

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): January 13, 2020

**TransMedics Group, Inc.**  
(Exact Name of Registrant as Specified in Charter)

Massachusetts  
(State or Other Jurisdiction  
of Incorporation)

001-38891  
(Commission  
File Number)

83-2181531  
(I.R.S. Employer  
Identification No.)

200 Minuteman Road  
Andover, Massachusetts 01810  
(Address of Principal Executive Offices, and Zip Code)

(978) 552-0900  
Registrant's Telephone Number, Including Area Code

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, no par value per share	TMDX	The Nasdaq Stock Market LLC (The Nasdaq Global Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

**Item 7.01 Regulation FD Disclosure.**

The Company is furnishing as Exhibit 99.1 to this Current Report on Form 8-K an investor presentation which may be used, in whole or in part, and subject to modification, on January 13, 2020 and at subsequent meetings with investors or analysts.

The information in this Item 7.01 (including Exhibit 99.1 attached hereto) is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Cautionary Note Regarding Forward-Looking Statements.** The Investor Presentation contains forward-looking statements that involve certain risks and uncertainties that could cause actual results to differ materially from those expressed or implied by these statements. Please refer to the cautionary notes in the Investor Presentation regarding these forward-looking statements.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Investors Presentation, dated January 13, 2020</a>

**SIGNATURE**

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 hereunto duly authorized.

**TRANSMEDICS GROUP, INC.**

Date: January 13, 2020

By: /s/ Stephen Gordon

Name: Stephen Gordon

Title: Chief Financial Officer, Treasurer and Secretary

## Organ Care System (OCS™)

# Redefining What's Possible in Organ Transplantation



**Paradigm shifting technology**  
that is transforming organ transplantation  
to a more dynamic environment



The OCS is the only technology platform  
addressing lung, heart and liver transplant therapy



## Cautionary Note Regarding Forward-Looking Statements

This presentation contains forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, including statements about our results of operations, commercial opportunity and the rate of adoption and benefits of the OCS. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement. Applicable risks and uncertainties include those related to our anticipation that we will continue to incur losses in the future; our potential need to raise additional funding; our existing and any future indebtedness, including our ability to comply with affirmative and negative covenants under our credit agreement, and our ability to obtain additional financing on favorable terms or at all; the fluctuation of our financial results from quarter to quarter; our ability to use net operating losses and research and development credit carryforwards; our dependence on the success of the OCS; the rate and degree of market acceptance of the OCS; our ability to educate patients, surgeons, transplant centers and private payors of benefits offered by the OCS; our ability to improve the OCS platform; our dependence on a limited number of customers for a significant portion of our net revenue; the timing of and our ability to obtain and maintain regulatory approvals or clearances for our OCS products; our ability to adequately respond to FDA follow-up inquiries in a timely manner; the performance of our third-party suppliers and manufacturers; the timing or results of clinical trials for the OCS; our manufacturing, sales, marketing and clinical support capabilities and strategy; attacks against our information technology infrastructure; the economic, political and other risks associated with our foreign operations; our ability to attract and retain key personnel; our ability to protect, defend, maintain and enforce our intellectual property rights relating to the OCS and avoid allegations that our products infringe, misappropriate or otherwise violate the intellectual property rights of third parties; our expectations for the pricing of the OCS, as well as the reimbursement coverage for the OCS in the United States and internationally; regulatory developments in the United States, European Union and other jurisdictions; the extent and success of competing products that are or may become available; the impact of any product recalls or improper use of our products; our estimates regarding revenues, expenses and needs for additional financing; and the risks identified under the heading "Risk Factors" and elsewhere in the final prospectus dated May 1, 2019 related to our initial public offering, and in our quarterly report on Form 10-Q for the quarter ended September 28, 2019, which are available on the SEC's website at [www.sec.gov](http://www.sec.gov). Additional information will be made available by our quarterly reports on Form 10-Q and other filings that we make from time to time with the SEC. These forward-looking statements (except as otherwise noted) speak only as of the date of this presentation. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by applicable law.

# Organ Transplant Therapy Benefits and Challenges



## Benefits of Transplantation

### PATIENTS:

- ✓ Longer life expectancy
- ✓ Better quality of life

### PROVIDERS:

- ✓ Treatment of choice for end-stage organ failure
- ✓ Revenue growth

### PAYORS:

- ✓ Cost-effective treatment for end-stage organ failure



## Current Market Challenges

### LOW UTILIZATION:

Need to Improve Utilization of Existing Donor Organs for Transplants

### CHALLENGING CLINICAL OUTCOMES:

Need to Improve Post-Transplant Clinical Outcomes

# Organ Preservation Lacked Innovation for 4 Decades – Critical Missing Link



## Pre-Transplant Innovations

- ✓ Medical Management
- ✓ Mechanical Circulatory Support Devices
- ✓ Cardiac Synchronization Devices
- ✓ Renal Dialysis



## Post-Transplant Innovations

- ✓ Surgical Techniques
- ✓ Anesthesia & Critical Care
- ✓ Post-Operative Care
- ✓ Immunosuppressives

## Cold Storage Limits Utilization of Donor Organs and Has Been Shown to Negatively Impact Post-Transplant Outcomes



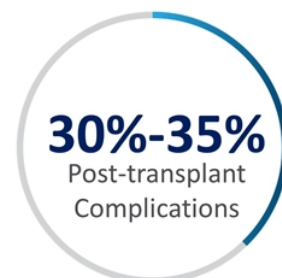
### Cold Storage

- X Severe Time-Dependent Injury (Ischemia)
- X No Organ Optimization Capabilities
- X No Assessment of Organ Viability



Significant Under Utilization

Only 2-3 out of 10 thoracic organs are used

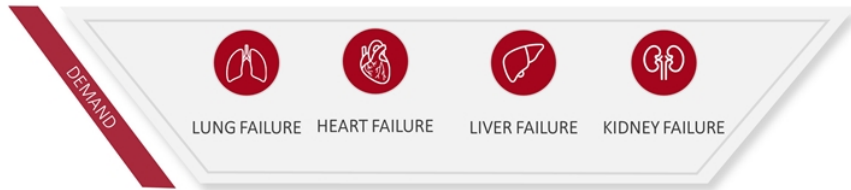


Challenging Post-Transplant Clinical Outcomes



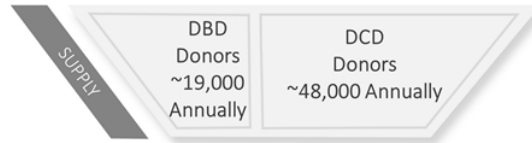
# Transplantation is a Supply Constrained Market Due To Limitations of Cold Storage Preservation Method

## High Demand for More Transplants



## Large Supply of Donor Organs Exists

DBD: Donor after Brain Death  
DCD: Donor after Circulatory Death



## Significant Underutilization of Available Organs for Transplantation



DBD Donors:  
23% Lungs – 32% Heart Utilization

DCD Donors:  
<5% Lung Utilization  
0% Heart Utilization

Source: U.S. Organ Procurement and Transplant Network (OPTN) 2016 Annual Report, Institute of Medicine of the National Academy of Science (2006)

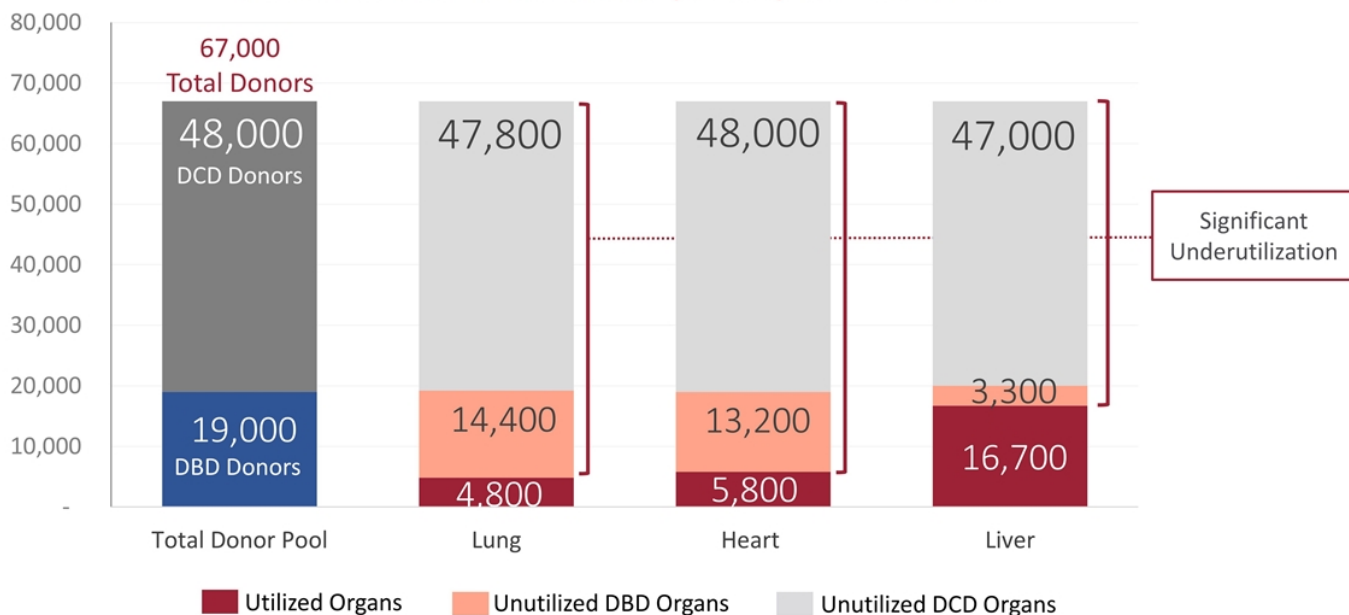
## **Organ Preservation is a Critical Weak Link**

Between Pre- and Post-  
Transplant State for  
Transplant Recipients



# Significant Market Opportunity for Currently Unutilized Organs

Estimated Annual Donor Pools: U.S., Canada, E.U. and Australia



Source: OPTN; Global Observatory on Donation and Transplantation; Institute of Medicine of the National Academy of Science (2006)

# TransMedics Organ Care System (OCS™) – Transforming Organ Transplantation

## OCS

- ✓ Significant Reduction in Ischemia
- ✓ Enable Organ Optimization Outside of the Human Body
- ✓ Allow for Organ Viability Assessment

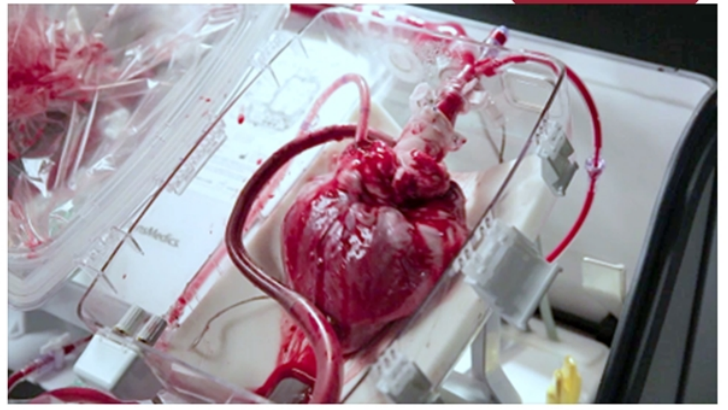


81-87% Utilization of Donor Lungs & Hearts



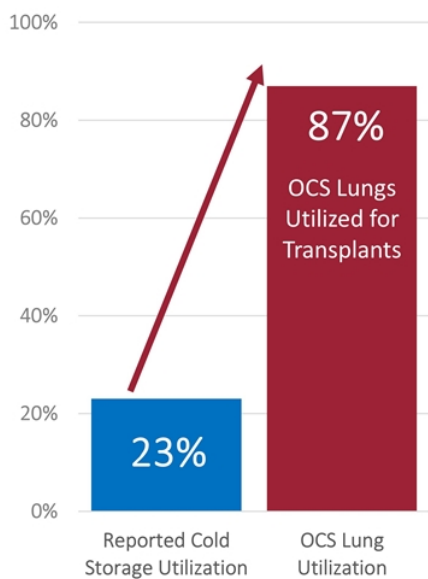
**10-14%**  
Post-transplant Complications

Significant Improvement of Clinical Outcomes

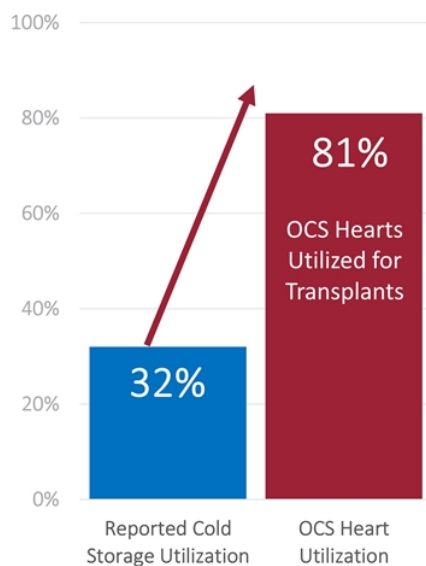


# The OCS™ Impact on Donor Organ Utilization

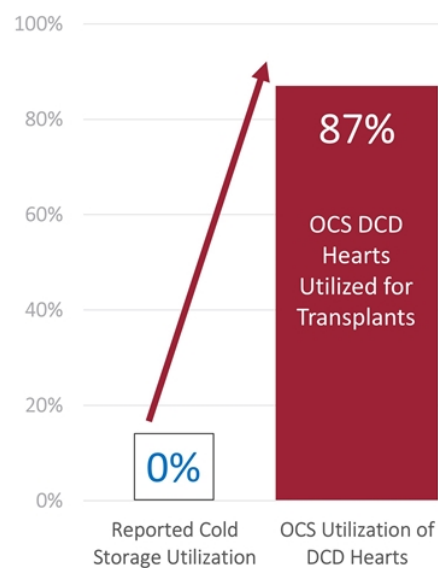
**OCS Lung EXPAND Trial Results**



**OCS Heart EXPAND Trial Results**



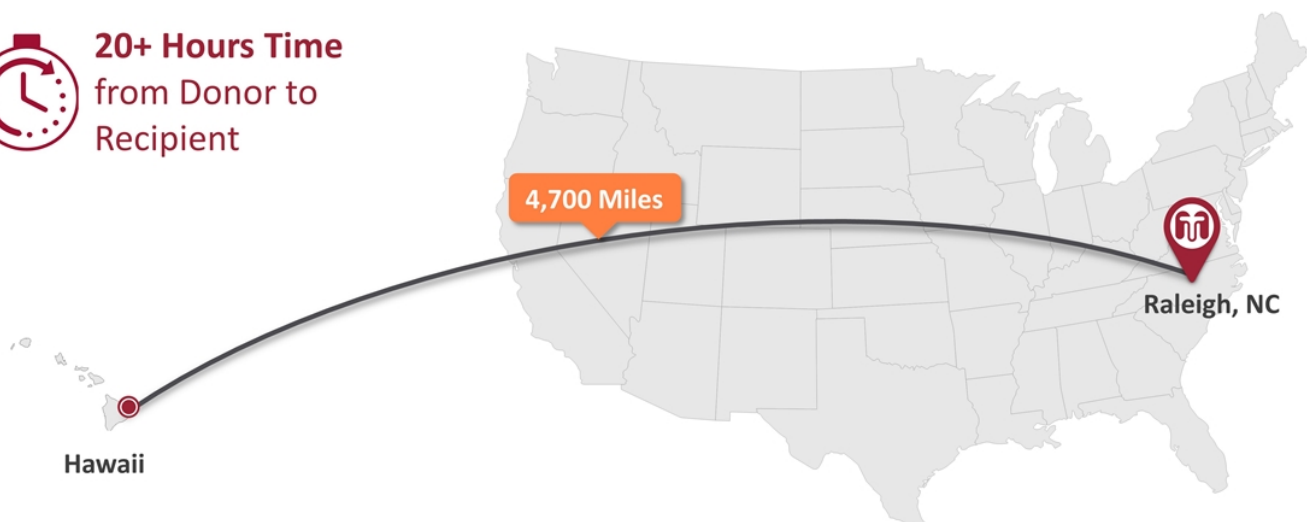
**OCS Heart OUS Commercial Use**



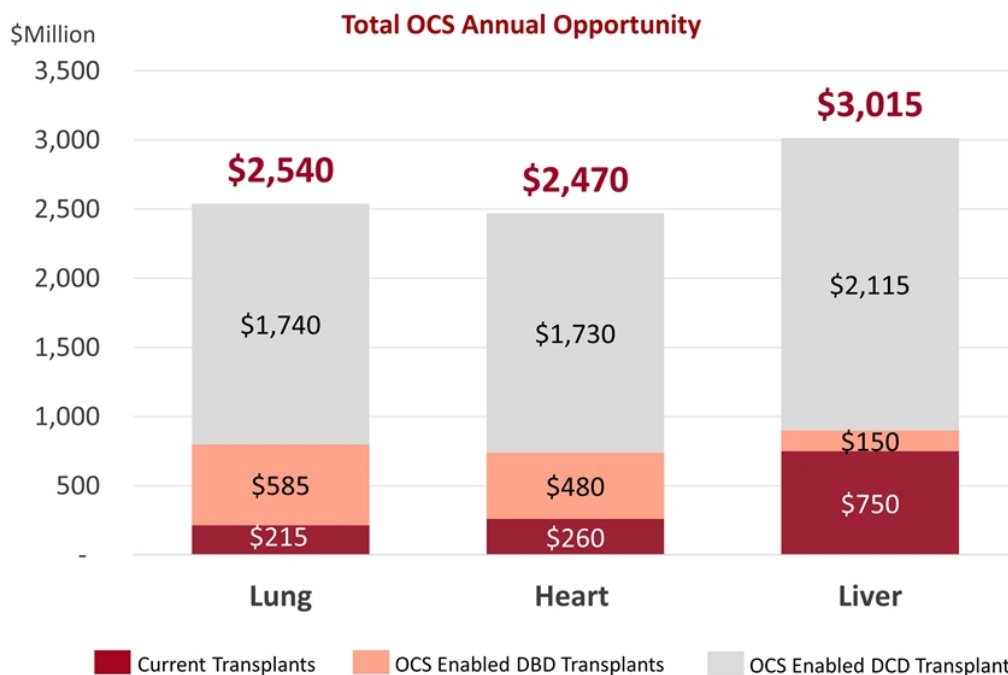
# Pushing Historical Boundaries of Cold Storage



**20+ Hours Time**  
from Donor to  
Recipient



# OCS™ Enables an \$8.0 Billion Potential Annual Opportunity





## Significant Multi-Organ Opportunity with Proven Evidence

### OCS™ Lung

~\$2.5 Billion Potential Opportunity

**87%** Utilization of lungs currently unused from DBD & DCD donors – good outcomes

**50%** Reduction of severe post-transplant complications

### OCS™ Heart

~\$2.5 Billion Potential Opportunity

**81%** Utilization of DBD hearts currently unused – good outcomes

**65%** Lower\* severe post-transplant complications

**ONLY** Technology to enable successful DCD heart transplants – hearts **NEVER** used before OCS

### OCS™ Liver

~\$3 Billion Potential Opportunity

**PROTECT Liver Trial** Completed enrollment – 300 patients

**PMA** To be filed H1 2020

↑ Hospital Profit Margin and ↑ Hospital Top-Line Transplant Revenue

\* Nicoara A., et al. Primary graft dysfunction after heart transplantation: Incidence, trends, and associated risk factors; Am J Transplant. 2018;18:1461–1470.

# OCS™ Product Offering – Disposable-Driven Business

## Hardware



OCS Console

## Single-Use Disposables



OCS Perfusion Set



OCS Solutions

# Key Market Drivers

## Clinical Users Transplant Centers

- Increase transplant volume
- Achieve better clinical outcomes
- Drive revenue and margin
- Achieve center of excellence status with payors
- Meet CMS performance metrics for outcomes

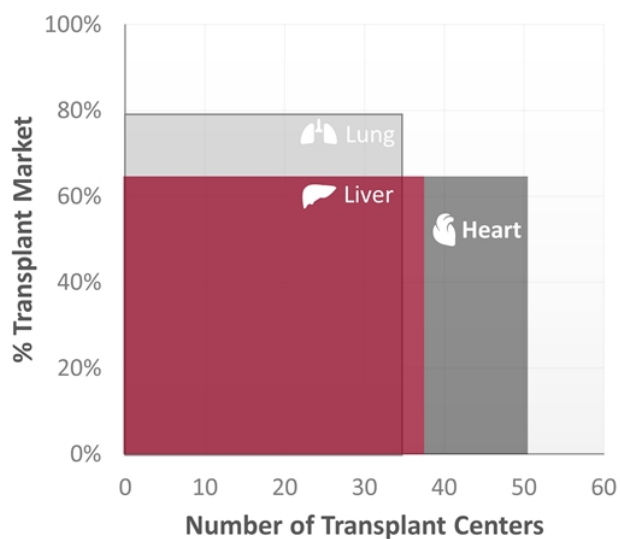
## Organ Procurement Organizations


- Utilize and allocate more donor organs for transplantation
- Meet their performance standard by CMS
- Drive revenue

## System Wide CMS, UNOS & HHS

- Utilize and allocate more donor organs for transplantation
- National allocation of organs to maximize utilization
- Drive OPOs to utilize more organs or lose CMS payments
- Drive more cost-effective organ transplants

# Ultraconcentrated Industry With Significant Overlap Between Organs




  
**~50-55 Transplant Centers Drive 70% of Lung, Heart and Liver Transplants in the U.S.**

Sources: OPTN Annual Report 2016, Global Observatory on Donation & Transplantation 2017 Newsletter



# TransMedics Strategy

## Deeper Clinical Adoption/Utilization

- Leverage the existing clinical knowledge base already in place to drive deeper utilization before expanding into new centers
- Use post-market registries to drive deeper adoption & expand clinical indications
- Minimize logistical barriers to broader adoption

## Organ Procurement Organizations

- Expand awareness of OCS™ positive impact on donor organ utilization
- Expand our offering to OPOs to leverage the clinical benefits of OCS to improve utilization rates of DBD and DCD organs
- Minimize logistical barriers to broader adoption

## System Wide CMS, UNOS & HHS

- Expand awareness of OCS positive impact on donor organ utilization
- Active engagement to coordinate national efforts to maximize donor organ utilization

# Potential Economic Benefits Further Support Market Adoption Positive System-Wide Impact for Multiple Stakeholders



Improved access to cost effective organ transplant treatment



Reduction of waiting list costs to payors



Reduction of complications improves margin and reduces payors exposure



Significant revenue growth for hospitals



**National Medicare Coverage**  
for OCS™ Lung, Heart and Liver  
Transplants Already Achieved During  
U.S. Pivotal Trials & Lung  
Commercialization

## Potential Growth Catalysts anticipated for 2020 & Beyond

### **OCS™ Lung**

- Continue to Drive Deeper Adoption and Utilization of OCS Lung

### **OCS™ Heart**

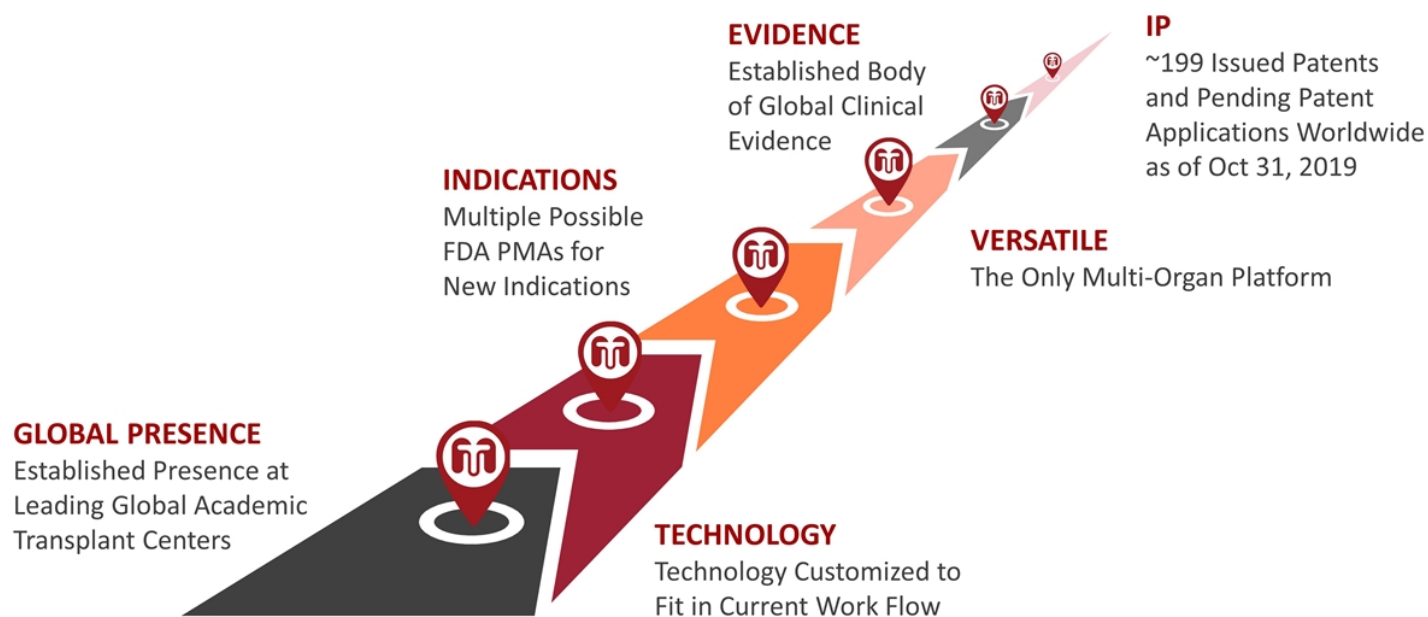
- FDA Panel in Q1
- FDA PMA Approval Q2
- U.S. Launch DBD Indication Q3
- OCS Heart DCD Trial – Actively Enrolling (10/55 patients transplanted to date)

### **OCS™ Liver**

- File PMA to FDA Q2
- PROTECT Trial Readout Q2
- Launch OCS Liver DCD Trial & CAP Protocol to Drive Clinical Momentum Q2



# TransMedics – Distancing from the Competition



## TransMedics: Significant Growth Opportunity

\$8 Billion Greenfield Opportunity

2 FDA PMAs Approved  
1 PMA Under Review &  
1 Planned for 2020

Paradigm Shifting Platform Technology

Disposable-Driven Business Model

Large Body of Clinical Evidence

Established U.S. Reimbursement

**1,500+ Patients** Have Received Life-Saving Organ Transplants Using TransMedics Organ Care System (OCS™) Technology



**Organ Care System (OCS™)**  
Redefining What's Possible  
in Organ Transplantation

