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, 2021

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	**27-1488943**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
440 Stevens Ave, Suite 200, Solana Beach, CA 92075	**(858) 224-1000**
(Address of principal executive offices and zip code)	**(Registrant's telephone number, including area code)**

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

Title of each class	Trading symbol	Name of Each Exchange on which registered
Common Stock, $0.001 par value	**ONVO**	**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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

As of November 1, 2021, a total of 8,705,454 shares of the registrant's Common Stock, $0.001 par value, were outstanding.

ORGANOVO HOLDINGS, INC.

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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)

	September 30, 2021 (Unaudited)	March 31, 2021
Assets		
Current Assets		
Cash and cash equivalents	$ 33,791	$ 37,364
Prepaid expenses and other current assets	512	1,034
Total current assets	34,303	38,398
Fixed assets, net	552	381
Restricted cash	111	111
Prepaid expenses and other assets, net	915	1,027
Total assets	$ 35,881	$ 39,917
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 958	$ 281
Accrued expenses	717	440
Total current liabilities	1,675	721
Stockholders' Equity		
Common stock, $0.001 par value; 200,000,000 shares authorized, 8,705,454 and 8,670,492 shares issued and outstanding at September 30, 2021 and March 31, 2021, respectively	9	9
Additional paid-in capital	336,526	335,479
Accumulated deficit	(302,328)	(296,291)
Treasury stock, 46 shares at cost	(1)	(1)
Total stockholders' equity	34,206	39,196
Total Liabilities and Stockholders' Equity	$ 35,881	$ 39,917

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, 2021	Three Months Ended September 30, 2020	Six Months Ended September 30, 2021	Six Months Ended September 30, 2020
Operating Expenses				
Research and development expenses	$ 679	$ 28	$ 1,259	$ 28
Selling, general and administrative expenses	2,828	8,922	4,807	11,708
Total costs and expenses	3,507	8,950	6,066	11,736
Loss from Operations	(3,507)	(8,950)	(6,066)	(11,736)
Other Income (Expense)				
Gain (loss) on fixed asset disposals	—	(5)	—	1
Interest income	2	4	4	12
Other income	—	1	25	6
Total Other Income (Expense)	2	—	29	19
Income Tax Expense	—	—	—	(2)
Net Loss	$ (3,505)	$ (8,950)	$ (6,037)	$ (11,719)
Net loss per common share—basic and diluted	$ (0.40)	$ (1.36)	$ (0.69)	$ (1.79)
Weighted average shares used in computing net loss per common share—basic and diluted	8,705,327	6,565,245	8,701,029	6,547,430
Comprehensive Loss:				
Net loss	$ (3,505)	$ (8,950)	$ (6,037)	$ (11,719)
Comprehensive loss	$ (3,505)	$ (8,950)	$ (6,037)	$ (11,719)

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, 2020						
	Common Stock		Additional Paid-in Capital	Treasury Stock		Accumulated Deficit	Total
	Shares	Amount		Shares	Amount		
Balance at March 31, 2020	**6,528**	**$ 7**	**$ 306,089**	**—**	**$ —**	**$ (279,465)**	**$ 26,631**
Issuance of common stock under employee and director stock option, RSU, and purchase plans	3	—	(1)	—	—	—	(1)
Stock-based compensation expense	—	—	925	—	—	—	925
Net loss	—	—	—	—	—	(2,769)	(2,769)
Balance at June 30, 2020 (Unaudited)	**6,531**	**$ 7**	**$ 307,013**	**—**	**$ —**	**$ (282,234)**	**$ 24,786**
Issuance of common stock under employee and director stock option, RSU, and purchase plans	201	—	13	—	—	—	13
Stock-based compensation expense	—	—	4,138	—	—	—	4,138
Treasury stock	—	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	—	(8,950)	(8,950)
Balance at September 30, 2020 (Unaudited)	**6,732**	**$ 7**	**$ 311,164**	**—**	**$ (1)**	**$ (291,184)**	**$ 19,986**

	Three and Six Months Ended September 30, 2021						
	Common Stock		Additional Paid-in Capital	Treasury Stock		Accumulated Deficit	Total
	Shares	Amount		Shares	Amount		
Balance at March 31, 2021	**8,671**	**$ 9**	**$ 335,479**	**—**	**$ (1)**	**$ (296,291)**	**$ 39,196**
Issuance of common stock from public offering, net	27	—	251	—	—	—	251
Stock-based compensation	—	—	415	—	—	—	415
Net loss	—	—	—	—	—	(2,532)	(2,532)
Balance at June 30, 2021 (Unaudited)	**8,698**	**$ 9**	**$ 336,145**	**—**	**$ (1)**	**$ (298,823)**	**$ 37,330**
Issuance of common stock under employee and director stock option, RSU, and purchase plans	7	—	(45)	—	—	—	(45)
Stock-based compensation	—	—	426	—	—	—	426
Net loss	—	—	—	—	—	(3,505)	(3,505)
Balance at September 30, 2021 (Unaudited)	**8,705**	**$ 9**	**$ 336,526**	**—**	**$ (1)**	**$ (302,328)**	**$ 34,206**

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, 2021	Six Months Ended September 30, 2020
Cash Flows From Operating Activities		
Net loss	$ (6,037)	$ (11,719)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on disposal of fixed assets	—	1
Depreciation and amortization	59	8
Stock-based compensation	841	5,063
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	—	92
Prepaid expenses and other assets	627	(2,011)
Accounts payable	677	(519)
Accrued expenses	277	(633)
Net cash used in operating activities	(3,556)	(9,718)
Cash Flows From Investing Activities		
Purchases of fixed assets	(223)	—
Proceeds from disposals of fixed assets	—	7
Net cash provided by (used in) investing activities	(223)	7
Cash Flows From Financing Activities		
Proceeds from issuance of common stock, net	251	—
Employee taxes paid related to net share settlement of equity awards	(45)	(2)
Proceeds from exercise of stock options	—	14
Purchase of treasury stock	—	(1)
Net cash provided by financing activities	206	11
Net decrease in cash, cash equivalents, and restricted cash	(3,573)	(9,700)
Cash, cash equivalents, and restricted cash at beginning of period	37,475	27,356
Cash, cash equivalents, and restricted cash at end of period	$ 33,902	$ 17,656
Reconciliation of cash, cash equivalents, and restricted cash to the condensed consolidated balance sheets		
Cash and cash equivalents	$ 33,791	$ 17,656
Restricted cash	111	—
Total cash, cash equivalent and restricted cash	$ 33,902	$ 17,656
Supplemental Disclosure of Cash Flow Information:		
Fixed asset reclass	$ —	$ 31
Income taxes paid	$ —	$ 2

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

Note 1. Description of Business

Nature of Operations

Organovo Holdings, Inc. ("Organovo Holdings," "Organovo," and the "Company") is an early-stage biotechnology company that focuses on building high fidelity, 3D tissues that recapitulate key aspects of human disease. The Company uses these models to identify gene targets capable of modulating the disease phenotype across multiple patients and intends to initiate drug discovery programs around these validated targets. The Company is initially targeting the intestine and has ongoing 3D tissue development efforts in Ulcerative colitis ("UC") and Crohn's disease ("CD"). The Company intends to add additional tissues/diseases/targets to its portfolio in the coming year. In line with these plans, the Company is building upon both its external and in house scientific expertise, which will be essential to its drug development effort.

The Company uses its proprietary technology to build functional 3D human tissues that mimic key aspects of native human tissue composition, architecture, function and disease. Organovo's advances include cell type-specific compartments, prevalent intercellular tight junctions, and the formation of microvascular structures. Management believes these attributes can enable critical complex, multicellular disease models that can be used to develop clinically effective drugs for a variety of therapeutic areas.

The Company's NovoGen Bioprinters® are automated devices that enable the fabrication of 3D living tissues comprised of mammalian cells. The Company believes that the use of its bioprinting platform as well as complementary 3D technologies will allow it to develop an understanding of disease biology that leads to validated novel drug targets, and that it can develop therapeutics to those targets to treat disease.

The majority of the Company's current focus is in inflammatory bowel disease ("IBD"), including CD and UC. The Company expects to create disease models, leveraging its prior work including the work found in its peer-reviewed publication on bioprinted intestinal tissues (Madden et al. Bioprinted 3D Primary Human Intestinal Tissues Model Aspects of Native Physiology and ADME/Tox Functions. iScience. 2018 Apr 27;2:156-167. doi: 10.1016/j.isci.2018.03.015.) The Company's current understanding of intestinal tissue models and IBD disease models leads it to believe that it can create models that provide greater insight into the biology of these diseases than are generally currently available. Using these disease models, the Company intends to identify and validate therapeutic targets. After finding novel therapeutic drug targets, the Company intends to develop novel small molecule, antibody, or other therapeutic drug candidates to treat the disease, and advance these novel drug candidates towards an Investigational New Drug ("IND") filing and clinical trials.

The Company expects to broaden its work into additional therapeutic areas over time and is currently exploring specific tissues for development. In the Company's work to identify the areas of interest, it evaluates areas that might be better served with 3D disease models than currently available models as well as the potential commercial opportunity.

Except where specifically noted or the context otherwise requires, references to "Organovo Holdings", "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.

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 emerged. While initially the outbreak was largely concentrated in China, it has since spread globally and has 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. In 2020, the Company adapted quickly to COVID-19, instituting universal masking and distancing in the lab and in the offices. The Company encouraged and enabled remote work whenever possible. The Company instituted safety check software to monitor symptoms and successfully maintained a robust level of progress while ensuring the safety of its employees. As the viral load and variants allow, the Company intends to carefully return to more typical lab and office work flow.

The extent to which COVID-19 impacts the Company's operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the rise of vaccine-resistant variants, duration of the outbreak, 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 various aspects of the Company's operations, including among others, the ability to raise additional capital, the timing and ability to pursue the Company's strategy, given the impact the pandemic 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, 2021 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, 2021, as filed with the Securities and Exchange Commission ("SEC"). Operating results for any interim period are not necessarily indicative of the operating results for any other interim period or the Company's full fiscal year ending March 31, 2022 (see "Note 1. Description of Business").

Liquidity

As of September 30, 2021, the Company had cash and cash equivalents of approximately $33.8 million, restricted cash of approximately $0.1 million and an accumulated deficit of approximately $302.3 million. The restricted cash was pledged as collateral for a letter of credit that the Company is required to maintain as a security deposit under the terms of the lease agreement for its facilities. The Company also had negative cash flows from operations of approximately $3.6 million during the six months ended September 30, 2021.

Through September 30, 2021, 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, 2021, the Company issued 0 and 27,545 shares of its common stock through its ATM facility and received net proceeds of approximately $0 and $0.3 million, respectively.

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. As the Company continues to recommence operations and focus its efforts on drug discovery and development, it 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 significant accounting estimates.

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 vesting of restricted stock units ("RSUs"), 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, 2021 and 2020 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 0.7 million at September 30, 2021 and 0.9 million at September 30, 2020.

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.

Note 3. Stockholders' Equity

Stock-based Compensation Expense and Valuation Information

Stock-based awards include stock options and RSUs under the Company's Amended and Restated 2012 Equity Incentive Plan ("2012 Plan"), inducement awards, performance-based RSUs under an Incentive Award Performance-Based Restricted Stock Unit Agreement, the Company's 2021 Inducement Equity Incentive Plan ("Inducement Plan"), 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, 2021	Three Months Ended September 30, 2020	Six Months Ended September 30, 2021	Six Months Ended September 30, 2020
Research and development	$ 80	$ 7	$ 156	$ 7
General and administrative	$ 346	$ 4,131	$ 685	$ 5,056
Total	$ 426	$ 4,138	$ 841	$ 5,063

The total unrecognized compensation cost related to unvested stock option grants as of September 30, 2021 was approximately $3.4 million and the weighted average period over which these grants are expected to vest is 2.44 years.

The total unrecognized compensation cost related to unvested RSUs (not including performance-based RSUs) as of September 30, 2021 was approximately $0.2 million, which will be recognized over a weighted average period of 3.29 years.

The Company uses either the Black-Scholes or Monte Carlo option-pricing models to calculate the fair value of stock options, depending on the complexity of the equity grants. Stock-based compensation expense is recognized over the vesting period using the straight-line method. 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 is 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 stock options was estimated at the grant date using the following weighted average assumptions:

	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Six Months Ended September 30, 2021	Six Months Ended September 30, 2020
Dividend yield	—	—	—	—
Volatility	116.83%	108.39%	116.83%	108.39%
Risk-free interest rate	0.73%	0.27%	0.73%	0.27%
Expected life of options	6.00 years	6.00 years	6.00 years	6.00 years
Weighted average grant date fair value	$ 6.52	$ 6.22	$ 6.52	$ 6.22

The fair value of each RSU and performance-based RSU 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 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 is based on U.S. Treasury rates. The expected life is the 6-month purchase period. There were no participants in the ESPP for the current purchase period (beginning September 1, 2021), nor any participants in the ESPP for the comparative 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

The Company previously had an effective shelf registration statement on Form S-3 (File No. 333-222929) and the related prospectus previously declared effective by the SEC on February 22, 2018 (the "2018 Shelf"), which registered $100.0 million of common stock, preferred stock, warrants and units, or any combination of the foregoing, that was set to expire on February 22, 2021. On January 19, 2021, the Company filed a shelf registration statement on Form S-3 (File No. 333-252224) to register $150.0 million of the Company's common stock, preferred stock, debt securities, warrants and units, or any combination of the foregoing (the "2021 Shelf") and a related prospectus. The 2021 Shelf was declared effective by the SEC on January 29, 2021 and replaced the 2018 Shelf at that time.

On January 29, 2021, the Company entered into a Sales Agreement ("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 2021 Shelf, pursuant to which the Company could 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 $50.0 million. Any shares offered and sold will be issued pursuant to the 2021 Shelf. During the three and six months ended September 30, 2021, the Company issued 0 and 27,545 shares of common stock for net proceeds of $0 million and $0.3 million in at-the-market offerings under the Sales Agreement, respectively. As of September 30, 2021, the Company has sold an aggregate of 1,580,862 shares of common stock in at-the-market offerings under the Sales Agreement, with gross proceeds of approximately $21.7 million. As of September 30, 2021, there was approximately $128.3 million available for future offerings under the 2021 Shelf, and approximately $28.3 million available for future offerings through the Company's ATM program under the Sales Ageement.

In March 2021, the Company's Board of Directors ("Board") approved the Inducement Plan. The Inducement Plan authorized the issuance of up to 750,000 shares of common stock for awards of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, RSUs, performance units, performance shares, and other stock or cash awards.

RSUs

The following table summarizes the Company's RSUs (not including performance-based RSUs) activity from March 31, 2021 through September 30, 2021:

	Number of Shares	Weighted Average Price
Unvested at March 31, 2021	21,057	$ 10.79
Granted	—	$ —
Vested	(290)	$ 21.72
Cancelled / forfeited	—	$ —
Unvested at September 30, 2021	20,767	$ 10.64

Performance-based RSUs

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 PBRSUs were issued pursuant to the 2012 Plan. The PBRSU Retention Awards vest in full upon the earlier of: (i) the Company's engagement in a pre-IND meeting with the FDA, (ii) twenty-four months from the grant date, or (iii) a change in control. As of September 30, 2021, 111,682 shares were forfeited due to terminations, vesting for 177,480 shares was accelerated due to a change in control that was triggered by changes to the Board in 2020, and the remaining 12,229 shares vested on July 1, 2021, twenty-four months from the grant date, as these particular shares required two of the conditions to be met in order to vest.

The following table summarizes the Company's performance-based RSUs activity from March 31, 2021 through September 30, 2021:

	Number of Shares	Weighted Average Price
Unvested at March 31, 2021	12,229	$ 9.80
Granted	—	$ —
Vested	(12,229)	$ 9.80
Cancelled / forfeited	—	$ —
Unvested at September 30, 2021	—	$ —

Stock Options

The following table summarizes the Company's stock option activity from March 31, 2021 to September 30, 2021:

	Options Outstanding	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at March 31, 2021	1,004,655	$ 20.03	$ 856,400
Options granted	12,000	$ 7.66	$ —
Options cancelled / forfeited	(354,530)	$ 40.95	$ —
Options exercised	—	$ —	$ —
Outstanding at September 30, 2021	662,125	$ 8.61	$ —
Vested and Exercisable at September 30, 2021	108,492	$ 7.61	$ —

The weighted average remaining contractual term of stock options exercisable and outstanding at September 30, 2021 was approximately 8.96 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, 2021, 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, 2021:

Common stock issuable pursuant to options outstanding and reserved under the 2012 Plan	662,125
Common stock reserved under the 2012 Plan	301,879
Common stock reserved under the ESPP	59,435
Common stock reserved under the Inducement Plan	750,000
Common stock issuable pursuant to RSUs outstanding under the 2012 Plan	20,767
Total at September 30, 2021	1,794,206

Note 4. 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.

In June 2021, the Company's U.S. Pat. Nos. 9,855,369 and 9,149,952, which relate to its bioprinter technology, became the subject of IPR proceedings filed by Cellink AB and its subsidiaries, MatTek Incorporated and Visikol, Inc. (collectively, "Cellink AB"). The objective of the IPR proceedings is to invalidate the claims in the noted patents. The Company filed a preliminary response to Cellink AB's IPR petition in September 2021. The Company expects the PTAB to reach a decision in December 2021 whether to institute Cellink AB's IPRs. As of the date of this filing, the Company concluded that the probability of a loss contingency or unfavorable outcome from this event is remote.

In addition, U.S. Patent Nos. 9,149,952, 9,855,369, 8,931,880, 9,227,339 and 9,315,043 (all assigned to Organovo, Inc.) and U.S. Patent Nos. 7,051,654 and 9,752,116 (licensed exclusively to Organovo) are subject to a declaratory judgment complaint against the Company brought by Cellink AB to obtain a declaration from the court that they do not infringe any claims of the noted patents (the "Action"). The Company filed a motion to dismiss the Action on July 29, 2021. As of the date of this filing, the Company concluded that the probability of a loss contingency or unfavorable outcome from this event is reasonably possible. However, the Company is currently unable to estimate a possible loss or range of loss related to the declaratory judgment complaint.

On July 28, 2021, the Company filed a complaint for patent infringement against Cellink AB in the United States District Court for the Western District of Texas (the "Patent Complaint"). The Patent Complaint alleges that Cellink AB has infringed U.S. Patent Nos. 9,149,952, 9,855,369 and 9,315,043 (all assigned to Organovo, Inc.) and U.S. Patent No. 9,752,116 (licensed exclusively to Organovo). The Company seeks an injunction against continuing infringement of the foregoing patents by Cellink AB and monetary damages. The Company cannot predict the ultimate outcome of the Patent Complaint.

In September 2021, Cellink AB filed two additional IPR proceedings against the Company's U.S. Pat. Nos. 9,315,043 and 9,752,116 (exclusively licensed by the Company from the MUSC Fourndation for Research and Development), which relate to its bioprinter technology. The objective of the IPR proceedings is to invalidate the claims in the noted patents. The Company may file a preliminary response to Cellink AB's IPR petition in December 2021. The Company expects the PTAB to reach a decision in March 2022 whether to institute Cellink AB's IPRs. As of the date of this filing, the Company concluded that the probability of a loss contingency or unfavorable outcome from this event is remote.

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. 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 5. Leases

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

Operating Leases

From October 2019 to July 2021, the Company rented office space in Solana Beach, California. This agreement was a month-to-month contract and could be terminated at-will by either party at any time. As such, the Company concluded that this agreement did not contain a lease and was be expensed as incurred (referred to as "rent expense"). Monthly rental payments were approximately $4,000 per month.

On November 23, 2020, the Company entered into two lease agreements, pursuant to which the Company temporarily leases approximately 3,212 square feet of office space (the "Temporary Lease") in San Diego and will permanently lease approximately 8,051 square feet of office space (the "Permanent Lease") in San Diego once certain tenant improvements for the Company's permanent premises have been completed by the landlord and the premises are ready for occupancy. The Temporary Lease commenced on November 27, 2020 and is intended to serve as temporary premises until the Permanent Lease is ready for occupancy. The Permanent Lease is projected to commence in the third quarter of fiscal 2022 and is intended to serve as the Company's permanent premises for approximately sixty-two months. Once the Permanent Lease commences, monthly rental payments will be approximately $32,000 with 3% annual escalators.

The Company determined that the Temporary Lease is considered a short term lease under ASC 842 and therefore elected an accounting policy for short term leases to recognize lease payments as an expense on a straight-line basis over the lease term (referred to as "short term lease expense"). Variable lease expenses related to the short term lease, 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. The Company also determined that the Permanent Lease will require the balance sheet recognition of a right-of-use asset and lease liability under ASC 842 once the Permanent Lease commences. The Company is currently evaluating the financial statement impact of the Permanent Lease.

The Company recorded rent expense of approximately $5,000 and $18,000 for the three and six months ended September 30, 2021, respectively, and $13,000 and $25,000 for the three and six months ended September 30, 2020, respectively. Variable lease expense was approximately $9,000 and $18,000 for the three and six months ended September 30, 2021, respectively, and $0 for the three and six months ended September 30, 2020. Lastly, for the three and six months ended September 30, 2021, short term lease expense was approximately $39,000 and $78,000, respectively, and $0 for the three and six months ended September 30, 2020.

Note 6. 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.

Note 7. Related Parties

From time to time, the Company will enter into an agreement with a related party in the ordinary course of its business. These agreements are ratified by the Board or a committee thereof pursuant to its related party transaction policy.

Viscient Biosciences ("Viscient") is an entity for which Keith Murphy, the Company's Executive Chairman, 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, previously served as outside legal counsel to Viscient through his law firm, Optima Law Group, APC. 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.

On December 28, 2020, the Company entered into an intercompany agreement (the "Intercompany Agreement") with Viscient and Organovo, Inc., the Company's wholly-owned subsidiary, which included an asset purchase agreement for certain lab equipment. Pursuant to the Intercompany Agreement, the Company agreed to provide Viscient certain services related to 3D bioprinting technology, which includes, but is not limited to, histology services, cell isolation, and proliferation of cells and Viscient agreed to provide the Company certain services related to 3D bioprinting technology, including bioprinter training, bioprinting services, and qPCR assays, in each case on payment terms specified in the Intercompany Agreement and as may be further determined by the parties. In addition, the Company and Viscient each agreed to share certain facilities and equipment and, subject to further agreement, to each make certain employees available for specified projects for the other party at prices to be determined in good faith by the parties. The Company evaluated the accounting for the Intercompany Agreement and concluded that any services provided by Viscient to the Company will be expensed as incurred, and any compensation for services provided by the Company to Viscient will be considered a reduction of personnel related expenses. Any services provided to Viscient do not fall under Topic 606 as the Intercompany Agreement is not a contract with a customer. For the three and six months ended September 30, 2021, the Company incurred approximately $10,000 and $20,000 in consulting expenses from Viscient, respectively. Additionally, for the three and six months ended September 30, 2021, the Company provided approximately $14,000 and $26,000 of histology services to Viscient, respectively.

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, 2021. This management's 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, 2021, filed with the Securities and Exchange Commission on June 15, 2021, 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. 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.

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, 2021, filed with the SEC on Form 10-K on June 15, 2021, 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.

Overview

We are an early-stage biotechnology company that is focusing on building high fidelity, 3D tissues that recapitulate key aspects of human disease. We use these models to identify gene targets capable of modulating the disease phenotype across multiple patients and intend to initiate drug discovery programs around these validated targets. We are initially targeting the intestine and have ongoing 3D tissue development efforts in Ulcerative colitis ("UC") and Crohn's disease ("CD"). We intend to add additional tissues/diseases/targets to our portfolio in the coming year. In line with these plans, we are building upon both our external and in-house scientific expertise, which will be essential to our drug development effort.

We use our proprietary technology 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. Management believes these attributes can enable critical complex, multicellular disease models that can be used to develop clinically effective drugs for selected therapeutic areas.

Our NovoGen Bioprinters® are automated devices that enable the fabrication of 3D living tissues comprised of mammalian cells. We believe that the use of our bioprinting platform as well as complementary 3D technologies will allow us to develop an understanding of disease biology that leads to validated novel drug targets, and therapeutics to those targets to treat disease.

The majority of our current focus is on inflammatory bowel disease ("IBD"), including CD and UC. We expect to create disease models, leveraging our prior work including the work found in our peer-reviewed publication on bioprinted intestinal tissues (Madden et al. Bioprinted 3D Primary Human Intestinal Tissues Model Aspects of Native Physiology and ADME/Tox Functions. iScience. 2018 Apr 27;2:156-167. doi: 10.1016/j.isci.2018.03.015.) Our current understanding of intestinal tissue models and IBD disease models leads us to believe that we can create models that provide greater insight into the biology of these diseases than are generally currently available. Using these disease models, we intend to identify and validate novel therapeutic targets. After finding therapeutic drug targets, we will focus on developing novel small molecule, antibody, or other therapeutic drug candidates to treat the disease, and advance these drug candidates towards an IND and clinical trials.

We expect to broaden our work into additional therapeutic areas over time and are currently exploring specific tissues for development. In our work to identify the areas of interest, we evaluate areas that might be better served with 3D disease models than currently available models as well as the commercial opportunity.

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 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. In 2020, we adapted quickly to COVID-19, instituting universal masking and distancing in the lab and in the offices. We encouraged and enabled remote work whenever possible. We instituted safety check software to monitor symptoms. We have successfully maintained a robust level of progress while ensuring the safety of our employees. As the viral load and variants allow, we intend to carefully return to more typical lab and office work flow.

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 rise of vaccine-resistant variants, duration of the outbreak, travel bans, restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns. In particular, the continued COVID-19 pandemic could adversely impact various aspects of our operations, including among others, our ability to raise additional capital, the timing and ability to pursue our revised strategy, given the impact the pandemic 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. Our employees and consultants have recently returned to working at our office and lab when necessary and we currently believe our operations have not 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. 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, 2021. For a description of critical accounting policies that affect our significant judgments and estimates used in the preparation of our audited 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, 2021, filed with the SEC on June 15, 2021.

Results of Operations

Comparison of the three months ended September 30, 2021 and 2020

The following table summarizes our results of operations for the three months ended September 30, 2021 and 2020 (in thousands, except %):

	Three Months Ended September 30,		Increase (decrease)	
	2021	2020	$	%
Research and development	$ 679	$ 28	$ 651	2,325%
Selling, general and administrative	$ 2,828	$ 8,922	$ (6,094)	(68%)
Other income	$ 2	$ -	$ 2	100%

Costs and Expenses

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2021 and 2020 (in thousands, except %):

	Three Months Ended September 30, 2021	% of total	Three Months Ended September 30, 2020	% of total	Increase $	Increase %
Research and development	$ 569	84%	$ 20	71%	$ 549	2,745%
Non-cash stock-based compensation	80	12%	7	25%	73	1,043%
Depreciation and amortization	30	4%	1	4%	29	2,900%
Total research and development expenses	**$ 679**	**100%**	**$ 28**	**100%**	**$ 651**	**2,325%**

For the three months ended September 30, 2021, research and development expenses were $0.7 million, an increase of 2,325% from the prior year period. For the three months ended September 30, 2020, we had less than $0.1 million research and development activities as we were in the midst of a process to evaluate strategic alternatives. Our average full-time research and development staff increased from zero full-time employees for the three months ended September 30, 2020 to an average of eight full-time employees for the three months ended September 30, 2021. Research and development activities consisted of $0.3 million in personnel related costs, $0.2 million in lab expenses, $0.1 million in facility costs, and $0.1 million in consulting fees, depreciation, and other miscellaneous expenses. Going forward, we intend to continue to increase headcount and 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, 2021 and 2020 (in thousands, except %):

	Three Months Ended September 30, 2021	% of total	Three Months Ended September 30, 2020	% of total	Increase (decrease) $	Increase (decrease) %
Selling, general and administrative	$ 2,478	88%	$ 4,787	54%	$ (2,309)	(48%)
Non-cash stock-based compensation	345	12%	4,131	46%	(3,786)	(92%)
Depreciation and amortization	5	0%	4	0%	1	25%
Total selling, general and administrative expenses	**$ 2,828**	**100%**	**$ 8,922**	**100%**	**$ (6,094)**	**(68%)**

For the three months ended September 30, 2021, selling, general and administrative expenses were approximately $2.8 million, a decrease of $6.1 million, or approximately 68%, compared to the prior year period. The decrease year over year is due to the change in business operations from fiscal 2021 to fiscal 2022. During the three months ended September 30, 2020, the majority of our costs were for personnel and general corporate costs, as we were in the midst of a strategic alternatives process and at the time we had an average of six full-time employees, three of whom were executives. A change in control occurred in September 2020, which triggered the resignations and related severance costs for the three executives. This included the accelerated vesting of any outstanding share based compensation. During the three months ended September 30, 2021, we had an average of four full-time employees, only one of whom is an executive. This decrease in headcount and a shift in business operations resulted in the decrease of personnel related costs by approximately $6.9 million year over year, which was offset by a $0.1 million increase in consulting costs year over year, as we

utilized part-time consultants for officer positions in the Company as well as various other consultants for operations. Lastly, we had an increase in corporate costs of $0.7 million year over year, which was a result of a shift in business operations. Our corporate costs during the three months ended September 30, 2021 were approximately $1.9 million. Of these corporate costs, approximately $0.2 million are legal costs directly related to IPR proceedings and $0.6 million are legal costs directly related to ongoing litigation regarding patent enforcement. See "Operations Funding Requirements" below for further information on these legal expenses.

Other Income (Expense)

Other income was less than $0.1 million for both of the three months ended September 30, 2021 and September 30, 2020.

Comparison of the six months ended September 30, 2021 and 2020

The following table summarizes our results of operations for the six months ended September 30, 2021 and 2020 (in thousands, except %):

	Six Months Ended September 30,		Increase (decrease)	
	2021	2020	$	%
Research and development	$ 1,259	$ 28	$ 1,231	4,396%
Selling, general and administrative	$ 4,807	$ 11,708	$ (6,901)	(59%)
Other income	$ 29	$ 19	$ 10	53%

Costs and Expenses

Research and Development Expenses

The following table summarizes our research and development expenses for the six months ended September 30, 2021 and 2020 (in thousands, except %):

	Six Months Ended September 30, 2021	% of total	Six Months Ended September 30, 2020	% of total	Increase (decrease) $	Increase (decrease) %
Research and development	$ 1,053	84%	$ 20	71%	$ 1,033	5,165%
Non-cash stock-based compensation	156	12%	7	25%	149	2,129%
Depreciation and amortization	50	4%	1	4%	49	4,900%
Total research and development expenses	**$ 1,259**	**100%**	**$ 28**	**100%**	**$ 1,231**	**4,396%**

For the six months ended September 30, 2021, research and development expenses were $1.3 million, an increase of 4,396% from the prior year period. For the six months ended September 30, 2020, we had less than $0.1 million in research and development activities as we were in the midst of a process to evaluate strategic alternatives. Our average full-time research and development staff increased from zero full-time employees for the three months ended September 30, 2020 to an average of seven full-time employees for the six months ended September 30, 2021. Research and development activities consisted of $0.7 million in personnel related costs, $0.3 million in lab expenses, $0.2 million in facility costs, and $0.1 million in consulting fees, depreciation, and other miscellaneous expenses. Going forward, we intend to continue to increase headcount and 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, 2021 and 2020 (in thousands, except %):

	Six Months Ended September 30, 2021	% of total	Six Months Ended September 30, 2020	% of total	Increase (decrease) $	Increase (decrease) %
Selling, general and administrative	$ 4,114	86%	$ 6,645	57%	$ (2,531)	(38%)
Non-cash stock-based compensation	684	14%	5,056	43%	(4,372)	(86%)
Depreciation and amortization	9	0%	7	0%	2	29%
Total selling, general and administrative expenses	**$ 4,807**	**100%**	**$ 11,708**	**100%**	**$ (6,901)**	**(59%)**

For the six months ended September 30, 2021, selling, general and administrative expenses were approximately $4.8 million, a decrease of $6.9 million, or approximately 59%, compared to the prior year period. The decrease year over year is due to the change in

business operations from fiscal 2021 to fiscal 2022. During the six months ended September 30, 2020, the majority of our costs were for personnel and general corporate costs, as we were in the midst of a strategic alternatives process and at the time we had an average of six full-time employees, three of whom were executives. A change in control occurred in September 2020, which triggered the resignations and related severance costs for the three executives. This included the accelerated vesting of any outstanding share based compensation. During the six months ended September 30, 2021, we had an average of four full-time employees, only one of whom is an executive. This decrease in headcount and a shift in business operations resulted in the decrease of personnel related costs by approximately $7.9 million year over year, and a decrease in facility costs of $0.2 million year over year, which was offset by a $0.4 million increase in consulting costs year over year, as we utilized part-time consultants for officer positions in the Company as well as various other consultants for operations. Lastly, we had an increase in corporate costs of $0.8 million year over year, which was a result of a shift in business operations. Our corporate costs during the six months ended September 30, 2021 were approximately $3.0 million. Of these corporate costs, approximately $0.2 million are legal costs directly related to IPR proceedings and $0.7 million are legal costs directly related to ongoing litigation regarding patent enforcement. See “Operations Funding Requirements” below for further information on these legal expenses.

Other Income (Expense)

Other income was less than $0.1 million for both of the six months ended September 30, 2021 and September 30, 2020.

Financial Condition, Liquidity and Capital Resources

We originally devoted our efforts to developing a platform technology to produce and study living tissues, with a focus on liver tissue, 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. These steps included reducing all commercial and research and development laboratory 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 lab equipment and other inventory, and reducing our workforce. We have retained certain key management, employees and consultants, our core intellectual property, licenses, collaborations with research institutions and universities, and proprietary equipment. Going forward, we intend to leverage our proprietary technology platform to develop therapeutic drugs. Our initial plan is to focus on IBD, including CD and UC with a goal of broadening our work into additional therapeutic areas over time. In connection with our new strategy, we intend to rebuild our research and development functions to support our screening and drug development efforts.

At September 30, 2021, we had cash and cash equivalents of approximately $33.8 million and an accumulated deficit of $302.3 million. We had negative cash flow from operations of $3.6 million during the six months ended September 30, 2021. At March 31, 2021, we had cash and cash equivalents of approximately $37.4 million and an accumulated deficit of $296.3 million.

At September 30, 2021, we had total current assets of approximately $34.3 million and current liabilities of approximately $1.7 million, resulting in working capital of $32.6 million. At March 31, 2021, we had total current assets of approximately $38.4 million and current liabilities of approximately $0.7 million, resulting in working capital of $37.7 million.

The following table summarizes the primary sources and uses of cash for the six months ended September 30, 2021 and 2020 (in thousands):

	Six Months Ended September 30,	
	2021	2020
Net cash (used in) provided by:		
Operating activities	$ (3,556)	$ (9,718)
Investing activities	(223)	7
Financing activities	206	11
Net decrease in cash, cash equivalents, and restricted cash	$ (3,573)	$ (9,700)

Operating activities

Net cash used in operating activities for the six months ended September 30, 2021 was approximately $3.6 million as compared to $9.7 million used in operating activities for the six months ended September 30, 2020. This $6.1 million decrease in operating cash usage can be attributed primarily to a change in business operations, resulting from the change in control in fiscal 2021.

Investing activities

Net cash used in investing activities, consisting primarily of fixed asset purchases, was $0.2 million for the six months ended September 30, 2021. Net cash provided by investing activities, consisting primarily of proceeds from the sale of assets, was less than $0.1 million for the six months ended September 30, 2020.

Financing activities

Net cash provided by financing activities was $0.2 million during the six months ended September 30, 2021 compared to net cash provided by financing activities of less than $0.1 million during the six months ended September 30, 2020. Financing in fiscal 2022 was driven by the sale of common stock through at-the-market ("ATM") offerings.

Operations funding requirements

Through September 30, 2021, we have financed our operations primarily through the sale of convertible notes, warrants, the private placement of equity securities, the sale of common stock through public and ATM offerings, and through revenue derived from products and research service-based agreements, collaborative agreements, licenses, and grants. During the six months ended September 30, 2021, we raised net proceeds of approximately $0.3 million through the sale of 27,545 shares of our common stock through ATM offerings.

Our ongoing cash requirements include research and development expenses, compensation for personnel, consulting fees, legal and accounting support, insurance premiums, facilities, maintenance of our intellectual property portfolio, license and collaboration agreements, listing on the Nasdaq Capital Market, and other miscellaneous fees to support our operations. We expect our total operating expense for the fiscal year ending March 31, 2022 will be between $12.0 million and $14.0 million. Based on our current operating plan and available cash resources, we believe we have sufficient resources to fund our business for at least the next twelve months.

In June 2021, our U.S. Pat. Nos. 9,855,369 and 9,149,952, which relate to our bioprinter technology, became the subject of IPR proceedings filed by Cellink AB and its subsidiaries, MatTek Incorporated and Visikol, Inc. (collectively, "Cellink AB"). The objective of the IPR proceedings is to invalidate the claims in the noted patents. We estimate the costs of these IPR proceedings to total between $850,000 and $950,000**.**

In September 2021, Cellink AB filed two additional IPR proceedings against our U.S. Pat. Nos. 9,315,043 and 9,752,116 (exclusively licensed by the Company from the MUSC Fourndation for Research and Development),which relate to our bioprinter technology. The objective of the IPR proceedings is to invalidate the claims in the noted patents. We estimate the costs of these IPR proceedings to total between $850,000 and $950,000**.**

As of September 30, 2021, we have incurred approximately $150,000 of total legal costs related to the IPR proceedings described above.

We previously had an effective shelf registration statement on Form S-3 (File No. 333-222929) (the "2018 Shelf") that registered $100.0 million of common stock, preferred stock, warrants and units, or any combination of the foregoing, that was set to expire on February 22, 2021. On January 19, 2021, we filed a shelf registration statement on Form S-3 (File No. 333-252224) to register $150.0 million of common stock, preferred stock, debt securities, warrants and units, or any combination of the foregoing (the "2021 Shelf") and a related prospectus. The 2021 Shelf registration statement was declared effective by the SEC on January 29, 2021 and replaced the 2018 Shelf at that time.

On January 29, 2021, we entered into a Sales Agreement ("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 2021 Shelf, pursuant to which we could offer and sell, from time to time through the Agents, shares of our common stock in ATM sales transactions having an aggregate offering price of up to $50.0 million. Any shares offered and sold are issued pursuant to our 2021 Shelf.

During the three and six months ended September 30, 2021, we sold 0 and 27,545 shares of common stock in ATM offerings, with net proceeds of approximately $0 and $0.3 million under the Sales Agreement, respectively. As of September 30, 2021, we have sold an aggregate of 1,580,862 shares of common stock in ATM offerings under the Sales Agreement, for gross proceeds of approximately $21.7 million. As of September 30, 2021, there was approximately $128.3 million available in future offerings under the 2021 Shelf, and approximately $28.3 million available for future offerings through our ATM program under the Sales Agreement.

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, we can obtain financing on terms favorable to our 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.

As of September 30, 2021, we had 8,705,454 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 301,879 shares remain available for issuance as of September 30, 2021, 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, 2021. We also have 750,000 available for issuance pursuant to the 2021 Inducement Equity Incentive Plan. 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 9,749,660 shares of common stock as of September 30, 2021.

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 4 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, 2021, filed with the SEC on June 15, 2021.

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, 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 rise of vaccine-resistant variants, duration of the outbreak, travel bans, 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 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 particular, we require access to a constant, steady, reliable supply of human cells to support our development activities. The COVID-19 pandemic could negatively impact our ability to obtain a reliable supply of sufficient human cells or a supply at cost effective prices, which would harm our business and our results of operations and could cause us to be unable to support our drug development efforts.

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. For example, from July 1, 2020 to September 30, 2021, our closing stock price ranged from $6.08 to $21.70 per share. Such increases and decreases in our stock price 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 3D tissue development activities. We purchase human cells from selected third-party suppliers based on quality assurance, cost effectiveness, and regulatory requirements. We need to continue to identify additional 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, including any impact to suppliers due to the COVID-19 pandemic, 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.

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 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. 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. 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.

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 contract research organizations ("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 who 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 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.

Risks Related to Government Regulation

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.

If we fail to obtain and sustain an adequate level of reimbursement for our potential products by third-party payors, potential future sales would be materially adversely affected.

There will be no viable commercial market for our drug candidates, if approved, without reimbursement from third-party payors. Reimbursement policies may be affected by future healthcare reform measures. We cannot be certain that reimbursement will be available for our current drug candidates or any other drug candidate we may develop. Additionally, even if there is a viable commercial market, if the level of reimbursement is below our expectations, our anticipated revenue and gross margins will be adversely affected.

Third-party payors, such as government or private healthcare insurers, carefully review and increasingly question and challenge the coverage of and the prices charged for drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. Reimbursement rates may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. There is a current trend in the U.S. healthcare industry toward cost containment.

Large public and private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, may question the coverage of, and challenge the prices charged for, medical products and services, and many third-party payors limit coverage of or reimbursement for newly approved healthcare products. In particular, third-party payors may limit the covered indications. Cost-control initiatives could decrease the price we might establish for products, which could result in product revenues being lower than anticipated. We believe our drugs will be priced significantly higher than existing generic drugs and consistent with current branded drugs. If we are unable to show a significant benefit relative to existing generic drugs, Medicare, Medicaid and private payors may not be willing to provide reimbursement for our drugs, which would significantly reduce the likelihood of our products gaining market acceptance.

We expect that private insurers will consider the efficacy, cost-effectiveness, safety and tolerability of our potential products in determining whether to approve reimbursement for such products and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business, financial condition and results of operations would be materially adversely affected if we do not receive approval for reimbursement of our potential products from private insurers on a timely or satisfactory basis. Limitations on coverage could also be imposed at the local Medicare carrier level or by fiscal intermediaries. Medicare Part D, which provides a pharmacy benefit to Medicare patients as discussed below, does not require participating prescription drug plans to cover all drugs within a class of products. Our business, financial condition and results of operations could be materially adversely affected if Part D prescription drug plans were to limit access to, or deny or limit reimbursement of, our drug candidates or other potential products.

Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. In many countries, the product cannot be commercially launched until reimbursement is approved. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. The negotiation process in some countries can exceed 12 months. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products to other available therapies.

If the prices for our potential products are reduced or if governmental and other third-party payors do not provide adequate coverage and reimbursement of our drugs, our future revenue, cash flows and prospects for profitability will suffer.

****Current and future legislation may increase the difficulty and cost of commercializing our drug candidates and may affect the prices we may obtain if our drug candidates are approved for commercialization.***

In the U.S. and some foreign jurisdictions, there have been a number of adopted and proposed legislative and regulatory changes regarding the healthcare system that could prevent or delay regulatory approval of our drug candidates, restrict or regulate post-marketing activities and affect our ability to profitably sell any of our drug candidates for which we obtain regulatory approval.

In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”) changed the way Medicare covers and pays for pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could limit the coverage and reimbursement rate that we receive for any of our approved products. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively the “PPACA”), was enacted. The PPACA was intended to broaden access to health insurance, reduce or constrain

the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The PPACA increased manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate amount for both branded and generic drugs and revised the definition of "average manufacturer price", which may also increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also expanded Medicaid drug rebates and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the rebates due on those drugs. The Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicaid Drug Rebate Program, also has proposed to expand Medicaid rebates to the utilization that occurs in the territories of the U.S., such as Puerto Rico and the Virgin Islands. Further, beginning in 2011, the PPACA imposed a significant annual fee on companies that manufacture or import branded prescription drug products and required manufacturers to provide a 50% discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the "donut hole." Legislative and regulatory proposals have been introduced at both the state and federal level to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products.

There have been public announcements by members of the U.S. Congress, regarding plans to repeal and replace the PPACA and Medicare. For example, on December 22, 2017, the Tax Cuts and Jobs Act of 2017 was signed into law, which, among other things, eliminated the individual mandate requiring most Americans (other than those who qualify for a hardship exemption) to carry a minimum level of health coverage, effective January 1, 2019. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the PPACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act of 2017, the remaining provisions of the PPACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court's ruling with respect to the individual mandate but remanded the case to the District Court to consider whether other parts of the law can remain in effect. In November 2020, the U.S. Supreme Court heard the case and on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the PPACA is unconstitutional in its entirety because the individual mandate was repealed by Congress. Accordingly, the PPACA will remain in effect in its current form. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the PPACA marketplace, which began on February 15, 2021 and will remain open through August 15, 2021. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the PPACA. It is possible that the PPACA will be subject to judicial or Congressional challenges in the future. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing approval testing and other requirements.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, in 2020, U.S. Department of Health and Human Services, or HHS, and CMS issued various rules that are expected to impact, among others, price reductions from pharmaceutical manufacturers to plan sponsors under Part D, fee arrangements between pharmacy benefit managers and manufacturers, manufacturer price reporting requirements under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. Multiple lawsuits have been brought against the HHS challenging various aspects of the rules. In January 2021, the Biden administration issued a "regulatory freeze" memorandum that directs department and agency heads to review new or pending rules of the prior administration. It is unclear whether these new regulations will be withdrawn or when they will become fully effective under the Biden administration. The impact of these lawsuits as well as legislative, executive, and administrative actions of the Biden administration on us and the pharmaceutical industry as a whole is unclear. We also expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our drug candidates, if approved for commercialization.

In Europe, the United Kingdom formally withdrew from the European Union on January 31, 2020, and entered into a transition period that ended on December 31, 2020. A significant portion of the regulatory framework in the United Kingdom is derived from the regulations of the European Union. We cannot predict what consequences the recent withdrawal of the United Kingdom from the

European Union will have on the regulatory frameworks of the United Kingdom or the European Union, or on our future operations, if any, in these jurisdictions, and the United Kingdom is in the process of negotiating trade deals with other countries. Additionally, the United Kingdom's withdrawal from the European Union may increase the possibility that other countries may decide to leave the European Union again.

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 for at least the next 12 months. 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.

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.

There can be no assurance that we will be able to raise sufficient additional capital on acceptable terms or at all. Raising additional funding through debt or equity financing is likely to be difficult or unavailable altogether given the early stage of our therapeutic candidates. If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, we may be required to delay, limit or eliminate the development of business opportunities and our ability to achieve our business objectives, our competitiveness, and our business, financial condition and results of operations will be materially adversely affected. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as 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. Any of these events could significantly harm our business, financial condition and prospects. 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, if we seek funds through arrangements with collaborative partners, these arrangements may require us to relinquish rights to our technology or potential future product candidates or otherwise agree to terms unfavorable to us.

****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 $6.1 million and $11.7 million for the six months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $302.3 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 collaboration or licensing arrangements with pharmaceutical companies to further develop and conduct clinical trials for any drug candidates we identify;
- obtaining any necessary regulatory approvals 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") inquiries 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.

We may identify material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements.

Our management team is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. generally accepted accounting principles. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

We cannot assure you that we will not have material weaknesses or significant deficiencies in our internal control over financial reporting. If we identify any material weaknesses or significant deficiencies that may exist, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, and our stock price may decline materially as a result.

Future strategic investments could negatively affect our business, financial condition and results of operations if we fail to achieve the desired returns on our investment.

Our ability to benefit from future external strategic investments depends on our ability to successfully conduct due diligence, evaluate prospective opportunities, and buy the equity of our target investments at acceptable market prices. Our failure in any of these tasks could result in unforeseen loses associated with the strategic investments.

We may also discover deficiencies in internal controls, data adequacy and integrity, product quality, regulatory compliance, product liabilities or other undisclosed liabilities that we did not uncover prior to our investment, which could result in us becoming subject asset impairments, including potential loss of our investment capital. In addition, if we do not achieve the anticipated benefits of an external investment as rapidly as expected, or at all, investors or analysts may downgrade our stock.

We also expect to continue to carry out strategic investments that we believe are necessary to expand our business. There are no assurances that such initiatives will yield favorable results for us. Accordingly, if these initiatives are not successful, our business, financial condition and results of operations could be adversely affected. If these risks materialize, our stock price could be materially adversely affected. Any difficulties in such investments could have a material adverse effect on our business, financial condition and results of operations.

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. Finally, certain of our executives also provide services to Viscient Biosciences, Inc. ("Viscient"). Executives that provide services to us and Viscient do not dedicate all of their time to us, as disclosed in our filings, and we may therefore compete with Viscient for the time commitments of our executive officers from time to time.

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, is the Chief Executive Officer, Chairman and principal stockholder of 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, the Chief Scientific Officer and a significant stockholder 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. In particular, pursuant to an Asset Purchase and Non-Exclusive Patent License Agreement with Viscient, dated November 6, 2019, as amended, we have provided a paid up, worldwide, irrevocable, perpetual, non-exclusive license to Viscient under certain of our patents and know-how to (a) make, have made, use, sell offer to sell, import and otherwise exploit the inventions and subject matter covered by certain patents regarding certain bioprinter devices and bioprinting methods, engineered liver tissues, engineered renal tissues, engineered intestinal tissue and engineered tissue for in vitro research use, (b) to use and internally repair the bioprinters, and (c) to make additional bioprinters for internal use only in connection with drug discovery and development research, target identification and validation, compound screening, preclinical safety, absorption, distribution, metabolism, excretion and toxicology (ADMET) studies, and in vitro research to complement clinical development of a therapeutic compound. 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.

On December 28, 2020, we entered into an intercompany agreement with Viscient and Organovo, Inc., our wholly-owned subsidiary (the "Intercompany Agreement"). Pursuant to the Intercompany Agreement, we agreed to provide Viscient certain services related to 3D bioprinting technology, which includes, but is not limited to, histology services, cell isolation, and proliferation of cells, and Viscient agreed to provide us certain services related to 3D bioprinting technology, including bioprinter training, bioprinting services, and qPCR assays, in each case on payment terms specified in the Intercompany Agreement and as may be further determined by the parties. In addition, Viscient and we each agreed to share certain facilities and equipment and, subject to further agreement, to each make certain employees available for specified projects to the other party at prices to be determined in good faith by the parties. Under the Intercompany Agreement, each party will retain its own prior intellectual property.

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 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. 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 OTC Bulletin Board would likely result in a reduction in some or all of the following, each of which could have a material adverse effect on stockholders:

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

****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"), beneficially own approximately 7.7% and 5.5%, respectively, of our outstanding stock and are able to exercise sufficient voting rights to significantly influence 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. These concentrated positions 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.

There is no assurance that an active market in our common stock will continue at present levels or increase in the future.

Our common stock is currently traded on the Nasdaq Capital Market, but 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.

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, 2021, there were an aggregate of 9,749,660 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 984,771 shares of our common stock that may be issued upon the vesting of 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 increase the number of shares authorized under our equity incentive plans and ESPP and we may issue additional authorized but previously unissued equity securities to raise funds to support our continued operations and to implement our business plan. We may also issue additional shares of our capital stock or other securities that are convertible into or exercisable for our capital stock in connection with hiring or retaining employees, future acquisitions, or for other business purposes. If we raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders may result. In addition, the future issuance of any such additional shares of capital stock may create downward pressure on the trading price of our common stock. There can be no assurance that we will not be required to issue additional shares, warrants or other convertible securities in the future in conjunction with any capital raising efforts, including at a price (or exercise prices) below the price at which shares of our common stock is currently traded on the Nasdaq Capital Market. Moreover, depending on market conditions, we cannot be sure that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or to our stockholders.

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

We have paid no dividends on our common stock to date and it is not anticipated that any dividends will be paid to holders of our common stock in the foreseeable future. While our future dividend policy will be based on the operating results and capital needs of our business, it is currently anticipated that any earnings will be retained to finance our future expansion and for the implementation of

our business plan. As an investor, you should take note of the fact that a lack of a dividend can further affect the market value of our stock and could significantly affect the value of any investment.

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

Our Certificate of Incorporation, as amended ("Certificate of Incorporation"), and Bylaws, as amended ("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;
- provide that each director may be removed by the stockholders only for cause;
- 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 General Corporation Law of the State of Delaware (the "DGCL"), 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.

****Our Bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state or federal court located in the State of Delaware) is the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.***

Our Bylaws provide that, unless we consent in writing to the slection of an alternative forum, the Court of Chancery in the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state or federal court located in the State of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for: (i) any derivative action or proceeding brought on behalf of the Company, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director or officer or stockholder of the Company to the Company or the Company's stockholder; (iii) any direct action asserting a claim against us or any of our directors or officers pursuant to any of the provisions of the DGCL, our Certificate of Incorporation or our Bylaws; (iv) any action asserting a claim governed by the internal affairs doctrine. This choice of forum provision is not intended to apply to any actions brought under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. However, our Bylaws do not relieve us of our duties to comply with federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations. Our Bylaws also provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and consented to this choice of forum provision.

This choice of forum provision in our Bylaws may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. In addition, stockholders who do bring a claim in the Court of Chancery in the State of Delaware could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. Furthermore, the enforceability of similar choice of forum provisions in other companies' governing documents has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provision in our Bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

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.

As previously disclosed, we have recommenced certain historical operations and are now focusing our future efforts on developing highly customized 3D human tissues as living, dynamic models for healthy and diseased human biology for drug development. Previously, 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 were limited treatment options other than organ transplant. We also explored the development of other potential pipeline in vivo tissue constructs. As we focus our business on developing highly customized 3D human tissues, we may sell, discontinue, adjust or abandon certain patents and patent applications relating to our historical operations. There can be no assurance that we will be successful at such efforts or sell or otherwise monetize such assets on acceptable terms, if at all. There is also no guarantee that our remaining patents will be sufficiently broad to prevent others from using our technologies or from developing competing products and technologies.

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.

Patents covering our products could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office (the "USPTO"), or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review ("IPR"), or interference proceedings or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications. Such challenges may result in loss of patent rights, in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology or products. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

For example, in June 2021, Cellink AB filed petitions for IPR at the USPTO's Patent Trial and Appeal Board (the "PTAB") of U.S. Pat. Nos. 9,855,369 and 9,149,952 (the "IPR Patents"), two of our issued U.S. patents that relate to our current bioprinter technology. Likewise, in September 2021, Cellink AB filed two additional IPR petitions against the Company's U.S. Pat. Nos. 9,315,043 and 9,752,116 (exclusively licensed by the Company from the MUSC Fourndation for Research and Development) which also relate to our current bioprinter technology. The PTAB may determine to institute IPR proceedings for one up to all of these patents. Although all claims of the IPR Patents remain valid and enforceable until the PTAB makes its rulings and any appeals of such rulings have been exhausted, if we are unsuccessful in the IPR proceedings, in whole or in part, we may lose all or some of our IPR patents or the scope of these patents may be narrowed, which could limit our ability to stop others from using or commercializing products and technology similar or identical to ours. In addition, the cost to us of the IPR proceedings or other proceedings, even if resolved in our favor, could be substantial. Also in June 2021, Cellink AB and its subsidiaries Cellink LLC, Mattek Corporation, and Visikol, Inc. filed a declaratory judgment complaint against us in the United States District Court for the District of Delaware (the "Action"). Under the Action, the Cellink AB and the other plaintiffs assert claims for declaratory judgments of non-infringement of U.S. Patent Nos. 9,149,952, 9,855,369, 8,931,880, 9,227,339 and 9,315,043 (all assigned to Organovo, Inc.) and U.S. Patent Nos. 7,051,654 and 9,752,116 (assigned to Clemson University and the University of Missouri, respectively). We filed a motion to dismiss the Action on July 29, 2021. In addition, in July 2021, we filed a complaint for patent infringement against Cellink AB in the United States District Court for the Western District of Texas (the "Patent Complaint"). The Patent Complaint alleges that Cellink AB has infringed U.S. Patent Nos. 9,149,952, 9,855,369 and 9,315,043 (all assigned to Organovo, Inc.) and U.S. Patent No. 9,752,116 (licensed exclusively to Organovo). We are seeking an injunction against continuing infringement of the foregoing patents by Cellink AB and monetary damages.

Some of our competitors, including Cellink AB, may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations. We may become involved in lawsuits to protect or enforce our inventions, patents or other intellectual property or the patents of our licensors, which could be expensive and time consuming.

In addition, if we initiate legal proceedings against a third party to enforce a patent covering our products, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise claims challenging the validity or enforceability of our patents before administrative bodies in the United States or abroad, even outside the context of litigation, including through re-examination, post-grant review, IPR, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patents in such a way that they no longer cover our products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products. Such a loss of patent protection would have a material adverse effect on our business, financial condition, and results of operations.

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. In addition, the drug candidates we pursue may also be pursued by other companies, and it is possible that patent claims relating to such drug candidates may also be asserted against us. Any patent claims asserted against us 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 and opposition proceedings outside of the United States. 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 and Clemson University for rights to use certain patents, pending applications, and know how. Failure to comply with or maintain 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 and Clemson University 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. In addition, certain patents licensed by us from the University of Missouri and Clemson University are subject to the Action. See the risk factor entitled "Patents covering our products could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad" above for additional information.

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.

General Risk Factors

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.

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

We satisfy certain U.S. federal and state tax withholding obligations due upon the vesting of restricted stock unit awards by automatically withholding from the shares being issued in connection with such a number of shares of our common stock with an aggregate fair market value on the date of vesting equal to the minimum tax withholding obligations. The following table sets forth information with respect to shares of our common stock repurchased by us to satisfy certain tax withholding obligations during the three months ended September 30, 2021:

	(a) Total Number of Shares (or Units) Purchased		(b) Average Price Paid Per Share (or Unit)
July 1, 2021 - July 31, 2021	4,999	(1)	$ 8.92
August 1, 2021 - August 31, 2021	48	(1)	$ 7.07
September 1, 2021 - September 30, 2021	—		$ —
Total	5,047		$ 8.90

(1) Represents shares of our common stock withheld from employees for the payment of taxes.

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	Certificate of Incorporation of Organovo Holdings, Inc. (Delaware) (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on February 3, 2012).
3.2	Certificate of Amendment of Certificate of Incorporation of Organovo Holdings, Inc. (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on July 27, 2018).
3.3	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).
3.4	Bylaws of Organovo Holdings, Inc. (Delaware) (incorporated by reference from Exhibit 3.2 to the Company's Current Report on Form 8-K, as filed with the SEC on February 3, 2012).
3.5	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).
31.1	Certification of Keith Murphy, Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.*
31.2	Certification of Thomas Hess, Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.*
32.1	Certification of Keith Murphy, Executive Chairman, and Thomas Hess, Principal Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended.*
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).*
101.SCH	Inline XBRL Taxonomy Extension Schema.*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.*
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).*

* Filed herewith.

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 8, 2021

By: */s/ Keith Murphy*
Name: Keith Murphy
Title: Executive Chairman

Date: November 8, 2021

By: */s/ Thomas Hess*
Name: Thomas Hess
Title: Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

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 8, 2021

/s/ Keith Murphy
Keith Murphy
Executive Chairman

Exhibit 31.2

CERTIFICATION

I, Thomas Hess, 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 8, 2021

/s/ Thomas Hess

Thomas Hess
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Organovo Holdings, Inc. (the "Company") for the period ended September 30, 2021, as filed with the Securities and Exchange Commission (the "Report"), I, Keith Murphy, Executive Chairman and I, Thomas Hess, 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 8, 2021

/s/ Keith Murphy
Keith Murphy
Executive Chairman

/s/ Thomas Hess
Thomas Hess
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.