

#### **Investor Presentation**

June 2019

CHANGING THE SHAPE
OF RESEARCH AND MEDICINE

## Forward-Looking Statements

This presentation contains statements about future events and expectations known as "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The Company has based these forward-looking statements on its current expectations and the information currently available to it, but any forward-looking statements are subject to a number of risks and uncertainties. Forward-looking statements include, but are not limited to, statements regarding the potential benefits and therapeutic uses of the Company's therapeutic liver tissue, including the benefits of an orphan designation; the Company's expectations regarding the FDA regulatory pathway and anticipated timelines for its regulatory filings; the Company's ability to successfully complete additional preclinical studies, improve its manufacturing processes and demonstrate the prolonged functionality and therapeutic benefits of its therapeutic liver tissue; the Company's ability to implement clinical scale manufacturing and quality processes; the Company's ability to meet market demand; the Company's ability to fund its future operations and business plans; and acceptance of its disease modeling and other in vitro tissue platforms. The factors that could cause the Company's actual future results to differ materially from current expectations include, but are not limited to, risks and uncertainties relating to the Company's ability to successfully improve or demonstrate the durability and functionality of its in vivo liver tissue candidate; the possibility that the results of future preclinical studies may be different from the Company's earlier pilot studies and may not support further clinical development of its tissue candidates; the Company's ability to successfully complete the required preclinical and clinical trials required to obtain regulatory approval on a timely basis or at all; the novelty of the Company's therapeutic tissue approach and the resulting heightened regulatory scrutiny, delays in clinical development or delays in commercial acceptance; the complexity of the manufacturing process for the Company's therapeutic tissues and the effort involved in developing GTP and GMP facilities; the Company's ability to raise significant additional funds to support its business plan and its regulatory objectives; the Company's reliance on third parties and a single supplier for clinical grade organs, including that the Company may not be able to obtain sufficient raw materials to meet clinical or commercial demand for its therapeutic products; competitive products may adversely impact the market opportunity for the Company's therapeutic tissue candidates and its disease modeling and other in vitro tissue products, services and technology; the Company's ability to successfully complete studies and provide the technical information required to support market acceptance of its disease modeling and other in vitro tissue products, services and technology, on a timely basis or at all; and the Company's ability to comply with Nasdag's continued listing requirements. These and other factors are identified and described in more detail in the Company's filings with the SEC, including its Annual Report on Form 10-K filed with the SEC on June 3, 2019.

Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this presentation. Except as required by applicable law, we do not intend to update any of the forward-looking statements to conform these statements to reflect actual results, later events or circumstances or to reflect the occurrence of unanticipated events.



#### Non-GAAP Financial Measures

In addition to disclosing financial results that are determined in accordance with U.S. GAAP, the Company provides net cash utilization as a supplemental measure to help investors evaluate the Company's fundamental operational performance. The Company defines net cash utilization as the net decrease in cash and cash equivalents during the reporting period less proceeds from the sale of common stock and the exercise of warrants and stock options during the reporting period. Net cash utilization is an operational measure that should be considered as additional financial information regarding our operations. This operational measure should not be considered without also considering our results prepared in accordance with U.S. GAAP, and should not be considered as a substitute for, or superior to, our U.S. GAAP results. The Company believes net cash utilization is a relevant and useful operational measure because it provides information regarding our cash utilization rate. Management uses net cash utilization to manage the business, including in preparing its annual operating budget, financial projections and compensation plans. The Company believes that net cash utilization is also useful to investors because similar measures are frequently used by securities analysts, investors and other interested parties in their evaluation of companies in similar industries. However, there is no standardized measurement of net cash utilization, and net cash utilization as the Company presents it may not be comparable with similarly titled operational measures used by other companies. Due to these limitations, the Company's management does not view net cash utilization in isolation but also uses other measurements, such as cash used in operating activities and revenues to measure operating performance.





Investment & Business Highlights

CHANGING THE SHAPE
OF RESEARCH AND MEDICINE

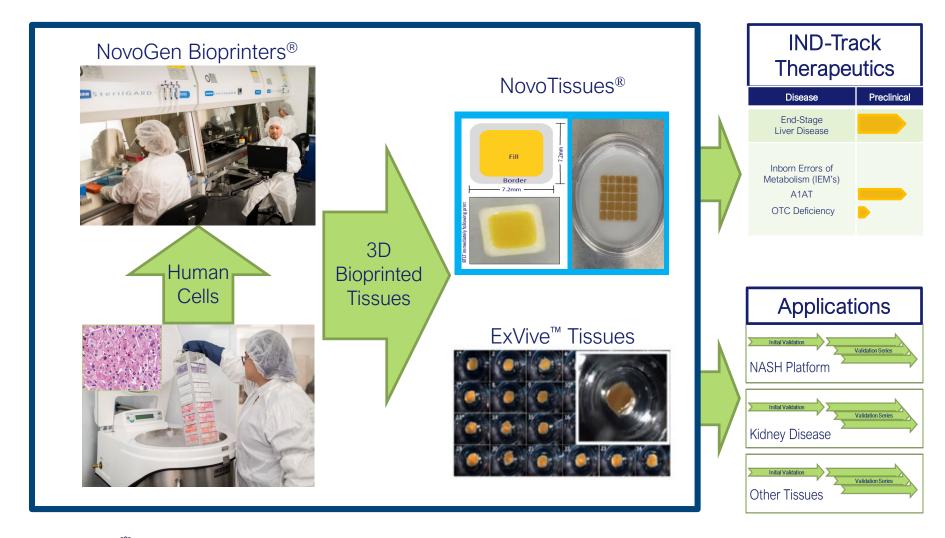
# PIONEERING BIOPRINTED HUMAN TISSUES TO TREAT RARE DISEASES



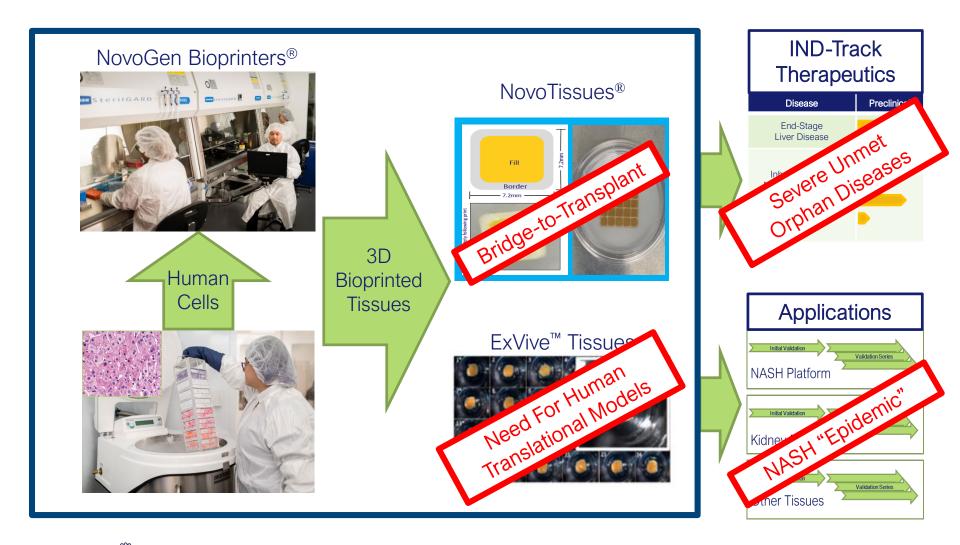
**Initial Focus on Liver** 



## Organovo's Platform



#### Addressing Critical Unmet Needs





# Key Corporate Goals<sup>(1)</sup>

#### Calendar 2019

#### Calendar 2020

Calendar 2021

- Optimize manufacturing process
- Additional studies to demonstrate consistent tissue durability and effectiveness

- Pre-IND meeting with FDA for NovoTissues<sup>®</sup> use in lead program
- Begin IND-enabling studies

# First IND Submission

(1) Guidance speaks only as of the date it was originally provided (May 22, 2019). Inclusion of guidance herein should not be interpreted as a re-affirmation by Organovo of its guidance. Organovo undertakes no obligation to update its guidance after the date it was originally provided.

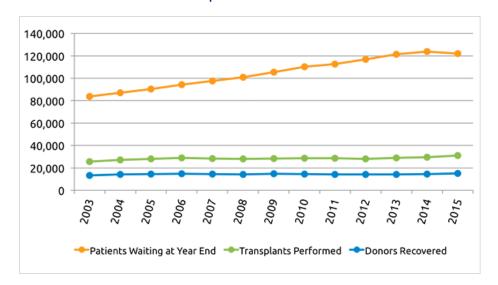


## Therapeutic Tissues Opportunity

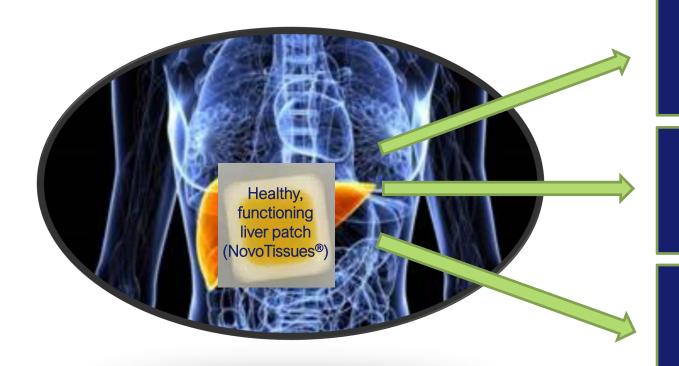
#### Advancing NovoTissues® bioprinted liver as first therapeutic tissue

- Donor shortage issues are a significant and growing challenge in transplant medicine
- Unmet medical needs including rare, genetic diseases; growing incidence of liver disease
- Postpone or reduce the need for transplant; lower patient care costs

U.S. Transplants 2003 – 2015<sup>(1)</sup>



# NovoTissues<sup>®</sup> Liver Tissue Strategy



End-Stage
Liver Disease
Potential to restore
function/bridge-totransplant

A1AT Deficiency
Potential to restore
function/delay
transplant

Other IEMs
Potential to restore
function/delay
transplant

Note: Liver tissue patch image not to scale



## Liver Therapeutic Tissue Pipeline

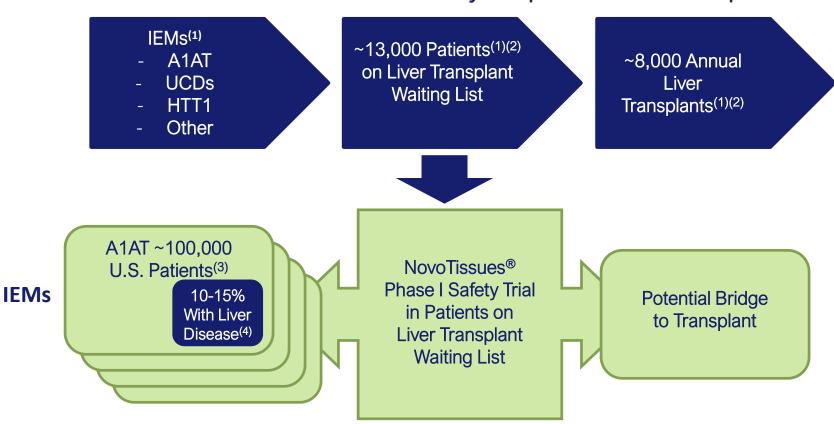
# Healthy liver tissue patch being evaluated in multiple therapeutic indications

Disease	Preclinical	IND- Enabling	Clinical	Regulatory Status
End-Stage Liver Disease			Potential: FastTrack	
Inborn Errors of Metabolism (IEM's) A1AT OTC Deficiency			and/or RMAT	Orphan Designation for A1AT



## Bridge-to-Transplant Gateway Strategy

#### Some IEM Patients Ultimately Require a Liver Transplant



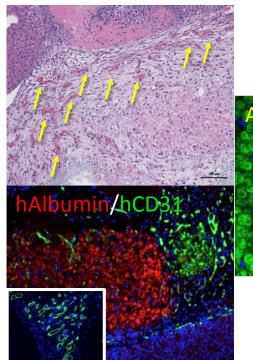
- (1) Organ Procurement & Transplantation Network (https://optn.transplant.hrsa.gov/data/) February 2019
- (2) American Liver Foundation https://liverfoundation.org/for-patients/about-the-liver/the-progression-of-liver-disease/liver-transplant/ 2016
- (3) Alpha-1 Foundation <a href="https://www.alpha1.org/Newly-Diagnosed/Learning-about-Alpha-1/Lung-Disease">https://www.alpha1.org/Newly-Diagnosed/Learning-about-Alpha-1/Lung-Disease</a> February 2019
- (4) NIH Genetics Home Reference https://ghr.nlm.nih.gov/condition/alpha-1-antitrypsin-deficiency February 2013

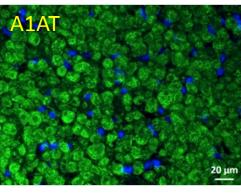


## A1AT Deficiency – Pilot Study

Hemizygous mouse disease model studies showed engraftment and functionality in a pilot study; conducting additional studies to evaluate durability and functionality of tissues

- Key evidence of synthetic function detectable in blood serum (albumin, fibrinogen)
- Robust staining for Alpha-1 antitrypsin enzyme
- ~75% reduction in the pathologic hallmarks of the disease in treated vs. non-treated control animals<sup>(1)</sup>



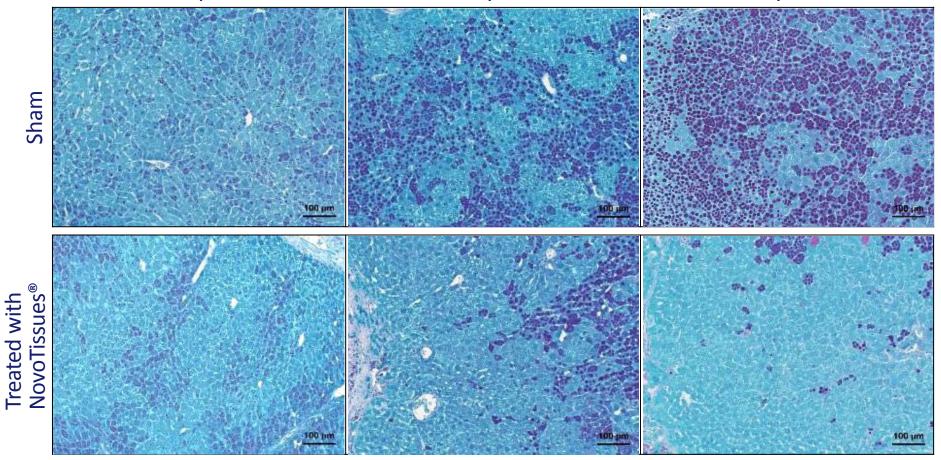


 AASLD, October 2017, Poster #805 – Long-Term Performance of Implanted Bioprinted Human Liver Tissue in a Mouse Model of Human Alpha-1 Antitrypsin Deficiency



## A1AT Deficiency-Hemizygous Mouse Pilot Study

PAS Staining Shows Reduction of Insoluble, Misfolded A1AT Variants<sup>(1)</sup>
Day 7
Day 90
Day 125



(1) AASLD, October 2017, Poster #805 – Long-Term Performance of Implanted Bioprinted Human Liver Tissue in a Mouse Model of Human Alpha-1 Antitrypsin Deficiency



## Recent Achievements – Liver Therapeutic Tissue

- Demonstrated ability to place multiple patches in rodents with successful engraftment
- o Bio-adhesives perform comparably to sutures for the attachment of liver patches
- Explored alternative placement strategies with rapid engraftment at all sites
- Confirmed engraftment on fibrotic liver in rodents (CCI4 hepatic fibrosis model)
- Commenced evaluation of placement of prototype clinical trial-sized patches in large animal study (pig)
- Confirmed beneficial impact in a disease model of A1AT (PiZ mouse model of A1AT deficiency)



## Safety Margins With Primary Cells

- No adverse effects detected to date on liver enzymes or histology in over 500 treated animals
- Primary cells (normal human cells used in liver transplant) not expected to lead to uncontrolled proliferation or tumors
- Hepatocyte transplantation of primary cells has been used in over 100 patients (historical studies)
- Patients will require immunosuppression
- Definitive toxicology studies still to be conducted





## Procurement of High-Quality Human Cells

#### Supports R&D mission and revenue contributor

- Provisions and delivers a broad range of specialized human liver cells in demand for customer's research programs
- Strong partnership with IIAM for receiving donated organs designated for research and clinical use
- Samsara team has collective experience processing more than 3,000 donated livers

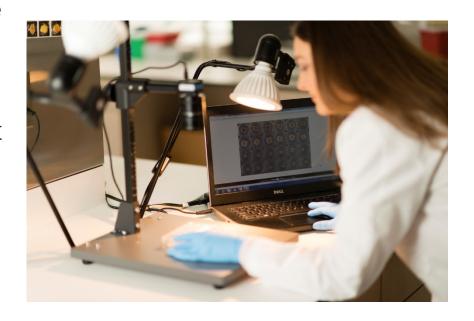




## ExVive™ In Vitro Testing Platform

Supports drug discovery & development; selectively pursuing collaborative, revenue-generating agreements

- "Patient on a plate"
- Create living tissues that emulate key aspects of human biology and disease
- Facilitate breakthrough translational research from target discovery to high-value drug profiling including custom NASH modeling
- Only 3D bioprinted tissue model that provides "gold standard" histology data readout

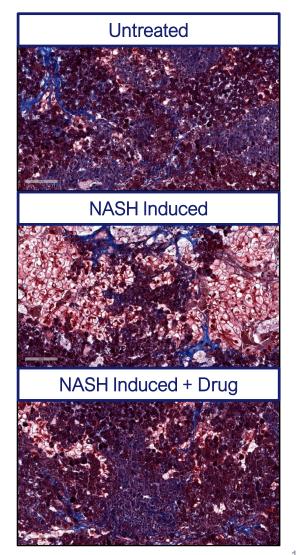




#### "NASH-in-a-Dish"

#### Proof-of-concept studies for drug testing

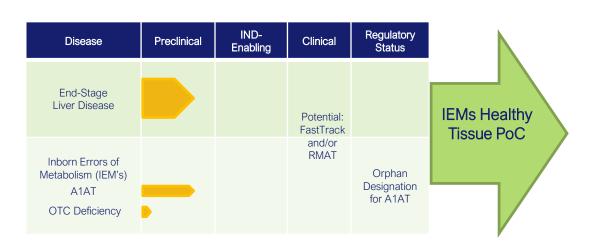
- Non-alcoholic fatty liver disease
   ("NAFLD") was induced in Organovo's
   3D bioprinted liver tissue model
- Diseased tissues were treated with a leading clinical compound – reduced disease phenotype (fat accumulation)<sup>(1)</sup>
- Proof-of-concept studies supported by NIH grant in collaboration with UC San Diego



(1) 2019 NASH-TAG Conference (Oral Presentation by Dr. David Brenner – UC San Diego - <a href="https://www.nash-tag.org/">https://www.nash-tag.org/</a>)



## Proof-of-Concept Fuels Expanding Pipeline













#### **Future Opportunity**

Disease	Preclinical
Liver Disease	
Kidney Disease	
Cardiovascular	
Ophthalmology	
Other	





Financial Overview

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## Key Financial Metrics & FY20 Outlook

Key Financial Met	(\$M)	
Cash & Cash Equivalents	\$36.5	
FY20 Outlook <sup>(2)</sup>		
Net Cash Utilization	\$20.0 million – \$22.0 million	

<sup>(2)</sup> Guidance speaks only as of the date it was originally provided (May 22, 2019). Inclusion of guidance herein should not be interpreted as a re-affirmation by Organovo of its guidance. Organovo undertakes no obligation to update its guidance after the date it was originally provided.



<sup>(1)</sup> As of 3/31/2019



Appendix

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## NovoGen Bioprinting Process

#### Emulate key aspects of human biology and disease



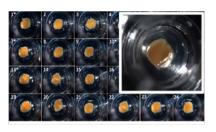


- o Multicellular
- o Cell:Cell
- o Cell:Hydrogel



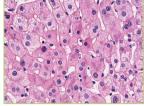
#### NovoGen Bioprinter® Platform (MMX-07)

- o Biocompatible
- Multimodal
- Spatial control



#### 3D Human Tissues

- 100% cellular Reproducible
- Scalable
- Durability (4 weeks in vitro)



#### **Human Cells**

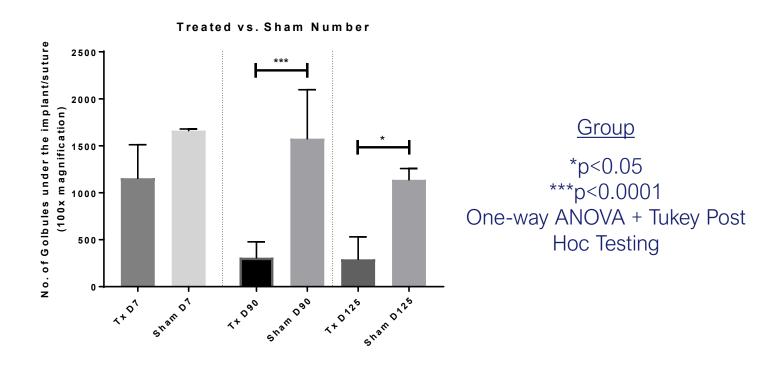
- o Primary or iPS
- Normal or diseased





## A1AT Deficiency in Hemizygous Mouse Model

Decrease in toxic globules near implant at 90 days and 125 days<sup>(1)</sup>



<sup>(1)</sup> AASLD, October 2017, Poster #805 – Long-Term Performance of Implanted Bioprinted Human Liver Tissue in a Mouse Model of Human Alpha-1 Antitrypsin Deficiency



#### IP Portfolio

#### A strong IP portfolio strengthens our first mover advantage

- Own or exclusively license approximately 100 patents and pending applications worldwide
- Exclusive licenses to foundational patents with early priority dates from three major U.S. universities
- Patent filings relate to bioprinting technology and its various uses in tissue creation, use in drug discovery and specific tissue constructs
- Potential opportunity for outlicensing revenue







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