the Company recorded rent expense for the office space of approximately \$13,000 and \$0 for the three months ended September 30, 2020 and 2019, respectively. The Company recorded rent expense for the



office space of approximately \$25,000 and \$0 for the six months ended September 30, 2020 and 2019, respectively. 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 expensed as incurred. Variable lease expense was approximately \$0 and \$130,000 for the three months ended September 30, 2020 and 2019, respectively. Variable lease expense was approximately \$0 and \$237,000 for the six months ended September 30, 2020 and 2019, respectively. Short-term lease cost for the three months ended September 30, 2020 and 2019 was approximately \$0 and \$22,000, respectively. Short-term lease cost for the six months ended September 30, 2020 and 2019 was approximately \$0 and \$37,000, respectively. The short-term lease was terminated in the second quarter of fiscal 2020.

## **Note 7. Concentrations**

### ***Credit risk***

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 was 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 September 30, 2020.

## **Note 8. 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 Board or a committee thereof pursuant to its related party transaction policy.

During fiscal 2020, the Company provided services to Viscient Biosciences ("Viscient"), an entity for which Keith Murphy, the Company's Executive Chairman and Principal Executive Officer, serves as the Chief Executive Officer and President. Dr. Jeffrey Miner, the Company's Chief Scientific Officer, is also the Chief Scientific Officer of Viscient, and Thomas Jurgensen, the Company's General Counsel, is outside legal counsel of Viscient. In addition to the services provided by Organovo, Viscient has purchased primary human cell-based products from its former subsidiary, Samsara. There was approximately \$19,000 of accounts receivable outstanding as of September 30, 2020 and \$71,000 of accounts receivable outstanding as of September 30, 2019. The Company and Viscient have agreed on a payment plan under which Viscient will make a payment of the remaining balance on or before October 22, 2020. Through the date of filing, Viscient has fully paid off its outstanding balance. Further, in July 2020, the Company entered into a Cooperation Agreement with Mr. Murphy and in September 2020, the Company hired three of Viscient's employees. See "Note 1. Description of Business" for more information.

## Note 9. Restructuring

In August 2019, after a rigorous assessment of the Company's lead liver therapeutic tissue program following completion of various preclinical studies, the Board 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 Board 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 percent 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 approximately \$1.7 million was paid out during the second quarter of fiscal 2020, approximately \$0.9 million was paid out during the third quarter of fiscal 2020, approximately \$0.1 million was paid out during the fourth quarter of fiscal 2020, and less than \$0.1 million was paid out during the first quarter of fiscal 2021.

The approval of the Advisory Nominees Proposal in September 2020 triggered a "Change of Control" under the Company's severance plan. As a result, the Company terminated the employment of its executive officers and recorded a restructuring charge of approximately \$2.8 million, related to employee severance and benefits costs, of which approximately \$2.6 million was paid out during the second quarter of fiscal 2021. The Company expects to pay approximately \$30,000 each quarter through the end of fiscal 2022 as part of the severance and benefit obligations.

Approximately \$2.8 million and \$2.5 million of restructuring charges were recorded during the three and six months ended September 30, 2020 and 2019, respectively.

	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Six Months Ended September 30, 2020	Six Months Ended September 30, 2019
Severance for Involuntary Employee Terminations	\$ 2,808	\$ 2,456	\$ 2,808	\$ 2,456
Total Restructuring Expense	\$ 2,808	\$ 2,456	\$ 2,808	\$ 2,456

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

	Severance for Involuntary Employee Terminations	
Balance at March 31, 2020	\$	21
Reserve established		—
Increase to reserve		2,808
Utilization of reserve:		
Payments		(2,605)
Balance at September 30, 2020	\$	224

## ITEM 2. 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 thereto included in our Annual Report on Form 10-K for the fiscal year ended March 31, 2020. This discussion and analysis contains forward-looking statements, such as statements related to our plans, objectives, expectations and intentions. Any statements that are not statements of historical fact are forward-looking statements. When used, the words “believe,” “plan,” “intend,” “anticipate,” “target,” “estimate,” “expect” and the like, and/or future tense or conditional constructions such as “will,” “may,” “could,” “should,” or similar expressions, identify certain of these forward-looking statements. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to risks and uncertainties, including those described in this Quarterly Report on Form 10-Q, as well as the risk factors disclosed in our Annual Report on the Form 10-K for the fiscal year ended March 31, 2020, filed with the Securities and Exchange Commission on May 28, 2020, and discussed in the section titled “Risk Factors” under Part II, Item 1A in this Quarterly Report on Form 10-Q, that could cause our actual results or events to differ materially from those expressed or implied by such forward-looking statements. Except to the limited extent required by applicable law, we do not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Quarterly Report.*

### **Basis of Presentation**

The unaudited condensed consolidated financial statements included in this Form 10-Q have been prepared in accordance with the Securities and Exchange Commission (the “SEC”) instructions to Quarterly Reports on Form 10-Q. Accordingly, the unaudited condensed consolidated financial statements presented elsewhere in this Form 10-Q and discussed below are unaudited and do not contain all the information required by U.S. generally accepted accounting principles (“GAAP”) to be included in a full set of financial statements. The audited financial statements for the year ended March 31, 2020, filed with the SEC on Form 10-K on May 28, 2020, include a summary of our significant accounting policies and should be read in conjunction with this Form 10-Q. In the opinion of management, all material adjustments necessary to present fairly the results of operations for such periods have been included in this Form 10-Q. All such adjustments are of a normal recurring nature. The results of operations for interim periods are not necessarily indicative of the results of operations for the entire year.

On August 18, 2020, the Company effected a 1-for-20 reverse stock split of its common stock (the “Reverse Stock Split”). Unless otherwise indicated, all share amounts, per share data, share prices, exercise prices and conversion rates set forth in these notes and the accompanying condensed consolidated financial statements have, where applicable, been adjusted retroactively to reflect the Reverse Stock Split.

*Unless the context otherwise requires, the terms “Organovo,” the “Company,” “we,” “us” and “our” in this Quarterly Report on Form 10-Q refer to Organovo Holdings, Inc. and its wholly owned subsidiaries, Organovo, Inc. and Opal Merger Sub, Inc.*

### **Overview**

We are an early-stage biotechnology company that is developing and utilizing highly customized 3D human tissues as dynamic models of healthy and diseased human biology for drug development. Our proprietary technology is being used to build functional 3D human tissues that mimic key aspects of native human tissue composition, architecture, function and disease. Our advances include cell type-specific compartments, prevalent intercellular tight junctions, and the formation of microvascular structures. We believe these attributes can enable critical complex, multicellular disease models that we will use to develop clinically effective drugs for selected therapeutic areas. Market opportunities may include externally-partnered or internally-directed drug discovery and the clinical development of new molecular entities or repurposed drugs in-licensed from other pharmaceutical companies. Our goal is to establish a pipeline of drug candidates in high-value disease areas, aiming to commence human clinical testing for at least one drug candidate within a three to five year timeframe.

### **Historical Operations and Strategic Alternatives Process**

Prior to August 2019, we focused our efforts 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 also explored the development of other potential pipeline *in vivo* tissue constructs in-house and through collaborations with academic and government researchers. In the past, we also explored the development of *in vitro* tissues, including proof of concept models of diseased tissues, for use in drug discovery and development.

In August 2019, after a rigorous assessment of our *in vitro* 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 Investigational New Drug (“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 (our “Board”) 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 with and into Tarveda (the “Merger”), with Tarveda becoming a wholly-owned subsidiary of Organovo and the surviving corporation of 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 scheduled for April 7, 2020 (the “Special Meeting”).

At the Special Meeting, the Merger was not approved by our stockholders. As a result, we terminated the Merger Agreement with Tarveda. Pursuant to the terms of the Merger Agreement, we were obligated to reimburse certain of Tarveda’s merger-related expenses not to exceed \$300,000, which was offset by Tarveda’s portion of shared expenses incurred by Organovo in fiscal 2020.

### **The Cooperation Agreement and Advisory Nominees Proposal**

Following the Special Meeting and the termination of the Merger Agreement, our Board continued to solicit stockholder feedback regarding our strategic alternatives and how to maximize stockholder value. In response to feedback from our largest stockholder regarding its desire for the Board to consider opportunities in the 3D bioprinting field and suggestion that the Board should speak with Keith Murphy, our founder, stockholder and former Chief Executive Officer and Chairman, for potential business ideas, our Board initiated discussions with Mr. Murphy. Based on these discussions, we entered into a Cooperation Agreement with Mr. Murphy on July 14, 2020 (the “Cooperation Agreement”). Under the terms of the Cooperation Agreement, the Board appointed Mr. Murphy and Adam K. Stern to the Board as Class III directors, and two of our existing directors, Richard Maroun and David Shapiro, resigned from the Board and the committees thereof. The Board also agreed to nominate, recommend, support and solicit proxies for the re-election of Messrs. Murphy and Stern at our 2020 Annual Meeting of Stockholders (the “2020 Annual Meeting”). The Board also agreed to nominate, recommend, support and solicit proxies for an advisory stockholder vote (the “Advisory Nominees Proposal”) at the 2020 Annual Meeting to appoint three individuals, Douglas Jay Cohen, David Gobel and Alison Tjosvold Milhous (collectively, the “Advisory Nominees”), to the Board. Mr. Murphy identified each of the Advisory Nominees. Our Board approved the appointment of the Advisory Nominees, to be automatically effective immediately following the final adjournment of the 2020 Annual Meeting if the final vote tabulation for the Advisory Nominees Proposal received more votes cast “FOR” than “AGAINST” its approval. In addition, each of our then-current directors (other than Messrs. Murphy and Stern) agreed to resign from the Board immediately following the appointment of the Advisory Nominees. At the 2020 Annual Meeting held on September 15, 2020, our stockholders approved the re-election of Messrs. Murphy and Stern to the Board as Class III directors to hold office until the 2023 Annual Meeting of Stockholders and the final vote tabulation for the Advisory Nominees Proposal received more votes cast “FOR” than “AGAINST” its approval and, accordingly, effective upon the final adjournment of the 2020 Annual Meeting, Ms. Milhous was appointed as a Class I director to hold office until the 2021 Annual Meeting of Stockholders and Messrs. Cohen and Gobel were appointed as Class II directors to hold office until the 2022 Annual Meeting (collectively, the “New Director Slate”) and Carolyn Beaver, Taylor Crouch, Mark Kessel and Kirk Malloy, Ph.D. each resigned as directors.

### **Current Drug Discovery Business**

Following the election of the New Director Slate, we have recommenced operations and are now focusing our future efforts on developing highly customized 3D human tissues as living, dynamic models of healthy and diseased human biology for drug development. Our proprietary technology is being used to build functional 3D human tissues that mimic key aspects of native human tissue composition, architecture, function and disease. Our advances include cell type-specific compartments, prevalent intercellular

tight junctions, and the formation of microvascular structures. We believe these attributes can enable critical complex, multicellular disease models that we will use to develop clinically effective drugs for selected therapeutic areas. Market opportunities may include externally-partnered or internally-directed drug discovery and the clinical development of new molecular entities or repurposed drugs in-licensed from other pharmaceutical companies. Our goal is to establish a pipeline of drug candidates in high-value disease areas, aiming to commence human clinical testing for at least one drug candidate within a three to five year timeframe.

We have a significant opportunity to change the classic model of drug discovery using 3D bioprinted human tissues and other 3D models (sometimes known as “organoids” or “organs on a chip”). Our new paradigm will involve augmenting or replacing available animal disease models, in the discovery process with more relevant human disease models utilizing 3D human tissues developed by us. Our 3D human tissues may enable us to study the treatment of human disease by replicating key aspects of human biology in areas where this is currently a challenge with existing models. Rather than offering contract research services (as we have done in the past), we will focus on identifying and developing our own drug candidates, including from unique compounds or repurposed drugs in-licensed from other pharmaceutical companies. After identifying a drug candidate, we may out-license the drug candidate or may elect to develop the drug candidate internally. In addition to drug discovery, we will continue to evaluate opportunities to monetize our intellectual property and technologies along the way as a means to generate funds to support our primary business. We will continue to identify and work with partners and collaborators, including leading academic research sites, to develop new enabling applications which can support our discovery and development mission.

To restart our research operations, we have commenced hiring a team of research and development professionals with drug discovery and 3D tissue development experience. This team will leverage 3D models of disease to discover and develop new drugs with improved clinical efficacy.

We expect our research and development staff to grow to seven to ten employees. We also expect to maintain or grow a general and administrative staff of three to five employees to support our operations and reporting requirements as a public company.

We expect to lease sufficient office and laboratory space to support our requirements. We will need space in the short term in the 5,000-10,000 sq. ft. range, with mixed office and laboratory space. We currently plan to lease a new facility in San Diego at prevailing market terms.

## **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 since spread globally and been declared a pandemic by the World Health Organization. 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 overall 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 our strategy, 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 to advance our research and development activities and pursue development 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 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 stock-based compensation expense and the valuation allowance on deferred tax assets. 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. 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, 2020. For a description of critical accounting policies that affect our significant judgments and estimates used in the preparation of our unaudited condensed consolidated financial statements, refer to Item 7.

“Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Note 1. Description of Business and Summary of Significant Accounting Policies” in the Notes to Consolidated Financial Statements contained in our Annual Report on Form 10-K for the year ended March 31, 2020, filed with the SEC on May 28, 2020.

## Results of Operations

### Comparison of the three months ended September 30, 2020 and 2019

The following table summarizes our results of operations for the three months ended September 30, 2020 and 2019 (in thousands, except %):

	Three months ended September 30,		Increase (decrease)	
	2020	2019	\$	%
Revenues	\$ -	\$ 1,230	\$ (1,230)	(100%)
Cost of revenues	\$ -	\$ 264	\$ (264)	(100%)
Research and development	\$ 28	\$ 1,445	\$ (1,417)	(98%)
Selling, general and administrative	\$ 8,922	\$ 6,348	\$ 2,574	41%
Other income	\$ -	\$ 535	\$ (535)	(100%)

## Revenues

We had no revenue for the three months ended September 30, 2020 compared to \$1.2 million of revenue for the three months ended September 30, 2019, due to an ending of revenue generating activities following our decision to restructure operations to preserve capital as we pursued various 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 zero for the three months ended September 30, 2020, compared to approximately \$0.3 million for the three months ended September 30, 2019. The decrease was due to the end of revenue generating activities following our decision to restructure operations to preserve capital as we pursued various strategic alternatives.

### Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2020 and 2019 (in thousands, except %):

	Three months ended September 30, 2020		Three months ended September 30, 2019		Increase (decrease)	
	\$	% of total	\$	% of total	\$	%
Research and development	\$ 20	71%	\$ 1,332	92%	\$ (1,312)	(98%)
Non-cash stock-based compensation	7	25%	10	1%	(3)	(30%)
Depreciation and amortization	1	4%	103	7%	(102)	(99%)
Total research and development expenses	\$ 28	100%	\$ 1,445	100%	\$ (1,417)	(98%)

Research and development expenses were less than \$0.1 million, a decrease of \$1.4 million, or approximately 98%, from the prior year period as we eliminated all research and development activities following our decision to pursue our strategic alternatives during the second quarter of fiscal 2020. This action caused a \$0.8 million reduction of personnel related costs, a \$0.3 million reduction in facilities costs, and a \$0.3 million reduction in all other costs. Our average full-time research and development staff decreased from an average of seventeen full-time employees for the three months ended September 30, 2019 to an average of zero full-time employees for the three months ended September 30, 2020. Going forward, we will pursue renewed research and development activities with an associated increase in expenses.

## Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses for the three months ended September 30, 2020 and 2019 (in thousands, except %):

	Three months ended September 30, 2020		Three months ended September 30, 2019		Increase (decrease)	
	\$	% of total	\$	% of total	\$	%
Selling, general and administrative	\$ 4,787	54%	\$ 5,051	80%	\$ (264)	(5%)
Non-cash stock-based compensation	4,131	46%	1,226	19%	2,905	237%
Depreciation and amortization	4	0%	71	1%	(67)	(94%)
<b>Total selling, general and administrative expenses</b>	<b>\$ 8,922</b>	<b>100%</b>	<b>\$ 6,348</b>	<b>100%</b>	<b>\$ 2,574</b>	<b>41%</b>

For the three months ended September 30, 2020, selling, general and administrative expenses were approximately \$8.9 million, an increase of \$2.6 million, or 41%, due to the approval of the Advisory Nominees Proposal in September 2020 triggering a “Change of Control” under our severance plan. These actions caused a \$2.8 million increase in personnel costs, related to one-time costs of \$3.5 million in stock-based compensation and \$2.8 million in severance, which were offset by a \$0.2 million decrease in all other costs. Our average selling, general and administrative headcount was six full-time employees for the three months ended September 30, 2020 compared to an average of thirteen full-time employees in the prior year period.

## Other Income (Expense)

Other income was less than \$0.1 million for the three months ended September 30, 2020 as compared to \$0.5 million for the three months ended September 30, 2019, due to a decrease in interest income caused by lower average yields and investment balances.

## Comparison of the six months ended September 30, 2020 and 2019

The following table summarizes our results of operations for the six months ended September 30, 2020 and 2019 (in thousands, except %):

	Six months ended September 30,		Increase (decrease)	
	2020	2019	\$	%
Revenues	\$ -	\$ 1,898	\$ (1,898)	(100%)
Cost of revenues	\$ -	\$ 315	\$ (315)	(100%)
Research and development	\$ 28	\$ 5,268	\$ (5,240)	(99%)
Selling, general and administrative	\$ 11,708	\$ 9,663	\$ 2,045	21%
Other income	\$ 19	\$ 733	\$ (714)	(97%)

## Revenues

We had no revenue for the six months ended September 30, 2020 compared to \$1.9 million of revenue for the six months ended September 30, 2019, due to an ending of revenue generating activities following our decision to restructure operations to preserve capital as we pursued various 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 zero for the six months ended September 30, 2020, compared to approximately \$0.3 million for the three months ended September 30, 2019. The decrease was due to the end of revenue generating activities following our decision to restructure operations to preserve capital as we pursued various strategic alternatives.

## Research and Development Expenses

The following table summarizes our research and development expenses for the six months ended September 30, 2020 and 2019 (in thousands, except %):

	Six months ended September 30, 2020		Six months ended September 30, 2019		Increase (decrease)	
	\$	% of total	\$	% of total	\$	%
Research and development	\$ 20	71%	\$ 4,860	93%	\$ (4,840)	(100%)
Non-cash stock-based compensation	7	25%	174	3%	(167)	(96%)
Depreciation and amortization	1	4%	234	4%	(233)	(100%)
<b>Total research and development expenses</b>	<b>\$ 28</b>	<b>100%</b>	<b>\$ 5,268</b>	<b>100%</b>	<b>\$ (5,240)</b>	<b>(99%)</b>

Research and development expenses were less than \$0.1 million, a decrease of \$5.2 million, or approximately 99%, from the prior year period as we eliminated all research and development activities following our decision to pursue our strategic alternatives during the second quarter of fiscal 2020. This action caused a \$2.5 million reduction of personnel related costs, a \$0.8 million reduction in lab supply costs, a \$1.1 million reduction in facilities costs, and a \$0.8 million reduction in all other costs. Our average full-time research and development staff decreased from an average of twenty-nine full-time employees for the six months ended September 30, 2019 to an average of zero full-time employees for the six months ended September 30, 2020. Going forward, we will pursue renewed research and development activities with an associated increase in expenses.

## Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses for the six months ended September 30, 2020 and 2019 (in thousands, except %):

	Six months ended September 30, 2020		Six months ended September 30, 2019		Increase (decrease)	
	\$	% of total	\$	% of total	\$	%
Selling, general and administrative	\$ 6,645	57%	\$ 7,235	74%	\$ (590)	(8%)
Non-cash stock-based compensation	5,056	43%	2,282	24%	2,774	122%
Depreciation and amortization	7	0%	146	2%	(139)	(95%)
<b>Total selling, general and administrative expenses</b>	<b>\$ 11,708</b>	<b>100%</b>	<b>\$ 9,663</b>	<b>100%</b>	<b>\$ 2,045</b>	<b>21%</b>

For the six months ended September 30, 2020, selling, general and administrative expenses were approximately \$11.7 million, an increase of \$2.0 million, or 21%, due to the approval of the Advisory Nominees Proposal in September 2020 triggering a “Change of Control” under our severance plan. These actions caused a \$1.9 million increase in personnel costs, related to one-time costs of \$3.5 million in stock-based compensation and \$2.8 million in severance, and a \$0.1 million increase in all other costs. Our average selling, general and administrative headcount was six full-time employees for the six months ended September 30, 2020 compared to an average of seventeen full-time employees in the prior year period.

## Other Income (Expense)

Other income was less than \$0.1 million for the six months ended September 30, 2020 as compared to \$0.7 million for the six months ended September 30, 2019, due to a decrease in interest income caused by lower average yields and investment balances.

## Financial Condition, Liquidity and Capital Resources

Until our decision in August 2019 to explore strategic alternatives, we had primarily devoted our efforts to developing and commercializing 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 took steps to manage our resources and extend our cash runway, including reducing all commercial and research and development laboratory activities, except for sales of primary human cells out of inventory, negotiating an exit from our long-term facility lease, selling lab equipment and inventory, and reducing our workforce to the minimum level necessary to explore and support these strategic alternatives and maintain our core intellectual property, licenses and collaborations with research institutions and universities. We are now recommencing operations and focusing our efforts on developing highly customized human tissues as living, dynamic models of human biology and disease for use in drug discovery and development.



As of September 30, 2020, we had cash and cash equivalents of approximately \$17.7 million and an accumulated deficit of \$291.2 million. We also had negative cash flow from operations of \$9.7 million during the six months ended September 30, 2020. At March 31, 2020, we had cash and cash equivalents of approximately \$27.4 million and an accumulated deficit of \$279.5 million.

At September 30, 2020, we had total current assets of approximately \$19.5 million and current liabilities of approximately \$0.7 million, resulting in working capital of \$18.8 million. At 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.

The following table summarizes the primary sources and uses of cash for the six months ended September 30, 2020 and 2019 (in thousands):

	Six months ended September 30,	
	2020	2019
<b>Net cash (used in) provided by:</b>		
<b>Operating activities</b>	\$ (9,718)	\$ (11,090)
<b>Investing activities</b>	7	27
<b>Financing activities</b>	11	4,936
<b>Net decrease in cash, cash equivalents, and restricted cash</b>	<b>\$ (9,700)</b>	<b>\$ (6,127)</b>

#### *Operating activities*

Net cash used in operating activities for the six months ended September 30, 2020 was approximately \$9.7 million as compared to \$11.1 million used in operating activities for the six months ended September 30, 2019. This \$1.4 million decrease in operating cash usage can be attributed primarily to a \$3.0 million improvement in the net loss less depreciation and amortization and stock-based compensation, resulting from our restructuring and reduction of headcount, which was offset by a \$1.6 million increase in the change in working capital between the two periods.

#### *Investing activities*

Net cash provided by investing activities was less than \$0.1 million for the six months ended September 30, 2020 and 2019.

#### *Financing activities*

Net cash provided by financing activities was less than \$0.1 million during the six months ended September 30, 2020 compared to net cash provided by financing activities of approximately \$4.9 million during the six months ended September 30, 2019. Financing in the prior year period was driven by the sale of common stock through at-the-market (“ATM”) offerings.

#### *Operations funding requirements*

Through September 30, 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.

Throughout the strategic alternatives assessment process, we took steps to manage our resources and extend our cash runway, including selling various assets and reducing our workforce to the minimum level necessary to explore and support these strategic alternatives as well as to support the remainder of our then on-going business activities and assets, including our intellectual property platform and collaborations with research institutions and universities.

We believe our cash and cash equivalents on hand will be sufficient to meet our financial obligations for at least the next 12 months of operations. As we recommence our operations and focuses our efforts on drug discovery and development, we will need to raise additional capital to implement this new business plan. We cannot predict with certainty the exact amount or timing for any future capital raises or the terms or structure of any such raises.

Based on our use of the 2018 Shelf through September 30, 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. We cannot be sure that additional financing will be available if and when needed, or that, if available, it can obtain financing on terms favorable to its stockholders. Any failure to obtain financing when required will have a material adverse effect on our business, operating results, financial condition and ability to continue as a going concern.

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 had until September 4, 2020 to regain compliance. On August 18, 2020, we effected a 1-for-20 reverse stock split of our common stock, and on September 2, 2020, we received notification from Nasdaq that the closing bid price of our common stock had been at \$1.00 per share or greater for ten consecutive business days and that Nasdaq had closed the matter. There can be no assurance that the Company will be able to maintain compliance with the Price-based Requirements or other listing requirements necessary to maintain the listing of its common stock on the Nasdaq Capital Market.

As of September 30, 2020, we had 6,732,090 total issued and outstanding shares of common stock.

In addition, our 2008 Equity Incentive Plan provided for the issuance of up to 76,079 shares of common stock upon the exercise of outstanding stock options, of which 44,812 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 1,427,699 shares of our common stock, of which 251,026 shares remain available for issuance as of September 30, 2020, to executive officers, directors, advisory board members, employees and consultants. Additionally, 75,000 shares of common stock have been reserved for issuance under the 2016 Employee Stock Purchase Plan (“ESPP”), of which 59,435 shares remain available for future issuance as of September 30, 2020. Lastly, 104,410 shares of common stock have been reserved for issuances under Inducement Award Agreements. In aggregate, issued and outstanding common stock 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 ESPP total 7,898,774 shares of common stock as of September 30, 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 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.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not required for smaller reporting companies under Item 305(e) of Regulation S-K.

## **ITEM 4. 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 Securities Exchange Act of 1934, as amended (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 principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of the end of the quarterly period covered by this report were designed and operating effectively.

### **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) of the Exchange Act) that occurred during the fiscal quarter 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 principal executive officer and our principal 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.

## PART II—OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

See Note 5 of the Notes to the Unaudited Condensed Consolidated Financial Statements within this Form 10-Q for a discussion of our legal proceedings and contingencies.

### 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 Quarterly 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.*

*Risk factors marked with an asterisk (\*) below include a substantive change from or an update to the risk factors included in our Annual Report on Form 10-K for the fiscal year ended March 31, 2020, filed with the SEC on May 28, 2020.*

#### 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 since spread globally and been declared a pandemic by the World Health Organization. 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 COVID-19 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. The continued COVID-19 pandemic could adversely impact our operations, including among others, 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 COVID-19 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 our Business

***\*We have recommenced our operations as an early-stage company focusing on 3D bioprinting technology to develop human tissues and disease models for drug discovery and development, which is an unproven business strategy that may never achieve profitability.***

Following the election of the new board of directors at our 2020 Annual Meeting of stockholders, we have recommenced operations and are focusing our efforts on utilizing our 3D bioprinting technology to develop human tissues and disease models for drug discovery and development. We have recommenced our operations as an early-stage company with an unproven business strategy, and may never achieve profitability. Our success will depend upon the viability of our platform technology and any disease models we develop, as well as on our ability to determine which drug candidates we should pursue. Our success will also depend on our ability to select an appropriate development strategy for any drug candidates we identify, including internal development or partnering or licensing arrangements with pharmaceutical companies. We may not be able to partner or license our drug candidates. We may never achieve profitability, or even if we achieve profitability, we may not be able to maintain or increase our profitability.

***\*We will incur substantial additional operating losses over the next several years as our research and development activities increase.***

We will incur substantial additional operating losses over the next several years as our research and development activities increase. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Our ability to generate revenue and achieve profitability will depend on, among other things:

- successfully developing human tissues and disease models for drug discovery and development that enable us to identify drug candidates;
- successfully outsourcing certain portions of our development efforts;
- entering into partnering or licensing arrangements with pharmaceutical companies to further develop and conduct clinical trials for any drug candidates we identify;
- obtaining any necessary regulatory approval for any drug candidates we identify; and
- raising sufficient funds to finance our activities and long-term business plan.

We might not succeed at any of these undertakings. If we are unsuccessful at one or more of these undertakings, our business, prospects, and results of operations will be materially adversely affected.

***\*Using our platform technology to develop human tissues and disease models for drug discovery and development is new and unproven.***

Utilizing our 3D bioprinting platform technology to develop human tissues and disease models for drug discovery and development will involve new and unproven technologies, disease models and approaches, each of which is subject to the risk associated with new and evolving technologies. To date, we have not identified or developed any drug candidates utilizing our new business model. Our future success will depend on our ability to utilize our 3D bioprinting platform to develop human tissues and disease models that will enable us to identify and develop viable drug candidates. We may experience unforeseen technical complications, unrecognized defects and limitations in our technology or our ability to develop disease models or identify viable drug candidates. These complications could materially delay or substantially increase the anticipated costs and time to identify and develop viable drug candidates, which would have a material adverse effect on our business and financial condition and our ability to continue operations.

***\*We will face intense competition in our drug discovery efforts.***

The biotechnology and pharmaceutical industry is subject to intense competition and rapid and significant technological change. There are many potential competitors for the disease indications we may pursue, 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;
- development of or access to disease models;
- identification and development of drug candidates;
- regulatory processes and approvals; and
- identifying and entering into agreements with potential collaborators.

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

In order to effectively compete, we may need to make substantial investments in our research and technology development, drug candidate identification and development, testing and regulatory approval and licensing and business development activities. There is no assurance that we will be successful in discovering effective drug candidates using our 3D bioprinted tissues or disease models. Our technologies and drug development plans also may be rendered obsolete or noncompetitive as a result of drugs, intellectual property, technologies, products and services introduced by competitors. Any of these risks may prevent us from building a successful drug discovery business or entering into a strategic partnership or collaboration related to, any drug candidates we identify on favorable terms, or at all.

***\*As we pursue drug development through 3D tissues and disease models, we will require access to a constant, steady, reliable supply of human cells to support our development activities.***

As we pursue drug development through 3D tissues and disease models, we will require access to a constant, steady, reliable supply of human cells to support our development activities. We previously purchased certain qualified human cells from selected third-party suppliers based on quality assurance, cost effectiveness, and regulatory requirements. We also formed our now dissolved, wholly-owned subsidiary, Samsara, to serve as a key source of the primary human cells we utilized in our business. As we recommence our development operations, we will need to identify one or more sources of qualified human cells and there can be no guarantee that we will be able to access the quantity and quality of raw materials needed at a cost-effective price. 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 support our drug development efforts.

***\*Our business will be adversely impacted if we are unable to successfully attract, hire and integrate key additional employees or contractors.***

Our future success depends in part on our ability to successfully attract and then retain key additional executive officers and other key employees and contractors to support our drug discovery plans. Recruiting and retaining qualified scientific and clinical personnel is critical to our success. Competition to hire qualified personnel in our industry is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. If we are unable to attract and retain high quality personnel, our ability to pursue our drug discovery business will be limited, and our business, prospects, financial condition and results of operations may be adversely affected.

***\*Our business will be adversely impacted if we are unable to secure adequate laboratory facilities and equipment.***

In connection with our strategic alternatives process and restructuring beginning in August 2019, we exited our lease agreement for our prior company headquarters (which included laboratory space) and sold most of our lab equipment (with the exception of our bioprinters). In order to proceed with our business plan, we will need to secure adequate lab space and equipment. If we are unable to secure such space and equipment at all, or on commercially reasonable terms, our business opportunity would be adversely impacted.

***\*We may 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 drug 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. Our existing cash, cash equivalents and interest thereon is expected to be sufficient to fund our projected operating requirements for at least the next 12 months. We have based these 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 Board of Directors decides that we should pursue further research and development activities than already proposed, we will require substantial additional funding to operate our proposed business, including expanding our facilities and hiring additional qualified personnel, and we 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.

Further, 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. Raising additional funding through debt or equity financing is likely to be difficult or unavailable altogether given the early stage of our technology and any drug candidates we identify. 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.

***\*Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and results of earlier studies and trials may not be predictive of future results.***

Before obtaining marketing approval from regulatory authorities for the sale of any drug candidates we identify, any such drug candidates must undergo extensive clinical trials to demonstrate the safety and efficacy of the drug candidates in humans. Human clinical testing is expensive and can take many years to complete, and we cannot be certain that any clinical trials will be conducted as planned or completed on schedule, if at all. We may elect to complete this testing, or some portion thereof, internally or enter into a

partnering or development agreement with a pharmaceutical company to complete these trials. Our inability, or the inability of any third party with whom we enter into a partnering or development agreement, to successfully complete preclinical and clinical development could result in additional costs to us and negatively impact our ability to generate revenues or receive development or milestone payments. Our future success is dependent on our ability, or the ability of any pharmaceutical company with whom we enter into a partnering or development agreement, to successfully develop, obtain regulatory approval for, and then successfully commercialize any drug candidates we identify.

Any drug candidates we identify will require additional clinical development, management of clinical, preclinical and manufacturing activities, regulatory approval in applicable jurisdictions, achieving and maintaining commercial-scale supply, building of a commercial organization, substantial investment and significant marketing efforts. We are not permitted to market or promote any of our drug candidates before we receive regulatory approval from the U.S. Food and Drug Administration (“FDA”) or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our drug candidates.

We, or any third party with whom we enter into a partnering or development agreement, may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to earn development or milestone payments or for any drug candidates to obtain regulatory approval, including:

- delays in or failure to reach agreement on acceptable terms with prospective CROs and clinical sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- failure to obtain sufficient enrollment in clinical trials or participants may fail to complete clinical trials;
- clinical trials of our drug candidates that may produce negative or inconclusive results, and as a result we, or any pharmaceutical company with whom we enter into a partnering or development agreement, may decide, or regulators may require, additional clinical trials;
- suspension or termination of clinical research, either by us, any third party with whom we enter into a partnering or development agreement, regulators or institutional review boards, for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- additional or unanticipated clinical trials required by regulators or institutional review boards to obtain approval or any drug candidates may be subject to additional post-marketing testing requirements to maintain regulatory approval;
- regulators may revise the requirements for approving any drug candidates, or such requirements may not be as anticipated;
- the cost of clinical trials for any drug candidates may be greater than anticipated;
- the supply or quality of any drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate or may be delayed;
- regulatory authorities may suspend or withdraw their approval of a product or impose restrictions on its distribution; and
- delays due to the recent COVID-19 pandemic, including with respect to the receipt of drug candidates or other materials, submission of New Drug Applications (“NDAs”), filing of Investigational New Drug (“INDs”), and starting any clinical trials for other indications or programs.

If we, or any third party with whom we enter into a partnering or development agreement, experience delays in the completion of, or termination of, any clinical trial of any drug candidates that we develop, or are unable to achieve clinical endpoints due to unforeseen events, such as the COVID-19 pandemic, the commercial prospects of our drug candidates will be harmed, and our ability to develop milestones, development fees or product revenues from any of these drug candidates will be delayed.

***\*We will rely upon third-party contractors and service providers for the execution of critical aspects of any future development programs. Failure of these collaborators to provide services of a suitable quality and within acceptable timeframes may cause the delay or failure of any future development programs.***

We plan to outsource certain functions, tests and services to contract research organizations (“CROs”), medical institutions and collaborators as well as outsource manufacturing to collaborators and/or contract manufacturers, and we will rely on third parties for quality assurance, clinical monitoring, clinical data management and regulatory expertise. We may elect, in the future, to engage a CRO to run all aspects of a clinical trial on our behalf. There is no assurance that such individuals or organizations will be able to provide the functions, tests, biologic supply or services as agreed upon or in a quality fashion and we could suffer significant delays in the development of our drug candidates or development programs.

In some cases, there may be only one or few providers of such services, including clinical data management or manufacturing services. In addition, the cost of such services could be significantly increased over time. We may rely on third parties and collaborators to enroll qualified patients and conduct, supervise and monitor our clinical trials. Our reliance on these third parties and collaborators for clinical development activities reduces our control over these activities. Our reliance on these parties, however, does not relieve us of our regulatory responsibilities, including ensuring that our clinical trials are conducted in accordance with Good Clinical Practice (“GCP”) regulations and the investigational plan and protocols contained in the regulatory agency applications. In addition, these third parties may not complete activities on schedule or may not manufacture under Current Good Manufacturing Practice (“cGMP”) conditions. Preclinical or clinical studies may not be performed or completed in accordance with Good Laboratory Practices (“GLP”) regulatory requirements or our trial design. If these third parties or collaborators do not successfully carry out their contractual duties or meet expected deadlines, obtaining regulatory approval for manufacturing and commercialization of our drug candidates may be delayed or prevented. We may rely substantially on third-party data managers for our clinical trial data. There is no assurance that these third parties will not make errors in the design, management or retention of our data or data systems. There is no assurance these third parties will pass FDA or regulatory audits, which could delay or prohibit regulatory approval.

In addition, we will exercise limited control over our third-party partners and vendors, which makes us vulnerable to any errors, interruptions or delays in their operations. If these third parties experience any service disruptions, financial distress or other business disruption, or difficulties meeting our requirements or standards, it could make it difficult for us to operate some aspects of our business.

***\*The near and long-term viability of our drug discovery and development efforts will depend on our ability to successfully establish strategic relationships.***

The near and long-term viability of our drug discovery and development efforts depend in part on our ability to successfully establish new strategic partnering, collaboration and licensing arrangements with biotechnology companies, pharmaceutical companies, universities, hospitals, insurance companies and or government agencies. Establishing strategic relationships is difficult and time-consuming. Potential partners and collaborators may not enter into relationships with us based upon their assessment of our technology or drug candidates or our financial, regulatory or intellectual property position. If we fail to establish a sufficient number of strategic relationships on acceptable terms, we may not be able to develop and obtain regulatory approval for our drug candidates or generate sufficient revenue to fund further research and development efforts. Even if we establish new strategic relationships, these relationships may never result in the successful development or regulatory approval for any drug candidates we identify for a number of reasons both within and outside of our control.

***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, we would be successful in our efforts to advance the programs and commercialize our products.

***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 prior 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 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

### ***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 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.

### ***In order 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 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. In addition, as of September 30, 2020, we were limited to an aggregate of one-third of our public float in the amount we could raise through primary offerings of securities in any consecutive 12-month period using shelf registration statements, including the 2018 Shelf.

### ***\*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 \$9.0 million and \$6.8 million for the three months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, we had incurred cumulative operating losses of \$241.7 million and cumulative net losses totaling \$291.2 million. We expect to incur substantial additional operating losses over the next several years as our research and development activities increase.

The amount of future losses and when, if ever, we will achieve profitability are uncertain. Our ability to generate revenue and achieve profitability will depend on, among other things:

- successfully developing human tissues and disease models for drug discovery and development that enable us to identify drug candidates;
- successfully outsourcing certain portions of our development efforts;
- entering into partnering or licensing arrangements with pharmaceutical companies to further develop and conduct clinical trials for any drug candidates we identify;

- obtaining any necessary regulatory approval for any drug candidates we identify; and
- raising sufficient funds to finance our activities and long-term business plan.

We might not succeed at any of these undertakings. If we are unsuccessful at one or more of these undertakings, our business, prospects, and results of operations will be materially adversely affected. 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 U.S. Securities and Exchange Commission (“SEC”) inquiry regarding certain of our prior disclosures and related operations;
- litigation;
- research and development expenditures, including commencement of preclinical studies and clinical trials;
- the timing of the hiring of new employees, which may require payments of signing, retention or similar bonuses; 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 could 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 ourselves, our employees and our 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.

***\*We may experience conflicts of interest with Viscient Biosciences, Inc. with respect to business opportunities and other matters.***

Keith Murphy, our Executive Chairman and Principal Executive Officer, is the Chief Executive Officer and Chairman of Viscient Biosciences, Inc. (“Viscient”), a private company that he founded in 2017 that is focused on drug discovery and development utilizing 3D tissue technology and multi-omics (genomics, transcriptomics, metabolomics). Jeffrey N. Miner, our Chief Scientific Officer, is a co-founder and the Chief Scientific Officer of Viscient, and Thomas Einar Jurgensen, our General Counsel, also serves as outside counsel to Viscient. In addition, Adam Stern, Douglas Jay Cohen and David Gobel (through the Methuselah Foundation and the Methuselah Fund), members of our Board, have invested funds through a convertible promissory note in Viscient, but do not serve as an employee, officer or director of Viscient. Additional members of our Research and Development organization also work at Viscient, and we expect that additional employees or consultants of ours will also be employees of or consultants to Viscient. We also expect to share certain facilities and equipment with Viscient. During fiscal 2020, we provided services to Viscient, and Viscient has previously purchased primary human cell-based products from our former subsidiary, Samsara Sciences, Inc. We expect to continue to provide services to Viscient and enter into additional agreements with Viscient in the future.

In addition, we license, as well as cross-license, certain intellectual property to and from Viscient and expect to continue to do so in the future. Although we have entered, and expect to enter, into agreements and arrangements that we believe appropriately govern the ownership of intellectual property created by joint employees or consultants of Viscient and/or using our or Viscient's facilities or equipment, it is possible that we may disagree with Viscient as to the ownership of intellectual property created by shared employees or consultants, or using shared equipment or facilities.

Due to the interrelated nature of Viscient with us, conflicts of interest may arise with respect to transactions involving business dealings between us and Viscient, potential acquisitions of businesses or products, the development and ownership of technologies and products, the sale of products, markets and other matters in which our best interests and the best interests of our stockholders may conflict with the best interests of the stockholders of Viscient. In addition, we and Viscient may disagree regarding the interpretation of certain terms of the arrangements we previously entered into with Viscient or may enter into in the future. We cannot guarantee that any conflict of interest will be resolved in our favor, or that, with respect to our transactions with Viscient, we will negotiate terms that are as favorable to us as if such transactions were with another third-party. In addition, executives that provide services to us and Viscient may not dedicate all of their time to us and we may therefore compete with Viscient for the time commitments of our executive officers from time to time.

#### **\*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. 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 had until September 4, 2020 to regain compliance. On August 18, 2020, we effected a 1-for-20 reverse stock split of our common stock (the "Reverse Stock Split"), and on September 2, 2020, we received notification from Nasdaq that the closing bid price of our common stock had been at \$1.00 per share or greater for ten consecutive business days. However, there can be no assurance that we will maintain compliance with the minimum bid price requirement or other listing requirements necessary for us to maintain the listing of our common stock on The Nasdaq Capital Market.

A delisting from The Nasdaq Capital Market and commencement of trading on the OTCBB 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 makers or broker-dealers for our common stock; and
- the availability of information concerning the trading prices and volume of shares of our common stock.

***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 (“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;
- our ability to execute on our new strategic plan;
- 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 September 30, 2020, there were an aggregate of 7,898,774 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 1,107,249 shares of our common stock that may be issued upon restricted stock units, the exercise of outstanding stock options, or is available for issuance under our equity incentive plans, and 59,435 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 Second Restated and Amended Certificate of Incorporation ("Certificate of Incorporation") and Amended and Restated Bylaws ("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 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 other patent applications at risk of not issuing. Additionally, our licensors may continue to 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 or substantial penalties. Moreover, patent disputes and related proceedings can distract management's attention and interfere with running our 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 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 University, 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 University, 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.

***\*We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.***

In order to protect our proprietary and licensed technology and processes, we rely in part on confidentiality agreements with our corporate partners, employees, consultants, manufacturers, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of our confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

*\*We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.*

We employ or engage individuals who were previously employed at other biopharmaceutical companies. Although we have no knowledge of any such claims against us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. To date, none of our employees have been subject to such claims.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. MINE SAFETY DISCLOSURE**

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.

## ITEM 6. EXHIBITS

The following exhibit index shows those exhibits filed with this report and those incorporated herein by reference:

Exhibit No.	Description
3.1	<a href="#"><u>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).</u></a>
3.2	<a href="#"><u>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).</u></a>
3.3	<a href="#"><u>Certificate of Second 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 August 17, 2020).</u></a>
3.4	<a href="#"><u>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).</u></a>
3.5	<a href="#"><u>Amendment to Organovo Holdings Bylaws, 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).</u></a>
10.1#	<a href="#"><u>Consulting Agreement, dated September 15, 2020, by and between Organovo and Multi Dimensional Bio Insight LLC.*</u></a>
10.2#	<a href="#"><u>Consulting Agreement, dated August 25, 2020, by and between Organovo and Danforth Advisors.*</u></a>
10.3#	<a href="#"><u>Offer Letter, dated September 15, 2020, between the Company and Jeffrey N. Miner.*</u></a>
10.4#	<a href="#"><u>Engagement Agreement, dated July 23, 2020, by and between Organovo and Optima Law Group of San Diego.*</u></a>
31.1	<a href="#"><u>Certification of Keith Murphy, Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.*</u></a>
31.2	<a href="#"><u>Certification of Chris Heberlig, Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.*</u></a>
32.1	<a href="#"><u>Certification of Keith Murphy, Principal Executive Officer, and Chris Heberlig, Principal Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended.*</u></a>
101	Interactive Data File*

\* Filed herewith.

# Indicates management or compensatory plan.

**SIGNATURES**

Pursuant to the requirements 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.**

Date: November 5, 2020

By: /s/ Keith Murphy  
Name: Keith Murphy  
Title: Executive Chairman  
(Principal Executive Officer)

Date: November 5, 2020

By: /s/ Chris Heberlig  
Name: Chris Heberlig  
Title: President and Chief Financial Officer  
(Principal Financial Officer)

**CONSULTING AGREEMENT**

This Consulting Agreement (the "Agreement") is made effective as of September 15, 2020 (the "Effective Date"), by and between Organovo, Inc., a Delaware corporation, with its principal place of business being 440 Stevens Avenue, Suite 200, Solana Beach, CA 92075 (the "Company") and Multi Dimensional Bio Insight LLC, a California limited liability corporation, with its principal place of business being 3 Pine Tree Lane, Rolling Hills, CA 90274 ("MDBI"). The Company and MDBI are herein sometimes referred to individually as a "Party" and collectively as the "Parties."

WHEREAS, the Company possesses know-how and proprietary technology related to 3D bioprinting and drug discovery; and

WHEREAS, MDBI and its consultants have expertise in corporate operations and strategy, especially within the Company's areas of operation and technology expertise; and

WHEREAS, MDBI desires to serve as an independent consultant for the purpose of providing the Company with certain strategic and financial advice and support services, as more fully described in Exhibit A attached hereto, (the "Services"); and

WHEREAS, it is further contemplated that MDBI will provide Services of Executive Chairman and other such executive officer positions as may be determined by the Company and Murphy from time to time; and

WHEREAS, the Company wishes to engage MDBI on the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt of which are hereby acknowledged, the Parties agree and covenant as follows.

1. Services of Consultant. MDBI will assist the Company with matters relating to the Services. The Services are more fully described in Exhibit A attached hereto. MDBI and the Company will periodically review the Services to prioritize and implement any items listed on Exhibit A.
  2. Compensation for Services. In full consideration of MDBI's full, prompt and faithful performance of the Services, the Company shall compensate MDBI a consulting fee as set forth in Exhibit A. MDBI shall, from time to time, but not more frequently than once per calendar month, provide the Company with an itemized invoice for Services rendered for that month, and such invoice will be paid upon 30 days of receipt. Each month the Parties shall evaluate jointly the current fee structure and scope of Services. MDBI reserves the right to an annual increase in consultant rates of up to 4%, effective January 1 of each year. Upon termination of this Agreement pursuant to Section 3, no compensation or benefits of any kind as described in this Section 2 shall be payable or issuable to MDBI after the effective date of such termination. In addition, the Company will reimburse MDBI for reasonable out-of-pocket business expenses, including but not limited to travel and parking, incurred by MDBI in performing the Services hereunder, upon submission
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by MDBI of supporting documentation in accordance with Company's travel policy (attached as Exhibit B) and reasonably acceptable to the Company. Any expenses that exceeds \$10,000 shall be submitted to the Company for its prior written approval.

Absent separate Company approval, the total hours provided by MDBI to the Company in any single Company fiscal year or calendar year and compensated as described in Exhibit A shall be no greater than 1,500 hours.

The Company agrees to provide compensation for services already rendered, covering the time period from July 15 to September 15, 2020, in the same manner as provided for in this Agreement. MDBI will provide an invoice for such services rendered subsequent to the signing of this Agreement, and the total amount of hourly compensation and reasonable expenses covered under this provision will be no greater than \$50,000.

All MDBI invoices and billing matters should be addressed to:

Company Accounts Payable Contact: Jordan Beltran, Assistant Controller  
Accounts Payable  
Email: [AP@organovo.com](mailto:AP@organovo.com)  
Phone: 858-224-1000  
Organovo Holdings, Inc.  
440 Stevens Avenue, Suite 200  
Solana Beach, CA 92075

All Company payments and billing inquiries should be addressed to:

MDBI Accounting: [pinetreelanepa@gmail.com](mailto:pinetreelanepa@gmail.com)  
MDBI  
Attn: Organovo Consulting  
3 Pine Tree Lane  
Rolling Hills, CA 90274

3. Term and Termination. The term of this Agreement will commence on the Effective Date and will continue for a four year term. Notwithstanding the foregoing, this Agreement may be terminated by either Party hereto: (a) with Cause (as defined below), upon 30 days prior written notice to the other Party; or (b) without cause upon 60 days prior written notice to the other Party. For purposes of this Section 3, "Cause" shall include: (i) a breach of the terms of this Agreement which is not cured within 30 days of written notice of such default or (ii) the commission of any act of fraud, embezzlement or deliberate disregard of a rule or policy of the Company.
  4. Time Commitment. MDBI will devote such time to perform the Services under this Agreement as may reasonably be required.
  5. Place of Performance. MDBI will perform the Services at such locations upon which the Company and MDBI may mutually agree. MDBI will not, without the prior written consent of the Company, perform any of the Services at any facility or in any manner that might give anyone other than the Company any rights to or allow for disclosure of any Confidential Information (as defined below).
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6. Compliance with Policies and Guidelines. MDBI will perform the Services in accordance with all rules or policies adopted by the Company that the Company discloses in writing to MDBI.
  7. Confidential Information. MDBI acknowledges and agrees that during the course of performing the Services, the Company may furnish, disclose or make available to MDBI business, technical, commercial and/or regulatory information, whether disclosed or provided in oral, written, graphic or electronic form including, but not limited to, material, compilations, data, licenses, formulae, models, discoveries, developments, inventions, techniques, patent disclosures, procedures, suppliers, pricing lists, processes, schematics, business plans, forecasts, projections, budgets, protocols, results of experimentation and testing, specifications, marketing plans, strategies and techniques, and all tangible and intangible embodiments thereof of any kind whatsoever (including, but not limited to, any apparatus, biological or chemical materials, animals, cells, compositions, documents, drawings, machinery, patent applications, records and reports), which is owned or controlled by the Company and is marked or designated as confidential at the time of disclosure or is of a type that is customarily considered to be confidential information (collectively the "Confidential Information"). MDBI acknowledges that the Confidential Information or any part thereof is the exclusive property of the Company and shall not be disclosed to any third party without first obtaining the written consent of the Company. MDBI further agrees to take all practical steps to ensure that the Confidential Information, and any part thereof, shall not be disclosed or issued to its affiliates, agents or employees, except on like terms of confidentiality. Notwithstanding the foregoing, Confidential Information shall not include any such information which Consultant can establish (i) was publicly known or made generally available prior to the time of disclosure to Consultant; (ii) becomes publicly known or made generally available after disclosure to Consultant through no wrongful action or inaction of Consultant; or (iii) is in the rightful possession of Consultant, without confidentiality obligations, at the time of disclosure as shown by Consultant's then-contemporaneous written records; provided that any combination of individual items of information shall not be deemed to be within any of the foregoing exceptions merely because one or more of the individual items are within such exception, unless the combination as a whole is within such exception. The above provisions of confidentiality shall apply for a period of five years.
  8. Consultant will hold in the strictest confidence, and take all reasonable precautions to prevent any unauthorized use or disclosure of Confidential Information, and Consultant will not (i) use the Confidential Information for any purpose whatsoever other than as necessary for the performance of the Services on behalf of the Company, or (ii) disclose the Confidential Information to any third party without the prior written consent of an authorized representative of Company, except that Consultant may disclose Confidential Information to the extent compelled by applicable law; *provided however*, prior to such disclosure, Consultant shall provide prior written notice to Company and seek a protective order or such similar confidential protection as may be available under applicable law. Consultant agrees that no ownership of Confidential Information is conveyed to the Consultant. Without limiting the foregoing, Consultant shall not use or disclose any Company property, intellectual property rights, trade secrets or other proprietary know-how of the Company to invent, author, make, develop, design, or otherwise enable others to invent, author, make, develop, or design identical or substantially similar designs as
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those developed under this Agreement for any third party. Consultant agrees that Consultant's obligations under this Section shall continue after the termination of this Agreement. Notwithstanding the foregoing, federal law provides immunity for any disclosure of trade secrets when such disclosure is made to a federal, state, or local government official, or to an attorney, if such disclosure is made solely for the purpose of reporting or investigating a suspected violation of law. In addition, the law provides immunity for any complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. 18 U.S.C. § 1833(b). Disclosures made in compliance with 18 U.S.C. § 1833(b) shall not create liability, either criminally or civilly."

9. Freedom to Work for Others. Except as expressly provided herein, nothing in this Agreement shall preclude MDBI or its service providers from consulting for or being employed by any other person or entity, provided that (a) such other service does not conflict with MDBI's or its service providers obligations to the Company, (b) MDBI devotes to the Company the time reasonably required to provide the Services to the Company contemplated in this Agreement, and (c) MDBI discloses all potential conflicts of interest promptly for consideration by the Company.
  10. Non Solicitation. All personnel representing MDBI are employees or contracted agents of MDBI. Accordingly, except for Murphy's service and as otherwise agreed to by the Company in writing, they are not retainable by the Company. Unless agreed to in writing by MDBI, the Company hereby agrees not to solicit, attempt to hire or retain their services for so long as they are employees or contracted agents of MDBI and for one year thereafter. The above notwithstanding, it is not a breach of this provision to hire an individual who applies to Company's job posting without being recruited by Company, in which case no liquidated damages shall be owed.
  11. No Implied Warranty. MDBI represents and warrants to the Company that MDBI possesses the business, professional and technical expertise and the resources, including without limitation equipment, facilities and employees to perform these Services. Except for any express warranties stated herein, the Services are provided on an "as is" basis, and the Company disclaims any and all other warranties, conditions, or representations (express, implied, oral or written), relating to the Services or any part thereof.
  12. Indemnification. Consultant agrees to indemnify and hold MDBI hereto, its directors, officers, agents and employees harmless against any claim based upon circumstances alleged to be inconsistent with such representations and/or warranties contained in this Agreement. Further, MDBI shall indemnify and hold harmless the Company against any claims, losses, damages or liabilities (or actions in respect thereof) that arise out of or are based on the Services performed hereunder, except for any such claims, losses, damages or liabilities arising out of the negligence or willful misconduct of the Company or any of its subcontractors.
  13. Independent Contractor. MDBI is not, nor shall MDBI be deemed to be at anytime during the term of this Agreement, an employee of the Company, and therefore MDBI shall not be entitled to any benefits provided by the Company to its employees, if applicable. MDBI's status and relationship with the Company shall be that of an independent contractor and consultant. MDBI shall not state or imply, directly or indirectly, that MDBI is empowered to bind the Company without the Company's prior written consent,
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provided that this sentence shall not prohibit a consultant for MDBI working as an officer of the Company may bind the company in their capacity as an officer determined by the Company and MDBI from time to time. Nothing herein shall create, expressly or by implication, a partnership, joint venture or other association between the parties. MDBI will be solely responsible for payment of all charges and taxes arising from its relationship to the Company as a consultant.

14. Records. Upon termination of MDBI's relationship with the Company, MDBI shall deliver to the Company any property or Confidential Information of the Company relating to the Services which may be in its possession including products, project plans, materials, memoranda, notes, records, reports, laboratory notebooks, or other documents or photocopies and any such information stored using electronic medium.
  15. Data Protection. Depending on the Services Service Provider performs, MDBI may be required to access, collect, retain, disclose or otherwise process individually identifiable health information or information identifying or, in combination with other information, identifiable to a living individual ("Personal Data"). For purposes of this Agreement, "Processing" (and its conjugates, including, without limitation, "Process") means any operation or set of operations that is performed upon Personal Data, including, without limitation, any collection, recording, retention, organization, storage, adaptation, alteration, retrieval, consultation, blocking erasure use, disclosure, access, transfer, or destruction, whether or not by electronic means. In that event, MDBI agrees to collect and process Personal Data solely as described in this Agreement and not use such Personal Data further for any other purpose or in any other manner except where such further use is required by applicable law, regulation or governmental authority. Further, MDBI agrees to abide by all applicable data protection and privacy laws while performing the Services, and shall afford Personal Data all the protections applicable to Confidential Information as set forth in this Agreement. MDBI shall maintain appropriate safeguards to ensure the confidentiality and security of the Personal Data and shall inform Company within three (3) days about any unauthorized or unintentional access to or disclosure of Personal Data ("Security Breach"), including the timing and nature of the Security Breach, and provide all reasonable assistance to remedy the Security Breach. Where applicable data protection laws require the parties to enter into additional agreements or undertakings, including international data transfer agreements, MDBI shall undertake to ensure that all necessary agreements are implemented and in place. In the event of a Security Breach, MDBI shall also
    - (i) reasonably cooperate with Company in connection with the investigation of such Security Breach and not make any public announcements relating to such Security Breach without Company's prior written approval;
    - (ii) take all necessary and appropriate corrective action, including without limitation, at the request of Company and at the expense of MDBI, provide notice to all persons whose Personal Information may have been affected by such Data Security Breach, whether or not such notice is required by applicable law; and
    - (iii) reimburse Company for all reasonable costs, including attorneys' fees, Company may incur in connection with remediation efforts.
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16. Notices. Any notice under this Agreement shall be in writing (except in the case of verbal communications, emails and teleconferences updating either Party as to the status of work hereunder) and shall be deemed delivered upon electronic delivery via email with confirmed receipt, personal delivery, one day after being sent via a reputable nationwide overnight courier service or two days after deposit in the mail or on the next business day following transmittal via facsimile. Notices under this Agreement shall be sent to the following representatives of the Parties:

If to the Company:

Name: Organovo, Inc.  
Title: Legal Department  
Address: 440 Stevens Avenue, Suite 200, Solana Beach, CA 92075  
Phone: 858-224-1000  
E-mail: [legal@organovo.com](mailto:legal@organovo.com)

If to MDBI:

Name: Multi Dimensional Bio Insight  
Title: Attn: Organovo Consulting  
Address: 3 Pine Tree Lane  
Rolling Hills, CA 90274  
E-mail: [pinetreelanepa@gmail.com](mailto:pinetreelanepa@gmail.com)

17. Assignment, Subcontracting, and Successors. This Agreement may not be assigned by a Party without the consent of the other which consent shall not be unreasonably withheld, except that each Party may assign this Agreement and the rights, obligations and interests of such Party, in whole or in part, to any of its Affiliates, to any purchaser of all or substantially all of its assets or to any successor corporation resulting from any merger or consolidation of such Party with or into such corporation. MDBI may not engage subcontracting companies under this Agreement without the Company's prior written approval, not to exclude sole providers, individuals or individual consultants providing services through MDBI.
18. Force Majeure. Neither Party shall be liable for failure of or delay in performing obligations set forth in this Agreement, and neither shall be deemed in breach of its obligations, if such failure or delay is due to natural disasters or any causes beyond the reasonable control of either Party. In the event of such force majeure, the Party affected thereby shall use reasonable efforts to cure or overcome the same and resume performance of its obligations hereunder.
19. Headings. The Section headings are intended for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.
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20. Integration; Severability. This Agreement is the sole agreement with respect to the subject matter hereof and shall supersede all other agreements and understandings between the Parties with respect to the same. If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, it is the intention of the Parties that the remainder of the Agreement shall not be affected.
21. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of California, excluding choice of law principles. The Parties agree that any action or proceeding arising out of or related in any way to this Agreement shall be brought solely in a Federal or State court of competent jurisdiction sitting in San Diego County in the State of California.
22. Attorneys' Fees. In any court action at law or equity that is brought by one of the Parties to this Agreement to enforce or interpret the provisions of this Agreement, the prevailing Party will be entitled to reasonable attorneys' fees, in addition to any other relief to which that Party may be entitled.
23. Counterparts. This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together will constitute one agreement.

If you are in agreement with the foregoing, please sign where indicated below, whereupon this Agreement shall become effective as of the Effective Date.

**MDBI, LLC**

By: /s/ Keith Murphy

Print Name: Keith Murphy

Title: President

**ORGANOVO, INC.**

By: /s/ Chris Heberlig

Print Name: Chris Heberlig

Title: President

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## **EXHIBIT A**

### **Description of Services and Schedule of Fees**

MDBI will perform mutually agreed to functions which are necessary to support the management and operations of the Company, certain of which are set forth below.

#### **Consulting Services (\$375/hour): Keith Murphy**

Consultant may provide the following services:

- Serve as an executive officer of the Company, including its Principal Executive Officer or Executive Chair
- Oversee Company staff activities
- Participate in longer-term strategic planning process
- Participate in financing activities, including additional capital raises and/or debt and equity restructurings
- Oversee an MDBI engagement team to provide totality of needed services
- Board, Audit, Compensation, and Corporate Governance committee meeting preparation, support and attendance
- Provide support for operational planning
- Participate in contract negotiation and cost reduction planning
- Assist with corporate and business development/licensing initiatives
- Perform planning and analysis
- Strategic opportunity assessment

## CONSULTING AGREEMENT

This Consulting Agreement (the "Agreement") is made effective as of August 25, 2020 (the "Effective Date"), by and between Organovo, Inc., a Delaware corporation, with its principal place of business being 440 Stevens Avenue, Suite 200, Solana Beach, CA 92075 (the "Company") and Danforth Advisors, LLC, a Massachusetts limited liability corporation, with its principal place of business being 91 Middle Road, Southborough, MA 01772 ("Danforth"). The Company and Danforth are herein sometimes referred to individually as a "Party" and collectively as the "Parties."

WHEREAS, the Company possesses know-how and proprietary technology related to 3D bioprinting and drug discovery; and

WHEREAS, Danforth has expertise in financial and corporate operations and strategy;

and

WHEREAS, Danforth desires to serve as an independent consultant for the purpose of providing the Company with certain strategic and financial advice and support services, as more fully described in Exhibit A attached hereto, (the "Services"); and

WHEREAS, the Company wishes to engage Danforth on the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt of which are hereby acknowledged, the Parties agree and covenant as follows.

1. Services of Consultant. Danforth will assist the Company with matters relating to the Services. The Services are more fully described in Exhibit A attached hereto. Danforth and the Company will review the Services on a monthly basis to prioritize and implement the tasks listed on Exhibit A.
  2. Compensation for Services. In full consideration of Danforth's full, prompt and faithful performance of the Services, the Company shall compensate Danforth a consulting fee more fully described in Exhibit A (the "Consulting Fee"). Danforth shall, from time to time, but not more frequently than once per calendar month, provide the Company with an itemized invoice for Services rendered for that month, and such invoice will be paid upon 30 days of receipt. Each month the Parties shall evaluate jointly the current fee structure and scope of Services. Danforth reserves the right to an annual increase in consultant rates of up to 4%, effective January 1 of each year. Upon termination of this Agreement pursuant to Section 3, no compensation or benefits of any kind as described in this Section 2 shall be payable or issuable to Danforth after the effective date of such termination. In addition, the Company will reimburse Danforth for reasonable out-of-pocket business expenses, including but not limited to travel and parking, incurred by Danforth in performing the Services hereunder, upon submission by Danforth of supporting documentation in accordance with Company's travel policy (attached as Exhibit B) and reasonably acceptable to the Company. Any such accrued expenses in any given three (3) month period that exceed \$1,000 shall be submitted to the Company for its prior written approval.
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All Danforth invoices and billing matters should be addressed to:

Company Accounts Payable Contact:

Jordan Beltran, Assistant Controller  
Accounts Payable  
Email: [AP@organovo.com](mailto:AP@organovo.com)  
Phone: 858-224-1000  
Organovo, Inc.  
440 Stevens Avenue, Suite 200 Solana Beach, CA 92075

All Company payments and billing inquiries should be addressed to:

Danforth Accounting:

Betsy Sherr [bsherr@danforthadvisors.com](mailto:bsherr@danforthadvisors.com) (508) 277-0031  
Danforth Advisors PO Box 335  
Southborough, MA 01772

3. Term and Termination. The term of this Agreement will commence on the Effective Date and will continue for a two year term ("Term") This Agreement may be terminated by either Party hereto: (a) with Cause (as defined below), upon 30 days prior written notice to the other Party; or (b) without cause upon 60 days prior written notice to the other Party. For purposes of this Section 3, "Cause" shall include: (i) a breach of the terms of this Agreement which is not cured within 30 days of written notice of such default or (ii) the commission of any act of fraud, embezzlement or deliberate disregard of a rule or policy of the Company.
  4. Time Commitment. Danforth will devote such time to perform the Services under this Agreement as may reasonably be required.
  5. Place of Performance. Danforth will perform the Services at such locations upon which the Company and Danforth may mutually agree. Danforth will not, without the prior written consent of the Company, perform any of the Services at any facility or in any manner that might give anyone other than the Company any rights to or allow for disclosure of any Confidential Information (as defined below).
  6. Compliance with Policies and Guidelines. Danforth will perform the Services in accordance with all rules or policies adopted by the Company that the Company discloses in writing to Danforth.
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7. Confidential Information. Danforth acknowledges and agrees that during the course of performing the Services, the Company may furnish, disclose or make available to Danforth business, technical, commercial and/or regulatory information, whether disclosed or provided in oral, written, graphic or electronic form including, but not limited to, material, compilations, data, licenses, formulae, models, discoveries, developments, inventions, techniques, patent disclosures, procedures, suppliers, pricing lists, processes, schematics, business plans, forecasts, projections, budgets, protocols, results of experimentation and testing, specifications, marketing plans, strategies and techniques, and all tangible and intangible embodiments thereof of any kind whatsoever (including, but not limited to, any apparatus, biological or chemical materials, animals, cells, compositions, documents, drawings, machinery, patent applications, records and reports), which is owned or controlled by the Company and is marked or designated as confidential at the time of disclosure or is of a type that is customarily considered to be confidential information (collectively the "Confidential Information"). Danforth acknowledges that the Confidential Information or any part thereof is the exclusive property of the Company and shall not be disclosed to any third party without first obtaining the written consent of the Company. Danforth further agrees to take all practical steps to ensure that the Confidential Information, and any part thereof, shall not be disclosed or issued to its affiliates, agents or employees, except on like terms of confidentiality. Notwithstanding the foregoing, Confidential Information shall not include any such information which Consultant can establish (i) was publicly known or made generally available prior to the time of disclosure to Consultant; (ii) becomes publicly known or made generally available after disclosure to Consultant through no wrongful action or inaction of Consultant; or (iii) is in the rightful possession of Consultant, without confidentiality obligations, at the time of disclosure as shown by Consultant's then-contemporaneous written records; provided that any combination of individual items of information shall not be deemed to be within any of the foregoing exceptions merely because one or more of the individual items are within such exception, unless the combination as a whole is within such exception. The above provisions of confidentiality shall apply for a period of five years.
8. During and after the term of this Agreement, Consultant will hold in the strictest confidence, and take all reasonable precautions to prevent any unauthorized use or disclosure of Confidential Information, and Consultant will not (i) use the Confidential Information for any purpose whatsoever other than as necessary for the performance of the Services on behalf of the Company, or (ii) disclose the Confidential Information to any third party without the prior written consent of an authorized representative of Company, except that Consultant may disclose Confidential Information to the extent compelled by applicable law; *provided however*, prior to such disclosure, Consultant shall provide prior written notice to Company and seek a protective order or such similar confidential protection as may be available under applicable law. Consultant agrees that no ownership of Confidential Information is conveyed to the Consultant. Without limiting the foregoing, Consultant shall not use or disclose any Company property, intellectual property rights, trade secrets or other proprietary know-how of the Company to invent, author, make, develop, design, or otherwise enable others to invent, author, make, develop, or design identical or substantially similar designs as those developed under this Agreement for any third party. Consultant agrees that Consultant's obligations under this Section shall continue after the termination of this Agreement. Notwithstanding the foregoing, federal law provides immunity for any disclosure of trade secrets when such disclosure is made to a federal, state, or local government official, or to an attorney, if such disclosure is made solely for
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the purpose of reporting or investigating a suspected violation of law. In addition, the law provides immunity for any complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. 18 U.S.C. § 1833(b). Disclosures made in compliance with 18 U.S.C. § 1833(b) shall not create liability, either criminally or civilly.”

9. Intellectual Property. Danforth agrees that all ideas, inventions, discoveries, creations, manuscripts, properties, innovations, improvements, know-how, designs, developments, apparatus, techniques, methods, and formulae that Danforth conceives, makes, develops or improves as a result of performing the Services, whether or not reduced to practice and whether or not patentable, alone or in conjunction with any other party and whether or not at the request or upon the suggestion of the Company (all of the foregoing being hereinafter collectively referred to as the “Inventions”), shall be the sole and exclusive property of the Company. Danforth hereby agrees in consideration of the Company’s agreement to engage Danforth and pay compensation for the Services rendered to the Company and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged that Danforth shall not, without the prior written consent of the Company, directly or indirectly, consult for, or become an employee of, any company which conducts business in the Field of Interest anywhere in the world. As used herein, the term “Field of Interest” shall mean the research, development, manufacture and/or sale of the products resulting from the Company’s technology. The limitations on competition contained in this Section 8 shall continue during the time that Danforth performs any Services for the Company, and for a period of three months following the termination of any such Services that Danforth performs for the Company. If any part of this section should be determined by a court of competent jurisdiction to be unreasonable in duration, geographic area, or scope, then this Section 8 is intended to and shall extend only for such period of time, in such area and with respect to such activity as is determined to be reasonable. Except as expressly provided herein, nothing in this Agreement shall preclude Danforth from consulting for or being employed by any other person or entity.
  10. Non Solicitation. All personnel representing Danforth are employees or contracted agents of Danforth. Accordingly, they are not retainable as employees or contractors by the Company and the Company hereby agrees not to solicit, attempt to hire or retain their services for so long as they are employees or contracted agents of Danforth and for one year thereafter. Should the Company violate this restriction, it agrees to pay Danforth liquidated damages equal to thirty 30% of the employee’s starting annual base salary and target annual bonus for each Danforth contracted agent hired by the Company in violation of this Agreement, plus Danforth’s reasonable attorneys’ fees and costs incurred in enforcing this agreement should the Company fail or refuse to pay the liquidated damages amount in full within 30 days following its violation. The above notwithstanding, it is not a breach of this provision to hire an individual who applies to Client’s job posting without being recruited by Client, in which case no liquidated damages shall be owed.
  11. Placement Services. In the event that Danforth is asked to refer potential employees to the Company, does refer a potential employee to the Company and that individual is hired, Danforth shall receive a fee equal to 20% of the employee’s starting annual base salary and target annual bonus (unless the individual had applied for a position prior to the referral by Danforth, in which case no fee is owed). This fee is due and owing whether an individual is hired, directly or indirectly on a permanent basis or on a contract or consulting basis by the Company, as a result of Danforth’s efforts during the Term of this Agreement. Such payment is due within 30 days of the
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employee's start date.

12. No Implied Warranty. Danforth represents and warrants to the Company that Danforth possesses the business, professional and technical expertise and the resources, including without limitation equipment, facilities and employees to perform these Services. Except for any express warranties stated herein, the Services are provided on an "as is" basis, and the Company disclaims any and all other warranties, conditions, or representations (express, implied, oral or written), relating to the Services or any part thereof. Further, in performing the Services Danforth is not engaged to disclose illegal acts, including fraud or defalcations, which may have taken place. The foregoing notwithstanding, Danforth will promptly notify the Company if Danforth becomes aware of any such illegal acts during the performance of the Services. Because the Services do not constitute an examination in accordance with standards established by the American Institute of Certified Public Accountants (the "AICPA"), Danforth is precluded from expressing an opinion as to whether financial statements provided by the Company are in conformity with generally accepted accounting principles or any other standards or guidelines promulgated by the AICPA, or whether the underlying financial and other data provide a reasonable basis for the statements.
  13. Indemnification. Consultant agrees to indemnify and hold Danforth hereto, its directors, officers, agents and employees harmless against any claim based upon circumstances alleged to be inconsistent with such representations and/or warranties contained in this Agreement. Further, Danforth shall indemnify and hold harmless the Company against any claims, losses, damages or liabilities (or actions in respect thereof) that arise out of or are based on the Services performed hereunder, except for any such claims, losses, damages or liabilities arising out of the negligence or willful misconduct of the Company or any of its subcontractors.
  14. Independent Contractor. Danforth is not, nor shall Danforth be deemed to be at any time during the term of this Agreement, an employee of the Company, and therefore Danforth shall not be entitled to any benefits provided by the Company to its employees, if applicable. Danforth's status and relationship with the Company shall be that of an independent contractor and consultant. Danforth shall not state or imply, directly or indirectly, that Danforth is empowered to bind the Company without the Company's prior written consent. Nothing herein shall create, expressly or by implication, a partnership, joint venture or other association between the parties. Danforth will be solely responsible for payment of all charges and taxes arising from his or her relationship to the Company as a consultant.
  15. Records. Upon termination of Danforth's relationship with the Company, Danforth shall deliver to the Company any property or Confidential Information of the Company relating to the Services which may be in its possession including products, project plans, materials, memoranda, notes, records, reports, laboratory notebooks, or other documents or photocopies and any such information stored using electronic medium.
  16. Data Protection. Depending on the Services Service Provider performs, Danforth may be required to access, collect, retain, disclose or otherwise process individually identifiable health information or information identifying or, in combination with other information, identifiable to a living individual ("Personal Data"). For purposes of this Agreement,
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“Processing” (and its conjugates, including, without limitation, “Process”) means any operation or set of operations that is performed upon Personal Data, including, without limitation, any collection, recording, retention, organization, storage, adaptation, alteration, retrieval, consultation, blocking erasure use, disclosure, access, transfer, or destruction, whether or not by electronic means. In that event, Danforth agrees to collect and process Personal Data solely as described in this Agreement and not use such Personal Data further for any other purpose or in any other manner except where such further use is required by applicable law, regulation or governmental authority. Further, Danforth agrees to abide by all applicable data protection and privacy laws while performing the Services, and shall afford Personal Data all the protections applicable to Confidential Information as set forth in this Agreement. Danforth shall maintain appropriate safeguards to ensure the confidentiality and security of the Personal Data and shall inform Company within three

(3) days about any unauthorized or unintentional access to or disclosure of Personal Data (“Security Breach”), including the timing and nature of the Security Breach, and provide all reasonable assistance to remedy the Security Breach. Where applicable data protection laws require the parties to enter into additional agreements or undertakings, including international data transfer agreements, Danforth shall undertake to ensure that all necessary agreements are implemented and in place. In the event of a Security Breach, Danforth shall also

- (i) reasonably cooperate with Company in connection with the investigation of such Security Breach and not make any public announcements relating to such Security Breach without Company’s prior written approval;
- (ii) take all necessary and appropriate corrective action, including without limitation, at the request of Company and at the expense of Danforth, provide notice to all persons whose Personal Information may have been affected by such Data Security Breach, whether or not such notice is required by applicable law; and
- (iii) reimburse Company for all reasonable costs, including attorneys’ fees, Company may incur in connection with remediation efforts.

17. Notices. Any notice under this Agreement shall be in writing (except in the case of verbal communications, emails and teleconferences updating either Party as to the status of work hereunder) and shall be deemed delivered upon electronic delivery via email with confirmed receipt, personal delivery, one day after being sent via a reputable nationwide overnight courier service or two days after deposit in the mail or on the next business day following transmittal via facsimile. Notices under this Agreement shall be sent to the following representatives of the Parties:

If to the Company:

Name: Organovo, Inc.  
Title: Legal Department  
Address: 440 Stevens Avenue, Suite 200, Solana Beach, CA 92075  
Phone: 858-224-1000  
E-mail: legal@organovo.com

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If to Danforth:

Name: Gregg Beloff  
Title: Managing Director  
Address: 91 Middle Road Southborough, MA 01772  
Phone: (617) 686-7679  
E-mail: [gbeloff@danforthadvisors.com](mailto:gbeloff@danforthadvisors.com)

18. Assignment, Subcontracting, and Successors. This Agreement may not be assigned by a Party without the consent of the other which consent shall not be unreasonably withheld, except that each Party may assign this Agreement and the rights, obligations and interests of such Party, in whole or in part, to any of its Affiliates, to any purchaser of all or substantially all of its assets or to any successor corporation resulting from any merger or consolidation of such Party with or into such corporation. Danforth may not engage subcontractors under this Agreement without the Company's prior written approval.
19. Force Majeure. Neither Party shall be liable for failure of or delay in performing obligations set forth in this Agreement, and neither shall be deemed in breach of its obligations, if such failure or delay is due to natural disasters or any causes beyond the reasonable control of either Party. In the event of such force majeure, the Party affected thereby shall use reasonable efforts to cure or overcome the same and resume performance of its obligations hereunder.
20. Headings. The Section headings are intended for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.
21. Integration; Severability. This Agreement is the sole agreement with respect to the subject matter hereof and shall supersede all other agreements and understandings between the Parties with respect to the same. If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, it is the intention of the Parties that the remainder of the Agreement shall not be affected.
22. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of California, excluding choice of law principles. The Parties agree that any action or proceeding arising out of or related in any way to this Agreement shall be brought solely in a Federal or State court of competent jurisdiction sitting in the State of California.
23. Attorneys' Fees. In any court action at law or equity that is brought by one of the Parties to this Agreement to enforce or interpret the provisions of this Agreement, the prevailing Party will be entitled to reasonable attorneys' fees, in addition to any other relief to which that Party may be entitled.
24. Counterparts. This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together will constitute one agreement.

If you are in agreement with the foregoing, please sign where indicated below, whereupon this Agreement shall become effective as of the Effective Date.

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**DANFORTH ADVISORS, LLC**

By: /s/ Chris Connors

Print Name: Chris Connors

Title: President

**ORGANOVO, INC**

By: /s/ Taylor Crouch

Print Name: Taylor Crouch

Title: Chief Executive Officer / President

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## **EXHIBIT A**

### **Description of Services and Schedule of Fees**

Danforth will perform mutually agreed to finance and accounting functions which are necessary to support the management and operations of the Company, certain of which are set forth below.

#### **Transition Support Prior to Organovo's Annual Meeting**

- In anticipation of a potential Change of Control, Consultant will spend a maximum of 20 hours of time between the Effective Date and the Company's Annual Meeting on September 15, 2020, coming up to speed on the Company's financial systems and preparing for a transition to take place following the Annual Meeting, assuming that the shareholders approve the proposed Change of Control.

#### **CFO Services (\$375/hour): Christopher Heberlig**

Assuming that Organovo's shareholders approve the proposed Change of Control, and subject to approval by the Company's Board of Directors following the Annual Meeting, Consultant may provide the following services:

- Serve as an officer of the Company
- Participate in longer-term strategic planning process
- Participate in financing activities, including additional capital raises and/or debt and equity restructurings
- Oversee the finance and accounting functions, including the Danforth engagement team
- Board, Audit, Compensation, and Corporate Governance committee meeting preparation, support and attendance
- Provide finance support for operational planning
- Participate in supplier contract negotiation and cost reduction planning
- Assist with corporate and business development/licensing initiatives
- Perform financial modeling, planning and analysis
- Strategic opportunity assessment
- Stock option plan management
- Capitalization table management

Organovo, Inc.  
440 Stevens Avenue, Suite 200  
Solana Beach, CA 92075

September 15, 2020

Jeffrey Miner, Ph.D.  
4572 Pauling Ave.  
San Diego, CA 92122

Dear Jeff:

On behalf of Organovo Inc., (“Organovo”) it is our great pleasure to extend you an offer of employment as Chief Scientific Officer of Organovo and Organovo Holdings, Inc. (the “Company”), contingent on approval by the Company’s Board of Directors (the “Board”), reporting to Keith Murphy, Executive Chairman. In making this offer, we are expressing our enthusiastic support for the skills and commitment you will bring to our exciting team. We are pleased to offer you the following:

**Salary:** Your base salary for this exempt position will be \$225,000.00 per year, paid bi-weekly and subject to deductions and income tax withholding as required by law or the policies of the Company. Future increases will be considered by the Compensation Committee in its review or executive compensation.

**Benefits:** The Company will be evaluating its benefits offerings and you will receive the benefits appropriate to the Company’s final offerings suitable for this level position after this review is completed and new benefits offerings are finalized.

**Bonus:** You are eligible to participate in the Company's Short-Term Incentive Plan, which is established annually by the Compensation Committee. Your target incentive bonus for fiscal 2021 will be 35% of your base salary; however, the actual bonus received will be based upon the Company's performance and your achievement of individual performance goals established by the Compensation Committee. Your fiscal 2021 bonus payment will be subject to required deductions, and withholdings and will be calculated on a prorated basis based on your W-2 earnings. The Company's Compensation Committee shall have the sole discretion to determine whether you have earned any bonus set forth in this paragraph, and if so, the amount of any such bonus.

**Equity Package:** In addition, subject to approval by the Board's Compensation Committee after your start date, we are pleased to offer you a Stock Option Award (the "Stock Option"). The Stock Option will be exercisable for 100,000 shares of the Company's common stock (the "Option Shares") (equal to approximately 2% of the Company's outstanding common stock as of the date of grant. The exercise price for the Option Shares will be set at the closing market price of the Company's common stock on the Nasdaq Stock Market on the date the Compensation Committee approves the grant. One-fourth (1/4th) of the Option Shares will vest one year from your start date at the Company (the "Vesting Commencement Date"), and the remaining Option Shares will vest on a quarterly basis thereafter over a period totaling four years from the Vesting Commencement Date, subject to your continuous service through such date.

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The Company intends to grant the equity awards as "inducement grants" within the meaning of Nasdaq Marketplace Rule 5635(c)(4) (the "Inducement Grant Rules"). While the equity grants will be granted outside of the Company's 2012 Equity Incentive Plan (the "Plan"), the other terms and conditions applicable to the options and RSUs will be consistent with those applicable to options and RSUs granted to the Company's executive officers under the Plan, as described in the applicable Stock Option Agreement and RSU Agreement. The Company will file a Registration Statement on Form S-8 to cover the issuance of the equity awards and the sale of the underlying shares of Company's common stock.

**Severance and Change in Control:** You are eligible to participate in the Company's Severance and Change in Control Plan (the "Plan"), which is attached hereto, as a Tier 2 Employee. The Plan has been approved by the Board and may be modified by the Board in the future.

**Start Date:** Should you find our offer attractive and contingent upon Board approval, we would like your start date to be September 15, 2020.

This employment offer is contingent upon you signing our Employee Confidentiality Agreement providing legally required evidence of your right to work in the United States as well as Organovo's successful completion of your references and background check. In consideration of your employment, you also agree to conform to the policies and standards of the Company.

Your employment as Chief Scientific Officer is a part-time position. While you render services to the Company, you agree to reserve sufficient time for our business activity (expected to be at least half-time) and to obtain the Board's approval for any changes to this expectation, pursuant to the Company's Corporate Governance Guidelines. The Board agrees to handle any such requests promptly and in good faith.

Your employment will be "at-will" and either party may terminate the relationship at any time with or without cause and with or without notice.

By your signature below, you acknowledge that you will be an exempt employee and that this offer letter supersedes any prior offer letters, arrangements or discussions between you and the Company (and its wholly-owned subsidiary Organovo Inc.), and represents the entire agreement between you and Organovo, and that no verbal or written agreements, promises or representations that are not specifically stated in this offer, are or will be binding upon Organovo. Any additions or modifications of these terms must be in writing and signed by you and Chair of the Compensation Committee. On the first day of employment, you will be required to provide the Company with the legally required proof of your identity and authorization to work in the United States. In addition, by signing this offer letter, you confirm to the Company that you have no contractual commitments or other legal obligations that would prohibit you from performing your duties for the Company.

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We hope that you'll accept this offer and look forward to welcoming you aboard! Please feel free to call me if you have any questions.

Sincerely,

/s/ Keith Murphy

Keith Murphy  
Executive Chairman

To accept this job offer:

- Sign and date this job offer letter where indicated below.
  - Return a signed and dated document back within 5 days of the date of this letter. A copy of the document should be retained for your records. The document should be scanned and returned electronically to [HR@organovo.com](mailto:HR@organovo.com).
-



**Accept Job Offer**

by signing and dating this offer letter, I, (name), accept this offer of employment from Organovo, Inc.

Signature: /s/ Jeff Miner

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Thomas E. Jurgensen  
tom@optimalawgroup.com  
858.946.4697

July 23, 2020

**VIA E-MAIL: JBush@organovo.com**

Organovo, Inc.  
440 Stevens Avenue, Suite 200  
Solana Beach, , CA 92121  
Attn: Jennifer Bush, J.D., Sr. VP, General Counsel and Corporate Secretary

Re: Engagement Agreement between Optima Law Group, APC and Organovo Holdings, Inc., and its subsidiaries (hereinafter, "Agreement")

Dear Jennifer:

We are pleased that you have retained Optima Law Group, APC, to provide legal services. Optima Law Group, APC strives to deliver high quality, cost effective legal services and will always work in your best interests, subject to our duties of professional responsibility. In accordance with California and Colorado law requiring a written fee agreement with each of our clients, we set forth below the terms of our engagement. Of course, I will be the contact for your legal work, although other attorneys and paralegals of this firm may participate in rendering services, as we consider appropriate.

We look forward to a mutually beneficial relationship, and if at any time you have any questions, comments, or require any additional information, please do not hesitate to contact me directly. If the terms of this Agreement are acceptable to you, please date and sign this engagement and return a fully executed electronic copy to us for our records, and retain a copy for your files.

**1. IDENTIFICATION OF PARTIES.** This Agreement, executed in duplicate with each party receiving an executed copy, is made between Optima Law Group, APC, a California Professional corporation hereinafter referred to as "Firm", and Organovo, a Delaware corporation located in Solana Beach, California, hereinafter referred to as "Organovo" or "Client."

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2. **LEGAL SERVICES TO BE PROVIDED.** The legal services to be provided by Firm to Client are in connection with intellectual property and corporate matters, including management of Client's IP portfolio and assistance with general corporate matters as well as such other matters as may be agreed upon from time to time by Firm and Client.

3. **LEGAL SERVICES SPECIFICALLY EXCLUDED.** If Client desires Firm to provide any legal services not to be provided under this Agreement, a separate agreement between Firm and Client will be required. Absent execution of a new agreement in writing, this Agreement will govern all future services Firm may perform for Client. Additionally, as previously discussed, Client understands that Firm provides transactional legal services. It does not represent clients in litigation.

4. **RESPONSIBILITIES OF FIRM AND CLIENT.** Firm will perform the legal services called for under this Agreement, keep Client informed of progress and developments, provide copies to Client of all appropriate correspondence for their internal records, and respond promptly to Client's instructions, inquiries and communications. In return, we need Client to keep us informed of any developments that affect the matter as soon as Client becomes aware of them, and to be available when we need to consult with Client including answering calls and responding timely to e-mails. Client will request services on reasonable timelines and in the event of an occasional emergency requiring a shorter timeline, Firm will do its best to accommodate Client. In this regard, Client acknowledges that the Firm has other clients to which it also has duties and obligations. Client will cooperate with Firm, keep all appointments, attend all meetings, arbitrations, mediations or court events as required, provide necessary declarations, promptly pay all fees and costs, and keep Firm informed of Client's whereabouts.

5. **RETAINER.** No retainer is required at this time. Payment of a retainer may be required prior to commencement of work on future projects, as determined by the Firm. We reserve the right to request another retainer should the amount of work requested of Firm increase or the retainer is depleted. We will render itemized monthly statements to you indicating the current status of your account, both for services rendered and for costs incurred on your behalf. Our fees will be offset against the retainer. Any retainer remaining after the completion of work will be refunded to you. In the event of any financing, equity, or acquisition transaction, all unpaid and accrued fees will be due at the closing.

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**6. REGULAR FEES.** The fees and costs for a matter not performed on a flat fee are not predictable, unless otherwise agreed to in writing. Fees billed to Client reflect Firm's judgment of the fair value of those legal services reasonably required. For work not covered by a flat fee arrangement, time will be accounted for in tenths of an hour and fees are calculated by applying hourly rates assigned to attorneys and other staff. Fees and expenses will be billed monthly and are due upon receipt. All rates are reviewed annually and may be adjusted periodically. The current ranges of rates for the members of professional staff who may be involved at this time are set forth below. Client will be notified in advance of any changes in staffing or changes in the rate schedule provided below.

Tom Jurgensen	\$495/hour
Of Counsel	\$325-\$395/hour
Paul Nardulli	\$325/hour
Associates	\$275-\$300/hour
Law Clerks	\$160-\$180/hour
Paralegals and Docketing Specialists	\$90-\$150/hour

**7. COSTS AND EXPENSES.** Other than as provided in a flat fee arrangement or project, including any projects described under paragraph 2 herein, the Client is responsible for all costs and expenses incurred by Firm in this representation, including expenses for filing, recording, service of process and sheriff's fees, experts, travel (as per the Client's travel policy, attached hereto as Exhibit A), lodging, meals, telephone calls, messengers, photocopying, facsimile, computer research, mileage, word processing, post- representation off-site records storage, and necessary clerical staff overtime. Certain support services that involve equipment or staffing or that require payments to third parties that are not included in any flat fee or project may include additional charges that reflect our internal costs. Several services include a standard overhead component when billed. These are set forth below. We can make arrangements to have Client billed directly by third parties, or pay directly invoices which we receive from third parties, including foreign associates, consultants, appraisers, court reporters or other parties that render billable services. Firm may advance any or all of these costs and expenses on behalf of Client, as deemed appropriate. If Firm advances these costs and expenses, and they are not covered by a flat fee or on a project basis, Client will remain ultimately liable for all such costs and expenses, and Client hereby agrees to reimburse Firm regardless of the outcome of this matter. The current schedule of costs is set forth below and is reconsidered annually:

Photocopying	\$0.20 per page
Color copying	\$1.00 per page
Facsimile	\$0.25 per page, plus telephone charges
Telephone	\$0.20 per min. domestic; \$0.25 per min. int'l
Mileage	\$0.58 per mile
Computer legal research	Database charges
Postage/Delivery Services	Cost

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**8. MONTHLY INVOICES AND LATE CHARGES.** The monthly invoices will show the dates, hours dedicated, professional staff utilized, specific IP Matter numbers and itemized and/or block billing descriptions for services performed. Block billing is when Firm includes descriptions of multiple tasks, related or unrelated, in the same entry to consolidate the length of invoices. Client acknowledges and accepts Firm's use of block billing. If Client has any objections or concerns about any invoice, they shall be communicated to the Firm within seven (7) business days from date of receipt. **Payment is due thirty days (30) upon receipt of each invoice.** A late charge of one and one half percent (1.5%) per month (18% per annum) will be assessed on the portion of your account owing for services performed and costs advanced remaining unpaid for more than sixty (60) days after the date of any invoice. We may also cease performing services to you at any time if an outstanding balance exists or a renewed retainer is not submitted by Client.

Any invoice remaining unpaid for more than ninety (90) days after the date of any statement may be assigned to collections. At our option, no further services will be rendered until the balance is paid in full and a retainer toward our fees and costs has been placed in a separate trust account.

**9. CONFLICTS OF INTEREST.** We have checked our records and have determined that there is no conflict of interest that prevents us from working on the matter based on the information you have provided to us at this time.

**10. REPRESENTATION OF ADVERSE INTERESTS.** Client is informed of the practical ramifications of our firm's representation of a large number of companies. We have represented, continue to represent, and will in the future represent numerous other companies in connection with various matters in which Client is or may be involved. We do not believe that our representation of such other companies will interfere or conflict in any way with our firm's representation of Client. However, because of the potential number of such matters, we think it is important to have a clear understanding that will govern our relationship.

Furthermore, even though we represent Client in this matter, we may represent current or new clients in matters where their interests are directly adverse to Client, but where the work is substantially unrelated to the matter. We agree that we will not use or disclose any confidential information obtained in representing Client, and that we will, at your request, erect an ethical wall to assure that confidential information is not exchanged between the teams working on the matter and that of the other client or company.

The Rules of Professional Conduct of the State Bars of California and Colorado require that before Firm may begin or continue to represent Client when Firm has or had a relationship with another party interested in the subject matter of Firm's proposed representation of Client, that Firm inform Client in writing of the relevant circumstances and of the actual and reasonably foreseeable adverse consequences to Client. Client is further informed that the Rules require that, before Firm may represent a party who has, in a separate matter, an interest adverse to that of Client's in the separate matter, Firm obtain the informed written consent of both parties. In the present case, Firm is unaware of any other relationships that represent an actual or potential interest adverse to Firm's representation of Client.

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**11. FIRM'S LIEN.** Firm will have a lien for Firm's fees and costs advanced with respect to the claim and on all proceeds of any recovery obtained whether by negotiation, settlement, arbitration award, or court judgment or on any property obtained, including by patent, trademark, copyright, rescission, specific performance or other means. This generally means that Firm has an ownership interest in any recovery by Client to the extent of Firm's unpaid fees and costs. Client acknowledges that he may seek the advice of an independent attorney of Client's choice as to this, or any other issue, and that Client has been given a reasonable opportunity to seek that advice.

**12. DISCHARGE OF FIRM.** Client may discharge Firm at any time by written notice effective when received by Firm. Unless specifically agreed by Firm and Client, Firm will provide no further services and advance no further costs on Client's behalf after receipt of the notice unless required to do so in order to protect Client's interests. Unless previously terminated, our representation of Client in the matter will end when we send our final statement of fees. After the matter ends, there might be changes in laws or regulations that might affect Client's future rights and liabilities, but our firm does not have an obligation to continue to advise Client about their future legal developments, unless Client engages us to do so. If Firm is Client's attorney of record in any proceeding, Client will execute and return a substitution-of-attorney form immediately upon its receipt from Firm. Notwithstanding Firm's discharge, Client shall pay Firm's contractual fees for all agreed-upon services provided and to reimburse Firm for all agreed upon costs incurred or advanced by Firm, before the discharge, incurred in effectuating the discharge and as necessary to protect the interests of Client.

**13. WITHDRAWAL OF FIRM.** Firm may withdraw at any time as permitted under the Rules of Professional Conduct of the State Bars of California and Colorado and pursuant to United States Patent and Trademark Office guidelines (collectively, the "Rules"). The circumstances under which the Rules permit such withdrawal include, but are not limited to, Client's consent or Client's conduct rendering it unreasonably difficult for Firm to carry out the employment effectively, Client pursues a course of action that is criminal, fraudulent, repugnant or imprudent, Client fails substantially to fulfill an obligation to Firm, or the representation will result in an unreasonable financial burden on Firm or has been rendered unreasonably difficult by Client. Additionally, Firm may be required or elect to withdraw if a conflict of interest develops between Client, any other persons and entities and/or Firm, including any conflict between the interests of Client and Firm and is not waived or waivable which adversely affects Firm's ability to provide the type of representation we have a duty or should provide to each of our clients, or if the matter requires an expertise which Firm does not have and it would not be practicable for us to try to develop under the circumstances. Notwithstanding Firm's withdrawal, Client shall pay pay Firm's contractual fees for all agreed upon services provided and to reimburse Firm for all agreed on costs incurred or advanced by Firm before the withdrawal or in the case of an adjudicatory proceeding, through the time when an order allowing the withdrawal is obtained.

- 14. RELEASE OF CLIENT'S PAPERS AND PROPERTY AND POST- REPRESENTATION STORAGE FEES.** At Client's request and/or upon termination of services, its papers and property (including electronic materials) will be returned promptly upon receipt of payment for outstanding fees and costs. Our own files, including attorney work product, pertaining to the matter will be retained by our firm. These firm files include, for example, firm administrative records, time and expense reports, personnel and staffing materials, credit and accounting records and internal attorney's work product such as drafts, notes, internal memoranda and legal and factual research, including investigative reports, prepared by or for the internal use of attorneys. All such documents retained by our firm will be transferred to the person responsible for administering our records retention program. Firm retains the right to make and retain an archival copy of Client's papers. For various reasons, we reserve the right to destroy or otherwise dispose of any such documents or other materials retained by us within a reasonable time after the termination of the engagement, unless Client requests otherwise. Pending destruction of documents, Firm may store Client's files on an external hard drive that is password protected.
- 15. ENTIRE AGREEMENT.** This Agreement contains the entire Agreement of the parties. No other agreement, statement, or promise made on or before the effective date of this Agreement will be binding on the parties.
- 16. SEVERABILITY IN EVENT OF PARTIAL INVALIDITY.** If any provision of this Agreement is held by a court or other tribunal of competent Jurisdiction, in whole or in part, to be unenforceable for any reason, the remainder of that provision and of the entire Agreement will be severable and remain in effect.
- 17. MODIFICATION BY SUBSEQUENT AGREEMENT.** This Agreement may be modified only in writing by a subsequent agreement executed by the parties identified herein.
- 18. ELECTRONIC COMMUNICATIONS.** Email, Extranet and other forms of electronic communication are increasingly important business tools, and we make appropriate use of them in communicating with our clients. However, there are risks associated with them. While we have no reason to suppose that our own email or other electronic communication systems are not secure, Client should be aware that information sent or stored electronically might be accessed by third parties. Firm may when appropriate communicate with Client by email unless Client asks us not to. Please note that email can be subject to delays and non- delivery; in appropriate circumstances Client should confirm with Firm that we have received and read email communications. Firm has measures in place to protect against sending or receiving viruses, but we cannot guarantee that these will be completely effective. Client should take precautions against possible virus infection.
- 19. ARBITRATION OF FEE DISPUTE.** If a dispute arises between Firm and Client regarding Firm's fees or costs under this Agreement and Firm files suit in any court, Client will have the right to stay that suit by timely electing to arbitrate the dispute under Business and Professions Code sections 6200-6204 and 6206 and the equivalent Colorado provisions, in which event Firm must submit the matter to such non-binding arbitration.

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**20. ARBITRATION OF MALPRACTICE CLAIM.** Although Firm certainly does not expect that differences will arise between us, as attorneys we recognize that disagreements can happen. If Client becomes dissatisfied with any aspect of our relationship, we encourage Client to bring the matter to our attention immediately. It is our belief that most problems can be resolved amicably through discussions between us. In the unlikely event that further resolution is required, by this Agreement Client and Firm are both agreeing in advance to resolve any dispute that may arise in the future through the less formal and more expeditious process of arbitration. Accordingly, if a dispute arises between Firm and Client (defined as including any agents, employees, officers, representatives or related entities or persons of Client ) as to whether any legal services rendered by Firm under this Agreement or otherwise, were improperly, negligently, or incompetently rendered, or otherwise rendered in breach of a contractual or ethical duty, including any counterclaims or defenses, the dispute shall, to the extent it cannot be resolved amicably, be resolved exclusively through private, confidential and binding arbitration, and Firm and Client will be bound by the result.

Client understands and acknowledges that, by agreeing to binding arbitration, Client waives the right to submit the dispute for determination by a court and thereby also waives the right to a jury trial. Client acknowledges that he has been informed that the grounds for appeal of an arbitration award are very limited compared to a court judgment or jury verdict.

It is further agreed and understood that initial resort to the courts by either party shall not be considered a waiver of that party's right to compel binding arbitration under this provision. Arbitration shall be in accordance with Code of Civil Procedure §1280 et seq. with each party selecting a party arbitrator who, in turn, shall select a neutral arbitrator unless the amount in controversy is less than Twenty Five Thousand Dollars (\$25,000) in which case the matter will be decided by a single neutral arbitrator. Firm and Client agree that Firm's office in San Diego shall be a proper venue for any legal proceedings hereunder. Firm and Client further agree that the parties will have the right to discovery as provided in the Civil Discovery Act of 1986, as amended, set forth in the California Code of Civil Procedure, except that the arbitrators, rather than the court, shall resolve all discovery disputes that arise. By signing below, Client represents that they have had an opportunity to review this specific provision and the entire Agreement with independent counsel of its choosing prior to signing this Agreement.

**21. DISCLAIMER OF GUARANTEE.** **Either at the beginning or during representation, we might express opinions or beliefs concerning the matter and the results that might be anticipated. Any such statement by us is an expression of opinion only and is not a promise or guarantee of results.** Client acknowledges that Firm has made no promises about the outcome, including the costs and expenses of any transaction or litigation, and that any opinion offered by Firm in the future will not constitute a guarantee.

**22. EFFECTIVE DATE OF AGREEMENT.** The effective date of this Agreement will be the latest date of signing by Client, and signing by a shareholder of Firm and its terms shall be retroactive to the date Firm first performed services for Client which are the subject of this Agreement.

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**23. OPPORTUNITY TO CONSULT WITH OTHER COUNSEL.** Client may wish to consult with another attorney before signing below. **BY SIGNING BELOW, CLIENT REPRESENTS THAT THEY HAVE HAD A FULL OPPORTUNITY TO REVIEW PARAGRAPHS 19 AND 20 (ARBITRATION OF FEE DISPUTE AND ARBITRATION OF MALPRACTICE CLAIM) AND THE ENTIRE AGREEMENT WITH INDEPENDENT COUNSEL OF ITS CHOOSING PRIOR TO SIGNING THIS AGREEMENT SHOULD THEY SO DECIDE.** Your authorized signature will certify that Client has either met with another attorney before signing or has chosen not to do so.

*[The remainder is intentionally left blank. Signature page to follow.]*

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“Firm”

**Optima Law Group, APC**

By: /s/ Thomas E. Jurgensen

Thomas E. Jurgensen, J.D.

C.E.O. & Managing Shareholder

The foregoing is agreed to by:

“Client”

**Organovo, Inc.**

By: /s/ Jennifer Bush

Name of Signatory: Jennifer Bush, Sr. VP, General Counsel and  
Corporate Secretary

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## CERTIFICATION

I, Keith Murphy, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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 consolidated 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 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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 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: November 5, 2020

/s/ Keith Murphy  
Keith Murphy  
Executive Chairman  
(Principal Executive Officer)

## CERTIFICATION

I, Chris Heberlig, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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 consolidated 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 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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 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: November 5, 2020

/s/ Chris Heberlig

Chris Heberlig  
President and Chief Financial Officer  
(Principal Financial Officer)

**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 Quarterly Report on Form 10-Q of Organovo Holdings, Inc. (the "Company") for the period ended September 30, 2020, as filed with the Securities and Exchange Commission (the "Report"), I, Keith Murphy, Executive Chairman and I, Chris Heberlig, President and Chief Financial Officer of the Company hereby certify, 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, as amended; and
- The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 5, 2020

/s/ Keith Murphy

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Keith Murphy  
Executive Chairman  
(Principal Executive Officer)

/s/ Chris Heberlig

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Chris Heberlig  
President and 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-Q 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-Q), irrespective of any general incorporation language contained in such filing.