# 2020 MDT INVESTOR DAY

## Session 2: Creating & Disrupting Big Markets

## Key Takeaways

OCTOBER 14, 2020

Medtronic

### *Surgical Robotics*

*Key Takeaways*

- Reiterating timeline: we're targeting CE Mark and U.S. IDE filing in 1Q CY2021
- Customer feedback continues to be excellent
- Our system designed to address two biggest barriers in robotic adoption: cost and utilization
- We believe that robotic technology, paired with data and analytics, can help reduce unwanted variability, improve patient outcomes, and, by extension, lower per-procedure cost
- By offering robotic systems alongside open and laparoscopic solutions, we will empower surgeons with unprecedented choice in trusted surgical technology and performance

*Digital Surgery*

- We're entering the robotics market now with the launch of Touch Surgery Enterprise.
- Touch Surgery Enterprise is artificial intelligence and image capturing platform that turns surgical video into CGI interactive training applications with future capabilities in instrumentation and anatomical tracking and procedural analytics.
- Touch Surgery Enterprise placements will support the acceleration of our robotic system installations, once cleared, allowing customers to realize the combined value of our surgical robotics and data and analytics solutions.

*Revenue Impact*

- Reiterated incremental contribution to MITG revenue growth first given at Medtronic Robot Investor Day in Sept. 2019:
    - FY21: <50 bps
    - FY22: 100-150 bps
    - FY23: 200-250 bps

### *Renal Denervation*

*Key Takeaways*

- We expect RDN to be a $1B market by 2026 growing to $3B by 2030

- We are developing a robust body of evidence to support RDN regulatory and reimbursement approvals.
- Recent data from the Global Registry demonstrate not only durability, but a continued increase in treatment effect with demonstrated reduction in blood pressure to just under 17 mm Hg at 3 years in a real-world population
- Plan is to present ON MED data at a major medical meeting in CY21, followed by approval in CY22.
- China Opportunity: Medtronic has been granted Green Channel priority review; positions for potential approval in China within a few months of U.S. approval

*Market Data*

- Hypertension affects 1/3 of adults globally and is the single largest contributor to death
    - About 1/2 of all diagnosed patients are non-adherent to their medical therapy within a year of initiating
    - About 2/3 remain uncontrolled despite the availability of pharmaceutical drugs
- We believe RDN will be a $1B global market by 2026
    - Could be a $3B market by end of decade; represents <1% penetration of expanded hypertension market
- Zero device or procedure-related major adverse events through 3 months in 3 RCTs

*Global Hypertension Segments*

- 150mmHg+ & 3+ Meds: 2M patients
- 150mmHg+: 18M patients
- 140mmHg+: 37M patients
- Global Unmet Needs
    - U.S.: 2.6M
    - Western Europe: 5M
    - China: 3M
    - Other: 7.4M

*OFF-MED Study*

- Met its primary efficacy endpoint and had no safety signal
- Reported office BP reductions of 9.2 mm Hg; statistically significant and highly clinically meaningful

*ON-MED Study*

- Goal is to present ON MED data at a major medical meeting in calendar 2021

- Goal of U.S. approval some time in CY 2022

*Global Symplicity Registry Study*

- Demonstrated durability, with reductions of BP 16.7 mm Hg at 3 years in a real-world population
    - 13.3 Hg at 6 months
    - 14.0 Hg at 1 year
    - 15.3 Hg at 2 years
    - 16.7 Hg at 3 years

*AFFIRM Study*

- We plan to initiate a study which will enroll a broad population in the US and collect data on typical treatment pathways

*Reimbursement*

- Breakthrough Device designation. Proposed rule from CMS would provide 4 years of Medicare coverage upon FDA approval.

*China Opportunity*

- Medtronic has been granted Green Channel priority review; positions for potential approval in China within a few months of U.S. approval
- 1.5M patients with a blood pressure above 150 mmHg and on 3 or more drugs

## *Cardiac Ablation Solutions*

*Key Takeaways*

- Medtronic has an opportunity to meaningful disrupt the $6B EP ablation market with its DiamondTemp ablation catheter followed by Pulsed Field Ablation.
- Medtronic has a history of disruption in this market, growing a <$50M business in FY08 to ~$700M in FY20.
- Expect ablation market to grow to >$8B by 2024.

*Cryoablation*

- ~38M patients worldwide diagnosed with atrial fibrillation
    - 30% of patients are eligible for ablation today
    - New clinical results have the potential to support early intervention with cryoablation, which would increase addressable market for AF ablation by 6M patients
- Recently received FDA approval to treat patients with Persistent AF with Arctic Front cryoablation

  - First system to receive a Persistent AF indication

- Plan to submit for "first line" therapy indication this fall
  - Using data from Stop AF First randomized controlled clinical trial
  - Demonstrated Medtronic cryoablation superiority with 75% freedom from AF
  - Compared to only 45 percent freedom from AF for antiarrhythmic drugs at 12 months
  - Trial met primary safety endpoint reinforcing the strong safety profile of Cryoablation

*DiamondTemp*

- Launched in limited European markets
- Collecting evidence to receive regulatory authorization to expand launch globally
- Currently under FDA review; if approved, targeting U.S. launch in 1H CY2021
- DIAMOND AF I trial is complete and expect publication soon
- DIAMOND AF II trial will complete enrollment this calendar year (2020)

*Pulsed Field Ablation*

- Could completely disrupt $6B EP ablation market
- PFA uses pulsed electric fields to ablate cardiac tissues through irreversible electroporation. Rather than heating or freezing the cells, the electrical fields destroy the cardiac cells causing the arrhythmia by making the cell membranes permeable, which leads to cell death.
- PFA does not require tissue contact because it is field based. This means lesions can be created in areas that are difficult to access with traditional catheters that require direct tissue contact.
- PULSED AF pivotal trial expected to commence enrollment early in CY 2021
  - In feasibility trial, pulmonary vein isolation was achieved in 100 percent of patients studied with no complications
- Allows for ablations in milliseconds vs minutes for other energy sources
- Received breakthrough device designation from FDA

## *Peripheral Vascular*

*Key Takeaways*

- Medtronic has the opportunity to redefine the markets for AV fistula creation and maintenance in dialysis patients
- IN.PACT AV is the first and only drug-coated balloon (DCB) to meet both its safety and efficacy endpoints in an AV access trial

- Medtronic announced acquisition of Avenu last month. Avenu's Ellipsys system is an innovative, image-guided, single catheter system used to percutaneously create an AV fistula for hemodialysis access
- Both IN.PACT AV and Ellipsys have the potential to become standard of care, and represent a $900M market opportunity in the U.S. alone

*Market Data*

- 2M dialysis patients globally
    - Majority of patients with end stage renal disease undergo dialysis ~3x per week
- Surgical fistulas have very poor success rates; estimated less than half used consistently for dialysis
- Requires 1-3 maintenance interventions per year to keep their AV fistula functioning
- $5B annual estimated U.S. dollars spent on vascular access and related complications

*IN.PACT AV DCB*

- Received FDA approval for IN.PACT AV DCB in November 2019
    - First approval of a DCB in a new vessel bed since paclitaxel safety panel
- IN.PACT AV is the first and only DCB in this vessel bed to meet both its safety and efficacy endpoints
    - IN.PACT AV DCB reduces the number of reinterventions required to maintain vessel patency 56%
    - 78% highest reported access circuit primary patency
    - 86% highest reported access lesion primary patency
    - No difference in mortality rates between the IN.PACT AV DCB and PTA through 12 months

*Avenu Medical*

- Medtronic announced the acquisition of Avenu last month
- Avenu's Ellipsys Vascular Access System creates an immediate and durable connection between an adjacent artery and vein
    - The system uses ultrasound guidance to insert a catheter through an arm vein that is then advanced to an artery, creates an anastomosis
    - Unlike surgery, there's no incision or suture the patient leaves with an adhesive bandage, just as if they had their blood drawn
    - 91.6% functional patency at 2 years
    - 23 Minutes Average procedure time
    - 0 device related serious adverse events

- Ellipsys is available today in the U.S. and EU
- Ellipsys percutaneous AVF's demonstrated significantly shorter procedure times without a need for radiation exposure and with superior secondary patency compared to Becton Dickinson's WaveLinQ

## *Transcatheter Mitral & Tricuspid*

### *Key Takeaways*

- Medtronic is building a transcatheter mitral and tricuspid portfolio with the potential to disrupt the current standards of care
- Intrepid TMVR system is leading the way in the study of transcatheter replacement with positive transfemoral experience in patients with both mitral and tricuspid valve disease
    - Recently approved EFS for patients with tricuspid regurgitation
    - Redesign of APOLLO pivotal trial to accelerate enrollment and commercial application
- Together with The Foundry, created Half Moon Medical in mid-2017 to develop an innovative transcatheter mitral repair (TMVr) technology
    - Half Moon Medical's innovative posterior leaflet augmentation device has the potential to disrupt the mitral repair market

### *Market Data*

- 20M+ patients with moderate and severe Mitral & Tricuspid Regurgitation
- Combined Mitral & Tricuspid Market: $800M today; growing to $3B+ by 2025

### *Intrepid Transcatheter Valve Replacement System*

- Treated ~300 patients with Intrepid globally
- Transfemoral system is now in clinical use in an early feasibility study

### *APOLLO Pivotal Trial (Transcatheter Mitral Valve Replacement)*

- Restructured to new single-arm design from 1-to-1 randomization of Intrepid vs. Surgery
    - Will accelerate enrollment and commercial applications

### Tricuspid

- Tricuspid Market: $200M by 2025
- In the U.S., nearly 2M patients suffering from moderate to severe tricuspid regurgitation
- Intrepid Tricuspid Early Feasibility Study is enrolling and expect first implant in coming weeks

*Half Moon Medical*

- In 2017, Medtronic invested seed money and IP to create Half Moon Medical in partnership with The Foundry
    - Medtronic holds an exclusive right to acquire Half Moon, contingent upon the achievement of certain technical and clinical milestones
- Fundamentally different than the edge-to-edge technology of Abbott's MitraClip
- Potential to fully eliminate mitral regurgitation (MR)
- Half Moon received FDA approval for early feasibility study in patients with severe symptomatic MR
    - Expects to commence initial implants in coming weeks

## *Gastrointestinal*

*Key Takeaways*

- We are disrupting the colon cancer market by enhancing screening, increasing patient compliance, and improving treatment
- We are announcing today a partnership with Amazon to bring our PillCam Genius technology to market
- We intend to start our pivotal trial for PillCam Genius in FY22 and to submit for CE Mark and for FDA clearance in late FY23

*Market Data*

- 1 in 4 U.S. adults will be impacted by a GI disease in their lifetime
- GI Disease Market growing 9% per year globally
- Medtronic's GI business was ~$400M in FY20, growing high-single digits pre-COVID

*Colon Cancer*

- 2nd deadliest cancer worldwide; most preventable, but least prevented form of cancer
- 1 in 20 U.S. adults will be diagnosed with colon cancer in their lifetime
    - 90% of patients beat it when it's caught early
- >10M screening colonoscopies in the U.S. per year
- 22M people in U.S. every year that should get screened but don't
    - Millions more will need screening as the American Cancer Society dropped the age recommendation from 50 to 45

*GI Genius*

- The first commercially available artificial intelligence device for finding colorectal polyps that physicians may miss
- Helps improve the accuracy of colonoscopies and reduce the number of undetected precancerous polyps
- Now available in Europe
- Submitted a De Novo application to the FDA in September and expect to launch in the U.S. following agency approval

*PillCam Genius*

- We're taking advances in cloud technology and artificial intelligence and implementing them into our PillCam device with the aim to create the only device that can see, size, and localize pre-cancerous lesions
- Partnering with Amazon — leveraging their delivery network, customer reach, and cloud-based technologies to bring PillCam™ Genius to the market
- Intend to start pivotal trial in FY22
- Intend to submit for CE Mark and FDA clearance in FY23

*ProdiGI*

- We are simplifying Endoscopic Submucosal Dissection (ESD) with ProdiGI, an innovative endoscopic resection platform intended to help clinicians more easily remove these lesions
- Our technology is designed to enable clinicians to perform ESD therapy with more control and fewer tools
- We launched this product in the U.S. in July, and we expect CE Mark approval in the next few weeks

## *Micra & EV-ICD*

*Key Takeaways*

- Medtronic has a $3B opportunity to disrupt historically mature markets for pacemakers and ICDs.
- Unrivaled leader in leadless pacing:
    - Micra AV seeing strong adoption since U.S. approval earlier this year
    - With a full Micra portfolio, we believe the leadless pacing segment will be a $2B market by 2030, growing almost 25% annually
- Extravascular ICD (EV-ICD) is a $1B opportunity:

  - First and only ICD that uses a lead placed outside the heart in the extravascular space under the patient's sternum
  - Offers brady backup pacing and anti-tachy pacing (ATP) all in the size of a traditional ICD and with the battery life of a traditional ICD
  - This would be a huge improvement over the S-ICD, which can only deliver painful high voltage shocks.

*Market Data and Medtronic's Position*

- 70K+ patients globally have benefited from Micra since its launch in 2016
- Single chamber pacing business growth of more than 45% and unprecedented market-share gains
- Leadless pacing segment will be $2B market by 2030, growing ~25% annually
- Only company with approved leadless pacing technology on the market

*Micra Transcatheter Pacing*

- Micra VR, received CE Mark and U.S. FDA approval in 2016
  - About 15% of patients need this type of pacing
- Leadless design of Micra VR results in 63% fewer major complications for patients
- Micra AV was launched earlier this calendar year
  - Micra AV can sense two chambers from its location in the ventricle, not just one
- With the combination of Micra VR and AV, leadless pacing is an option for ~50% of all patients who require a pacemaker
- Micra AR will reside in the atrium, the upper chamber of the heart and offer pacing to those with sinus node dysfunction

*EV-ICD*

- The extravascular segment is a slow growth niche segment estimated at $300M today
- We can accelerate the Extravascular market to double digit growth; $1B by 2030
- Goal for EV-ICD to be first and only ICD that uses a lead placed outside the heart in the extravascular space under the patient's sternum
  - It will also be able to provide brady backup pacing and anti-tachy pacing
  - Medtronic EV-ICD: 33cc size; 11-year longevity
  - Boston Scientific S-ICD: 60cc size; 7-year longevity
- Completed three clinical studies and currently enrolling our global pivotal trial to support market entry in 1HCY22 in Europe; 1HCY23 in the U.S.