

Medtronic

Renal Denervation: The Next Big Thing in Cardiovascular Devices

Medtronic has a growth problem. As we've articulated previously, roughly 60% of its sales today are in businesses that over the next 3-5 years a) are unlikely to grow and b) face average annual price erosion of 4-5%. It is with this in mind that the company has stepped up its efforts in recent years to augment growth through acquisitions and entry into new markets. Some of these are well known to investors (i.e. TAVI), while others, particularly hypertension, represent new frontiers for device-based intervention. Medtronic's \$800M acquisition of Ardian in November 2010 positioned it as the leader in this emerging field, one which we expect to develop into the next big market in cardiovascular devices. Our forecast, which we outline in this report, calls for a **\$700M market by 2016, climbing to \$2.3B by 2020.**

- **Hypertension is an epidemic, affecting nearly a billion people worldwide.** In the US alone, the CDC estimates that more than 56 million adults suffer from high blood pressure, making it more common than cancer, diabetes, and coronary artery disease combined and rivaling obesity in its scope. While many patients are asymptomatic, hypertension exacts a heavy toll on the healthcare system as a major risk factor for heart disease, stroke, and renal disease. And despite the widespread use of antihypertensive meds, just 50% of US patients are well controlled, leading to significant investment in recent years to develop a device-based therapy.
- **Renal denervation may be the answer.** Medtronic's Symplicity system uses RF energy to ablate the sympathetic renal nerves, which play a critical role in regulating several functions that influence hypertension. The procedure itself is remarkably simple, lasting just 40 minutes on average. The ablation catheter is delivered to the renal arteries using standard interventional techniques and the operator performs 4-6 burns along the length of each artery to achieve denervation.
- **Clinical results to date have been more than impressive,** suggesting that this approach can have a significant impact on even the most difficult hypertension patients. In the HTN-2 trial, drug-refractory hypertensives treated with Symplicity achieved a 32 mmHg and 12 mmHg reduction at 6 months in their systolic and diastolic pressures, respectively, compared to virtually no improvement in the control arm (baseline SBP ≥ 160 mmHg or ≥ 150 mmHg with type 2 diabetes). The earlier HTN-1 study demonstrated that improvements of this magnitude are durable as well, with patients sustaining improvements of more than 30 mmHg (systolic) and 14 mmHg (diastolic) out to two years.

Medtronic, Inc. (MDT;MDT US)

| FYE Apr | 2010A | 2011A | 2012E | 2013E | 2014E | 2015E |
|-----------------------|-------|-------|-------|-------|-------|-------|
| EPS (\$) | | | | | | |
| Q1 (Jul) | 0.79 | 0.80 | 0.79A | - | - | - |
| Q2 (Oct) | 0.77 | 0.82 | 0.82 | - | - | - |
| Q3 (Jan) | 0.77 | 0.86 | 0.86 | - | - | - |
| Q4 (Apr) | 0.89 | 0.90 | 0.97 | - | - | - |
| FY | 3.22 | 3.37 | 3.44 | 3.74 | 3.92 | 4.20 |
| CY | 3.32 | 3.42 | 3.64 | 3.86 | 4.11 | 4.36 |
| Bloomberg EPS FY (\$) | 3.21 | 3.40 | 3.46 | 3.74 | - | - |

Source: Company data, Bloomberg, J.P. Morgan estimates. 'Bloomberg' above denotes Bloomberg consensus estimates.

See page 25 for analyst certification and important disclosures.

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Neutral

MDT, MDT US

Price: \$32.26

Price Target: \$39.00

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Price Performance



Company Data

| | |
|-----------------------|---------------|
| Price (\$) | 32.26 |
| Date Of Price | 05 Oct 11 |
| 52-week Range (\$) | 43.33 - 30.18 |
| Mkt Cap (\$ mn) | 34,505.30 |
| Fiscal Year End | Apr |
| Shares O/S (mn) | 1,070 |
| Price Target (\$) | 39.00 |
| Price Target End Date | 31 Dec 12 |

- **To put these results in perspective**, drug studies have demonstrated that a 5 mmHg reduction in systolic pressure in this population is associated with a 14% decrease in stroke risk, a 9% decline in the incidence of heart disease, and 7% drop in overall mortality. **A 30 mmHg improvement in systolic pressure in drug-refractory patients is, in short, remarkable.** Decades of research shows that the risk of mortality from ischemic heart disease or stroke doubles with every 20 mmHg increase in systolic pressure or 10 mmHg increase in diastolic pressure. This is what makes the potential impact of a 30 mmHg reduction in systolic pressure and a 14 mmHg reduction in diastolic pressure from a simple, easy-to-perform catheter-based procedure so profound. Unlike angioplasty and stenting, which has no impact on mortality and is a largely palliative procedure, renal denervation could have a dramatic, clinically meaningful benefit to an incredibly large and underserved population.
- **We expect FDA approval for Symplicity in drug refractory patients by early 2014, with a limited EU launch already underway.** In July, Medtronic received conditional IDE approval from the FDA to begin its HTN-3 US pivotal trial. The study is expected to enroll 500 patients at 60 US centers, with a primary endpoint of change in blood pressure from baseline at 6 months. Patients will be randomized 2:1 to either renal denervation and drug therapy or drug therapy alone. The company is also exploring the potential benefits of RDN in other disease states, including patients with heart failure, sleep apnea, and renal impairment. The connection between hypertension and each of these disease states is meaningful and makes the opportunity and potential impact of RDN much larger than just hypertension, even though that market alone is tremendous. For example, 80% of patients with drug-resistant hypertension have sleep apnea, and more than 50% of sleep apnea patients have hypertension. As a result, there are already clinicians in Europe looking at the potential impact of RDN on OSA patients. At the same time, Medtronic is preparing to launch the SYMPPLICITY HF study, a feasibility trial of RDN in class II/III heart failure patients. Enrollment is expected to start in the next few weeks. Meanwhile, Medtronic continues to make progress on its European launch, with an initial focus on Germany, which is the one country where the company now has formal reimbursement.
- **Renal denervation has the potential to be a multi-billion dollar market.** We estimate that 45 million US adults will be on antihypertensive meds by the time Medtronic launches Symplicity domestically in 2014. Even with continued improvement in the efficacy of drug therapy, however, more than a quarter of these patients will not be able to achieve their target blood pressure range with medication alone and close to 2 million are likely to still have Stage II hypertension or worse despite a multi-drug regimen. Even after making conservative assumptions for anatomical restrictions and other co-morbid conditions that could preclude interventional treatment, we still estimate that this leaves a initial, on-label target population of 1.2 million patients in the US alone. Assuming a \$6,000 ASP, this implies an initial market opportunity of \$7 billion. This is before considering potential applications for RDN in earlier patients (e.g. SBP 140-160mmHg) or in markets such as heart failure, renal insufficiency, or sleep apnea.
- **The key question for Medtronic, in our view, is how long it will be able to keep this opportunity to itself.** Already, more than half a dozen companies (both public and private) have either announced their intention to develop a RDN system or have taken steps which indicate that they plan to in the near future. Of the public competitors, we believe that St. Jude is the furthest along clinically, with details on its technology and early animal data scheduled to be presented at the TCT conference in November. **St.**

Jude's first-in-man trial, called ARSENAL, is also days away from beginning enrollment. ARSENAL is a 60 patient trial scheduled for 6-month follow-up with a CE Mark submission expected to occur shortly thereafter (JPM estimate: 3Q12), followed by the start of a US trial (JPM estimate: 4Q12-1Q13). Over time, we believe that Boston Scientific, J&J, C.R. Bard, and Abbott could also look to enter the space. Meanwhile, a number of private companies are pursuing novel approaches to the therapy, including the use of alternative energy sources, targeted drug delivery, and even non-invasive technologies.

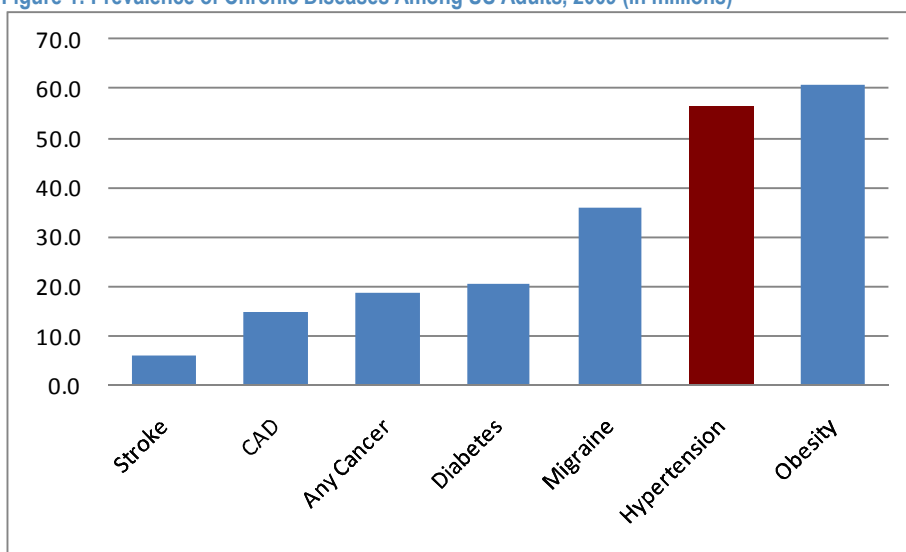
- **In the end, it will likely be up to the courts to determine how big a lead Medtronic is afforded.** Management cited Ardian's intellectual property portfolio as a key factor in its decision to go the M&A route as opposed to pursuing an internal development pathway and the company owns a wide array of patents reading on the concept of catheter-based renal denervation. As MedTech investors are well aware from the DES wars, a solid IP position isn't always enough to dissuade competition. However, we expect Medtronic to be aggressive in asserting its rights, and for the battle around the Ardian IP to be as intense as any we've seen in the cardiovascular space.
- **For Medtronic, the value of intellectual property and its ability to keep out competition will dictate whether this is a \$1.0B or \$2.0B opportunity by 2020.** With a >\$16B top line, it's not easy to move the needle at Medtronic. However, renal denervation is a market opportunity that can do just that and has the potential to be one of the most compelling new growth segments in MedTech over the next decade. While competition is clearly a risk given the simplicity of the underlying technology, we believe that Medtronic is entering the field from a position of strength. We expect investor focus on Ardian's progress to increase going forward, driving improving sentiment on the company's long-term growth potential.

Renal Denervation: The Next Big Thing

Hypertension Background

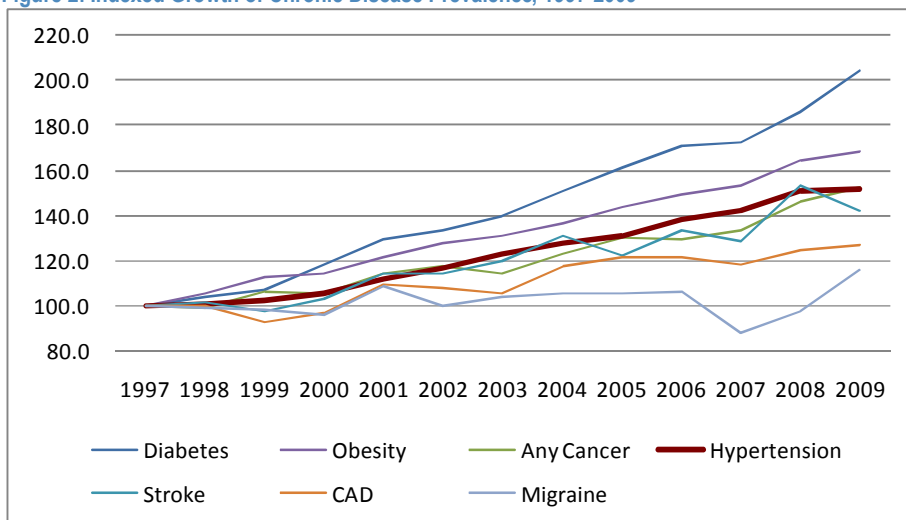
Hypertension, or high blood pressure, is one of the most common chronic diseases in the world today, affecting approximately 970 million individuals globally according to the World Heart Federation. In the US, the CDC estimates that more than 56 million adults are hypertensive, making it more common than cancer, diabetes, and coronary artery disease combined and rivaling obesity in its scope. The frequency of the disease is increasing as well, with hypertension now affecting 25% of US adults up from just 19% in 1997.

Figure 1: Prevalence of Chronic Diseases Among US Adults, 2009 (in millions)



Source: National Health Income Survey 2009

Figure 2: Indexed Growth of Chronic Disease Prevalence, 1997-2009



Source: National Health Income Survey 2009

High blood pressure is a major risk factor for heart disease, stroke, congestive heart failure, and renal disease. According to the CDC, hypertension was listed as a primary or contributing death of 326,000 Americans in 2006, with the total cost of the disease to the healthcare system estimated at more than \$76B last year. The AHA estimates that cardiovascular mortality risk doubles for every 20mmHg increase in systolic blood pressure above 115mmHg. Conversely, a 5 mmHg reduction in systolic pressure for a hypertensive patient is associated with a 14% decrease in stroke risk, 9% decline in the incidence of heart disease, and 7% drop in overall mortality.

Hypertension is generally defined as a sustained systolic (maximum) pressure of 120mmHg or more and/or diastolic (minimum) pressure of greater than 80mmHg. As Table 1 shows, hypertensive patients can be divided into categories based on the severity of their disease, with pre-hypertensive and Stage I patients usually prescribed lifestyle modifications such as weight loss, exercise, and dietary changes (reduced salt, increased potassium). Patients with more significant disease are generally treated with a cocktail of drugs, including diuretics, ACE inhibitors, beta blockers, calcium channel blockers, and angiotensin II receptor antagonists. According to IMS's 2010 annual report, each of these drug classes was among the top 20 most prescribed categories in the US, with more than 674 million scripts combined (~17% of all US Rx volume).

Table 1: Classes of Essential Hypertension

| Category | Sustained Blood Pressure Ranges | | Comment | Current Treatment Options |
|----------------------------------|---------------------------------|-------------------|---|--|
| | Systolic | Diastolic | | |
| Normal Blood Pressure | < 120 mmHg | and/or < 80 mmHg | | |
| Pre-hypertension | 120-139 mmHg | and/or 80-89 mmHg | | Lifestyle Modification |
| Mild Hypertension (Stage I) | 140-159 mmHg | and/or 90-99 mmHg | Signs include tachycardia and increased cardiac output, but patients are asymptomatic | Lifestyle Modification |
| Moderate Hypertension (Stage II) | > 160 mmHg | and/or > 100 mmHg | Warning signs increase but end organ damage has yet to materialize | Lifestyle Modification & Antihypertensive Rx |
| Severe Hypertension (Stage III) | > 180 mmHg | and/or > 110 mmHg | Patient begins to exhibit end organ damage, including LV enlargement and renal insufficiency, and micro hemorrhages of ocular blood vessels | Antihypertensive Rx |

Source: American Heart Association

Despite the widespread use of antihypertensive meds, however, many patients are not able to control their disease. According to the CDC's National Health and Nutrition Examination Survey (NHANES), just 50% of US hypertension patients were well controlled in 2007-2008 (see Table 2). This was up from just 25% in 1988-1991, due to a combination of improved awareness (81% vs. 69%), higher medical treatment rates (73% vs. 52%), and improved treatment efficacy (69% vs. 47%).

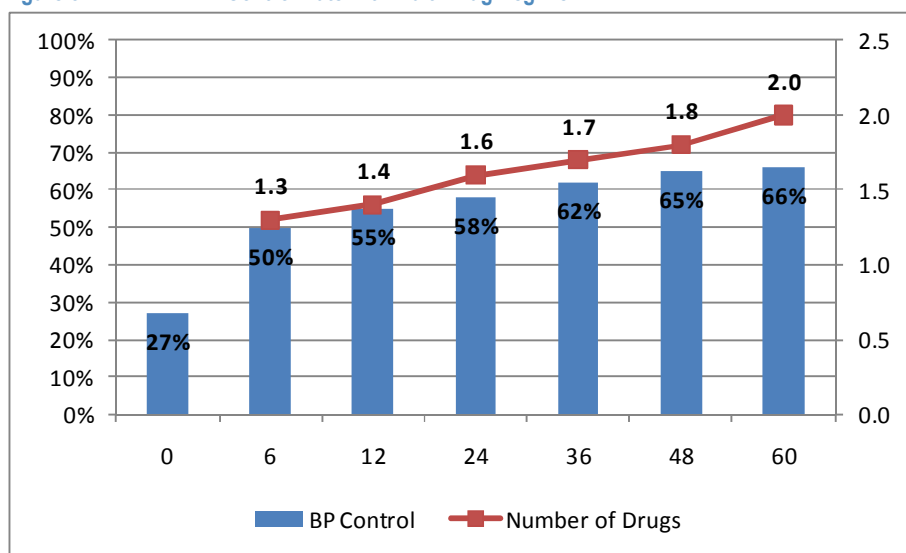
Table 2: Trends in US Hypertension Treatment (1988-2008)

| | 1988-1991 | 1991-1994 | 1999-2000 | 2007-2008 |
|--|--------------|--------------|--------------|--------------|
| Aware (as % of prevalence) | 69.2% | 67.8% | 68.9% | 80.7% |
| Medically Treated (as % of prevalence) | 52.4% | 52.0% | 58.4% | 72.5% |
| Controlled (as % of treated) | <u>46.9%</u> | <u>43.6%</u> | <u>53.0%</u> | <u>69.1%</u> |
| Controlled (as % of prevalence) | 24.6% | 22.7% | 31.0% | 50.1% |

Source: NHANES

However, despite this impressive improvement, the majority of which was achieved in just the past decade, half of all hypertension patients today still fail to achieve their target levels. In many cases this is despite good compliance with a multi-drug treatment regimen, a condition known as drug-resistant hypertension (DRH). Studies suggest that 20-30% of the hypertensive population may be drug resistant. The ALLHAT trial enrolled more than 33,000 patients from 1994 to 1998 with an average baseline BP of 145/83mmHg. At five years of follow-up, only 67% were able to achieve adequate BP control (see Figure 3). This was despite a) these patients being relatively healthy (just 14% had baseline SBP >160mmHg) and b) an average treatment regimen of two drugs per patient (27% were on three or more).

Figure 3: ALLHAT – BP Control Rate with Multi-Drug Regimen



Source: Cushman, et al. J Clinical Hypertension 2002; 4:393-404

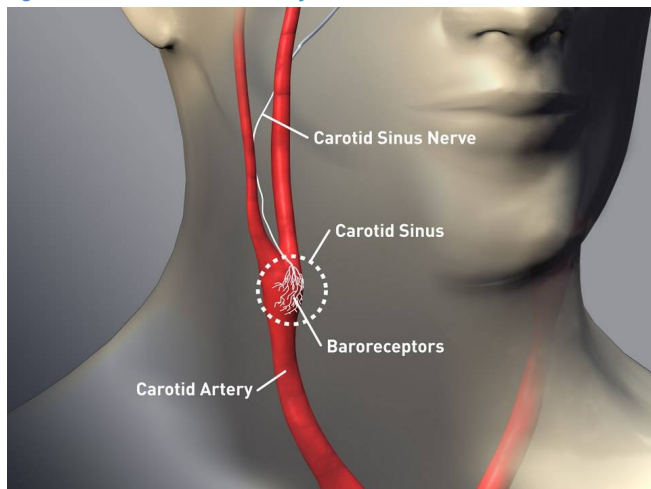
Finding a Device-Based Solution Has Proven Challenging

Given this large unmet medical need, there has been substantial interest in recent years in finding a device-based solution for DRH. Privately-held CVRx has raised more than \$200M in venture capital to date to fund the development of its Rheos neuromodulation technology, which seeks to treat persistent hypertension by activating baroreceptors on the carotid arteries. This essentially tricks the brain into perceiving a spike in blood pressure and elicits a hormonal response that leads to vasodilation. Early results with this technology were encouraging, demonstrating a sustained systolic blood pressure reduction of 35-40mmHg out to two years in extremely sick patients.

However, at the ACC conference in April, mixed results were presented from the company's US pivotal trial. This study enrolled 265 patients who had a mean sustained BP of 179/103mmHg at baseline, despite taking an average of 5.2 antihypertensive medications. All patients were implanted with the system and were then randomized 2:1 to either an ON or OFF group for the first six months, after which OFF patients were allowed to cross over. While the trial met 3 of its 5 co-primary endpoints, it failed to demonstrate either a) a difference in short-term acute response between the two arms, defined as a >10mmHg reduction in SBP at 6 months (54% vs. 46%; p=0.97) or b) an acceptable short-term procedural event rate

(25% vs. pre-specified performance goal of 18%) due to reports of nerve injury, surgical complications, and respiratory complaints. On the other hand, the long-term efficacy of the system appeared robust, with 88% of all patients deemed responders at 12 months of follow-up vs. the 65% performance criteria ($p < 0.001$). The study also met its endpoints for a) short-term complications related to the therapy itself and b) long-term adverse events.

Figure 4: Carotid Sinus Anatomy



Source: CVRx

Figure 5: CVRx Barostim Neo System



Source: CVRx

Following these results, we believe that CVRx has been in discussions with the FDA about the appropriate next steps for the US clinical pathway, with the need for another trial likely in our view. In the meantime, the company recently received CE Mark approval for its second generation Barostim Neo system in Europe. Neo features a redesigned unilateral lead which CVRx believes will simplify implantation and reduce complications, as well as a smaller generator with longer battery life. Results from the CE Mark study suggest that this new system may be able to achieve comparable efficacy to Rheos with a substantial improvement in safety and shorter procedure times.

Is Renal Denervation the Answer?

While baroreceptor neuromodulation represents an intriguing potential therapy option for DRH patients, the hunt has also been on for an interventional solution centered around the role of the renal nerves in perpetuating chronic hypertension. The renal nerves play a critical role in regulating several functions that influence hypertension. Signals traveling from the brain to the kidney (efferent) control renal blood flow, fluid retention, and the renin-angiotensin-aldosterone system cascade. The RAAS is a hormonal system responsible for regulating blood pressure, vasoconstriction, and water balance. Meanwhile, signals traveling from the kidneys to the brain (afferent) activate the sympathetic nervous system, leading to increased cardiac output and greater peripheral resistance. Chronic sympathetic overactivation is believed to play a key role in both hypertension and heart failure.

In 2005, Ardian (a play on the acronym for renal denervation) was founded to explore the potential for catheter-based denervation of the renal arteries as a treatment for hypertension. While this was a novel interventional concept, it actually

had its roots in a surgical technique used more than half a century ago. In 1956, Smithwick et al reported in *JAMA* on the results of surgical splanchnicectomy (excision of the splanchnic nerves near the spine) in 1,266 patients with severe hypertension. While this procedure was found to have a significant beneficial impact on both blood pressure and heart failure, it was largely abandoned due to its invasiveness and high complication rate.

Ardian's system, Symplicity, uses a radio frequency ablation catheter to interrupt renal nerve activity through a controlled series of burns along the interior of the renal arteries. The system is powered by a RF generator that uses proprietary algorithms to ensure successful neural block while minimizing the potential for complications such as arterial stenosis. Because this approach is based on standard interventional techniques, the procedure can be completed in roughly 40 minutes and, unlike a neuromodulation solution, has the potential to provide a durable treatment solution with a single intervention without the need for a chronic implant.

Figure 6: Symplicity Catheter



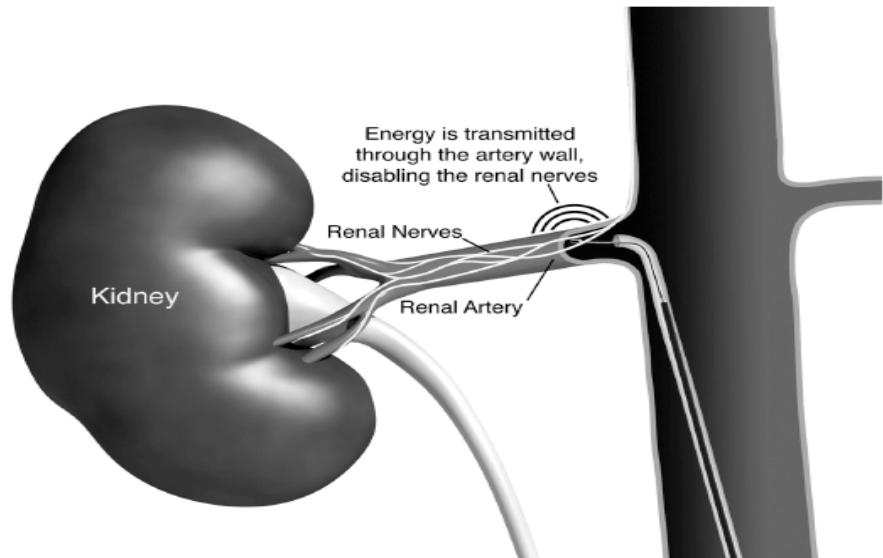
Source: Medtronic

Figure 7: Symplicity Generator



Source: Medtronic

Figure 8: Renal Denervation Procedure



Source: Medtronic

Results with Symplicity Have to Date Been Encouraging

The SYMPLICITY HTN-1 trial enrolled 153 patients with drug-resistant hypertension at 20 sites in Australia, Europe, and the US. Participants were required to have a systolic blood pressure of >160 mmHg and to be on three or more antihypertensive drugs, one of which had to be a diuretic. As Table 3 shows, the average baseline BP for the patients who were enrolled was 176/98 mmHg, despite being on a regimen of 5.0 antihypertensive drugs apiece.

Table 3: SYMPLICITY HTN-1: Baseline Patient Demographics

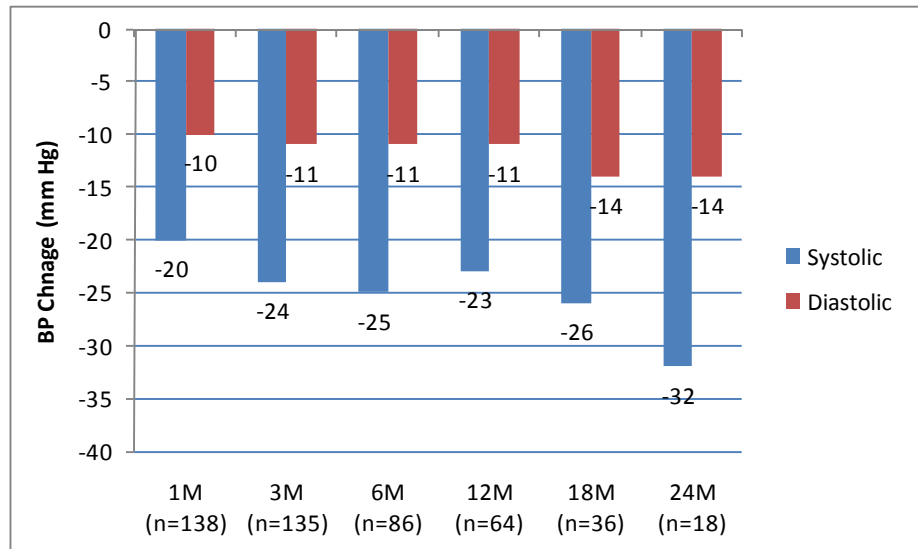
| | | |
|--------------------|-----------------------------------|--------|
| Demographics | Age (years) | 57 |
| | Gender (% female) | 39% |
| | Race (% non-Caucasian) | 5% |
| Co-morbidities | Diabetes Mellitus II (%) | 31% |
| | CAD (%) | 22% |
| | Hyperlipidemia (%) | 68% |
| | eGFR (mL/min/1.73m ²) | 83 20 |
| Blood Pressure | Baseline BP (mmHg) | 176/98 |
| | Number of anti-HTN meds (mean) | 5.0 |
| | ACE/ARB (%) | 90% |
| | Beta-blocker (%) | 82% |
| | Calcium channel blocker (%) | 75% |
| | Vasodilator (%) | 19% |
| | Diuretic (%) | 95% |
| Spironolactone (%) | 21% | |

Source: TCT 2010

Patients received an average of 4 ablations per artery, with a mean procedure time of just 38 minutes. No device malfunctions or major adverse events were observed peri-procedurally, although there was one renal artery dissection prior to energy delivery and three reports of access site complications, all of which were resolved without further incident. Longer-term, no change in renal function was observed. One patient did experience progression of a pre-existing renal artery stenosis, which was successfully stented. The stenosis did not occur at a site of energy delivery, although it could not be determined if manipulation of the catheter itself contributed. Lastly, two deaths during the follow-up period were both determined to be unrelated to the procedure.

In terms of efficacy, patients treated with Symplicity saw a significant reduction in both systolic and diastolic blood pressure 30 days post procedure, a result that was sustained out to two years of follow-up. At one month, the average reduction in SBP/DBP was 20/10 mmHg. Physicians were encouraged to keep medication regimens constant during the first year of follow-up to isolate the impact of the procedure and assess its durability. The 12-month reduction of 23/11 mmHg is encouraging in this regard. Longer-term, physicians were given the option to titrate the patients meds, with 27 (18%) choosing to reduce either dosing or the number of drugs and 18 (12%) increasing. This led to an even greater reduction from baseline at 24 months (32/14 mmHg). Importantly, more than half of the patients who had their meds increased had experienced a BP reduction during the first year, suggesting a high responder rate.

Figure 9: SYMPLICITY HTN-1: BP Change from Baseline



Source: TCT 2010

Following the strong HTN-1 results, Ardian began enrolling the SYMPLICITY HTN-2 trial in June 2009. HTN-2 randomized 106 patients at 24 centers in Europe, Australia, and New Zealand to either renal denervation with the Symplicity system or to continuation of their previous drug regimen. As with HTN-1, patients were required to have a SBP >160 mmHg despite being on three or more antihypertensive drugs. An initial 2-week observation period was employed to ensure sustained BP above this level. And again, as with HTN-1, the trial enrolled an extraordinarily sick patient group, with an average baseline BP of 178/97 mmHg despite more than five antihypertensive medications per patient.

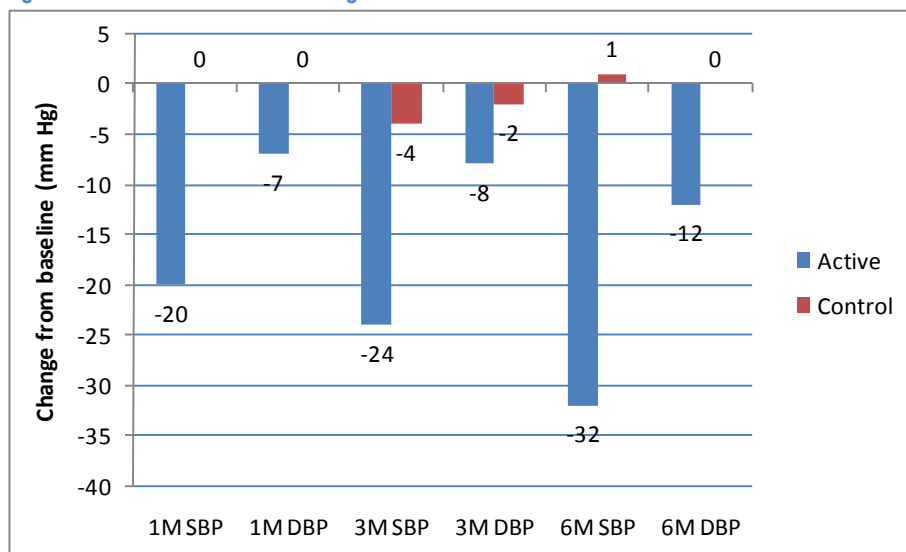
Table 4: SYMPLICITY HTN-2: Baseline Patient Demographics

| | Symplicity (N=52) | Control (N=54) | | Symplicity (N=52) | Control (N=54) |
|---|-------------------|----------------|--|-------------------|----------------|
| Demographics | | | Co-Morbidities | | |
| Age (years) | 58 (12) | 58 (12) | Type 2 Diabetes | 21 (40%) | 15 (28%) |
| Sex (female) | 18 (35%) | 27 (50%) | Coronary Artery Disease | 10 (19%) | 4 (7%) |
| Race (white) | 51 (98%) | 52 (96%) | Hypercholesterolaemia | 27 (52%) | 28 (52%) |
| Body-mass index (kg/m ²) | 31 (5) | 31 (5) | | | |
| Blood Pressure | | | Drug Regimen | | |
| Baseline SBP (mm Hg) | 178 (18) | 178 (16) | Number of antihypertension meds | 5.2 (1.5) | 5.3 (1.8) |
| Baseline DBP (mm Hg) | 97 (16) | 98 (17) | Patients on meds for more than 5 years | 37 (71%) | 42 (78%) |
| eGFR (MDRD, ml/min/1.73m ²) | 77 (19) | 86 (20) | Patients on five or more meds | 35 (67%) | 31 (57%) |
| eGFR 45-60 (%) | 11 (21%) | 6 (11%) | Patients receiving drug class: | | |
| Serum creatine (umol/L) | 91 (25) | 78 (18) | ACEi/ARB | 50 (96%) | 51 (94%) |
| Urine albumin-to-creatinine ratio | 128 (363) | 109 (254) | Direct renin inhibitor | 8 (15%) | 10 (19%) |
| Cystatin C (mg/L) | 0.9 (0.2) | 0.8 (0.2) | Beta-blocker | 43 (83%) | 37 (69%) |
| Heart rate (bpm) | 75 (15) | 71 (15) | Calcium channel blocker | 41 (79%) | 45 (83%) |
| | | | Diuretic | 46 (89%) | 49 (91%) |
| | | | Aldosterone antagonist | 9 (17%) | 9 (17%) |
| | | | Vasodilator | 8 (15%) | 9 (17%) |
| | | | Alpha-1 receptor blocker | 17 (33%) | 10 (19%) |
| | | | Centrally acting sympatholytics | 27 (52%) | 28 (52%) |

Source: Esler, et al. Renal sympathetic denervation in patients with treatment-resistant hypertension. *Lancet* 2010.

Of the 190 patients who were screened for eligibility, 106 (56%) were randomized. Twenty seven (14%) were disqualified because their BP failed to stay above the threshold level following the 2-week observational period, 24 (13%) withdrew or were excluded due to medical conditions discovered during the screening process (stenotic valvular disease, unstable angina, etc), and 33 (17%) were excluded due to “suboptimal renal anatomy” (diameter <4mm, length <20mm, or more than one renal artery). The primary endpoint of the study was the change in SBP at 6 months.

Figure 10: SYMPLICITY HTN-2: Change in BP from Baseline



Source: Esler, et al. Renal sympathetic denervation in patients with treatment-resistant hypertension. *Lancet* 2010.

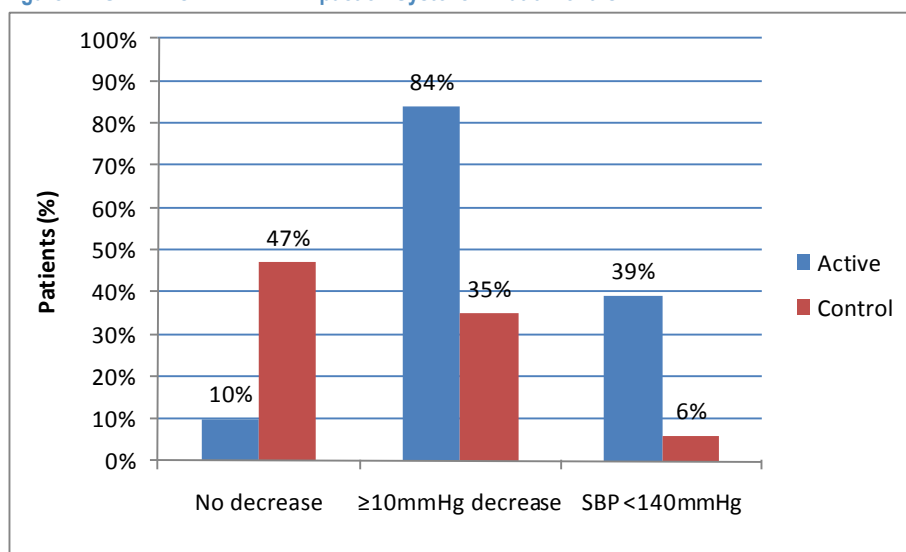
Consistent with what we saw in HTN-1, patients treated with the Symplicity system experienced a significant drop in blood pressure 30 days post their procedure, with an average reduction of 20/7 mmHg. This improved to 24/8 mmHg at 3 months and 32/12 mmHg at 6 months. This 6-month difference was statistically significant both compared to the baseline readings for those patients ($p < 0.0001$) and vs. the control arm of the study ($p < 0.0001$), which experienced negligible changes in blood pressure over the course of the study.

Secondary metrics also strongly favored the treatment arm (see Figure 11). Just 10% of the Symplicity patients saw no decrease in their BP over the course of the trial vs. 47% of those in the control arm. Meanwhile, 84% achieved a reduction of 10 mmHg or more compared to just 35% of those who did not undergo the procedure. Many clinicians consider this the magnitude of change necessary for a treatment to be considered clinically impactful. Finally, 39% of the Symplicity patients had a sustained SBP of less than 140 mmHg at 6 months, meaning that they had gone from severe hypertension to having their blood pressure under control, something which only 6% of the control patients achieved. Each of these endpoints was statistically significant ($p < 0.0001$).

While physicians were encouraged to keep medications constant during the course of the trial, some patients did have changes. Ten (20%) patients in the treatment arm and 3 (6%) in the control arm had their meds reduced prior to the 6-month endpoint, while 4 (8%) treatment and 6 (12%) control subjects had increases. Importantly,

however, these changes did not influence the primary endpoint. An analysis of only those patients whose medications stayed the same or were reduced showed a relative reduction of 31/11 mmHg for the treatment arm, consistent with what was seen in the trial overall.

Figure 11: SYMPLICITY HTN-2: Impact on Systolic BP at 6 Months



Source: Esler, et al. Renal sympathetic denervation in patients with treatment-resistant hypertension. *Lancet* 2010.

From a safety perspective, the results were also fairly clean. No serious device-related adverse events were reported. Seven (13%) RDN patients experienced transient peri-procedural bradycardia requiring atropine, all of which were resolved without further incident. One patient developed a femoral pseudoaneurysm that was treated with manual compression. Other minor complications included one case of paraesthesias (tingling in the extremities), a urinary tract infection, and one patient who required analgesics for lower back pain. Importantly, renal function was maintained. One patient had a mild renal artery stenosis at a non-ablation site which did not require treatment.

In July, Medtronic received conditional IDE approval from the FDA to begin a US pivotal trial for Symplicity, SYMPLICITY HTN-3. The study is expected to enroll 500 patients at 60 US centers, with a primary endpoint of change in blood pressure from baseline at 6 months. Patients will be randomized 2:1 to either renal denervation and drug therapy or drug therapy alone. Unlike in HTN-2, however, control patients will undergo a sham procedure at baseline and then have the opportunity to crossover after they've completed 6-month follow-up.

Medtronic is also exploring the potential benefits of RDN in other disease states, starting with heart failure. Enrollment in the SYMPLICITY HF feasibility study is expected to begin in the next few weeks. Meanwhile, the company continues to make progress on its European launch, with an initial focus on Germany given favorable reimbursement. Our model assumes an early 2014 FDA approval and US launch for Symplicity, with worldwide revenues approaching \$500M in 2016 and \$1.1B in 2020.

RDN Represents a Multi-Billion Dollar Market Opportunity

According to the CDC, more than 56 million American adults had hypertension in 2009. By the time Medtronic receives FDA approval for Symplicity in 2014, we expect this figure to grow to nearly 66 million. This includes both essential hypertension (85-90% of total) and secondary hypertension, in which the patient's high blood pressure is the result of some other underlying disease. Excluding secondary hypertension patients, we estimate the addressable adult hypertension population in 2014 at roughly 56 million.

As we noted previously, awareness and pharmaceutical treatment of hypertension have improved markedly over the past decade. However, a significant portion of patients are still left untreated (27.5% in NHANES 2006-2008 update). After excluding both a) those patients who go undiagnosed and b) those that are aware of their disease but fail to seek treatment, we arrive at an estimate for the total medically treated population of 45 million.

Table 5: US RDN Market Opportunity (in thousands)

| | |
|--------------------------------|--------------------|
| 2014E US Adult Hypertensives | 65,940 |
| (-) Secondary HTN | <u>9,891</u> |
| Essential HTN | 56,049 |
| (-) Undiagnosed | <u>9,891</u> |
| Medical Candidates | 48,875 |
| (-) Untreated | <u>3,867</u> |
| Rx Population | 45,007 |
| (-) Controlled | <u>33,643</u> |
| Drug Resistant Population | 11,364 |
| (-) Stage I | <u>9,659</u> |
| RDN Candidates (initial label) | 1,705 |
| (-) Anatomical Restrictions | <u>852</u> |
| RDN Target Population | 1,193 |
| Estimated ASP | <u>\$6,000</u> |
| US Market Opportunity | \$7,160,000 |

Source: Company reports and J.P. Morgan estimates.

The NHANES data also shows that many patients fail to respond to drug therapy, with just 69% of those who were treated actually achieving BP control. We estimate the drug resistant population at more than 11 million, with at least 15% of these individuals having Stage II or III disease. It is this group (~1.7 million patients) that we believe will be the initial target for renal denervation therapy.

However, 13% of patients enrolled in HTN-2 withdrew or were excluded from the trial due to medical conditions discovered during screening, such as valvular disease. A further 17% were excluded from the study due to complex renal anatomies that could have impacted treatment. Therefore, while exclusion criteria would likely loosen in a commercial setting, we conservatively assume that 30% of the target population will be contraindicated for treatment. Even after this adjustment, our analysis still yields an addressable patient population of just under 1.2 million individuals in the US alone. Assuming a \$6,000 ASP for the Symplicity catheter (we believe current ASPs in Europe are ~\$5,200), this implies a domestic market opportunity of \$7.16B.

To be clear, this is in our view a conservative estimate. We have made several cuts to the data and are being intentionally conservative in estimating both the Stage II-III population and percentage of patients with anatomical restriction. If we assume instead of 15%, that 20% patients are Stage II or III and that only 20% of patients have anatomical restrictions (versus the 30% in our model), the market opportunity in the US grows from \$7.16B to \$10.89B. It's that big.

Outside the US the market is even bigger, particularly in Europe and Japan where the prevalence of hypertension is higher (46% of European adults and 52% of adults in Japan vs. 26% in the US). The percentage of patients diagnosed with the disease isn't as good in Europe or Japan, but that still leaves a target population of 1.56 million Stage II/III patients in Europe and 1.80 million in Japan. After backing out those with assumed anatomical restrictions (30%), that still leaves 1.09 million patients in Europe and 1.26 million in Japan, resulting in a global market of at more than 3.5 million patients before factoring in Canada, Australia, Latin America, Eastern Europe, China, and India. Based on our pricing assumptions in Europe and Japan, and **before factoring in the other countries, this works out to a global market opportunity of \$20 billion.**

Table 6: European Market Opportunity

| (in thousands) | |
|------------------------------------|--------------------|
| European Adult Hypertensives | 167,961 |
| ~ (-) Secondary HTN | <u>25,194</u> |
| Essential HTN | 142,767 |
| ~ (-) Undiagnosed | <u>99,351</u> |
| Medical Candidates | 43,416 |
| ~ (-) Untreated | <u>4,012</u> |
| Rx Population | 39,404 |
| ~ (-) Controlled | <u>28,765</u> |
| Drug Resistant Population | 10,639 |
| ~ (-) Stage I | <u>9,043</u> |
| RDN Candidates (initial label) | 1,596 |
| ~ (-) Anatomical Restrictions | <u>479</u> |
| RDN Target Population | 1,117 |
| European ASP | €3,700 |
| Conversion to US\$ | <u>\$4,995</u> |
| European Market Opportunity | \$5,600,000 |

Source: J.P. Morgan estimates.

Table 7: Japanese Market Opportunity

| (in thousands) | |
|------------------------------------|--------------------|
| Japanese Adult Hypertensives | 57,958 |
| ~ (-) Secondary HTN | <u>8,694</u> |
| Essential HTN | 49,264 |
| ~ (-) Undiagnosed | <u>26,106</u> |
| Medical Candidates | 23,088 |
| ~ (-) Untreated | <u>7,193</u> |
| Rx Population | 15,896 |
| ~ (-) Controlled | <u>4,217</u> |
| Drug Resistant Population | 11,679 |
| ~ (-) Stage I | <u>9,927</u> |
| RDN Candidates (initial label) | 1,752 |
| ~ (-) Anatomical Restrictions | <u>526</u> |
| RDN Target Population | 1,226 |
| Japanese ASP | ¥500,000 |
| Conversion to US\$ | <u>\$6,536</u> |
| European Market Opportunity | \$6,500,000 |

Source: J.P. Morgan estimates.

Table 8: European Renal Denervation Market Opportunity

| <i>in millions</i> | 2011E | 2012E | 2013E | 2014E | 2015E | 2016E | 2017E | 2018E | 2019E | 2020E |
|-----------------------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|
| Europe | | | | | | | | | | |
| Adult Population (millions) | 366.7 | 368.9 | 371.1 | 373.3 | 375.5 | 377.7 | 379.9 | 382.2 | 384.4 | 386.7 |
| % of total | 72.8% | 73.1% | 73.3% | 73.6% | 73.8% | 74.1% | 74.3% | 74.6% | 74.8% | 75.1% |
| Hypertension | 168.0 | 169.7 | 171.4 | 173.2 | 175.0 | 176.8 | 178.6 | 180.4 | 182.2 | 184.0 |
| % of total | 45.8% | 46.0% | 46.2% | 46.4% | 46.6% | 46.8% | 47.0% | 47.2% | 47.4% | 47.6% |
| Essential HTN | 142.8 | 144.2 | 145.7 | 147.2 | 148.7 | 150.3 | 151.8 | 153.3 | 154.9 | 156.4 |
| % of prevalence | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% |
| Secondary HTN | 25.2 | 25.5 | 25.7 | 26.0 | 26.2 | 26.5 | 26.8 | 27.1 | 27.3 | 27.6 |
| Diagnosed | 43.4 | 43.8 | 44.2 | 44.6 | 45.0 | 45.4 | 45.9 | 46.3 | 46.8 | 47.2 |
| % of prevalence | 30.4% | 30.4% | 30.3% | 30.3% | 30.3% | 30.2% | 30.2% | 30.2% | 30.2% | 30.2% |
| Medically Treated | 39.4 | 40.0 | 40.5 | 41.1 | 41.6 | 42.2 | 42.8 | 43.4 | 44.0 | 44.6 |
| % of prevalence | 27.6% | 27.7% | 27.8% | 27.9% | 28.0% | 28.1% | 28.2% | 28.3% | 28.4% | 28.5% |
| Controlled | 28.8 | 29.5 | 30.1 | 30.7 | 31.3 | 32.0 | 32.6 | 33.3 | 34.0 | 34.7 |
| % of Rx treated | 73.0% | 73.7% | 74.2% | 74.7% | 75.3% | 75.8% | 76.3% | 76.8% | 77.3% | 77.8% |
| Uncontrolled | 10.6 | 10.5 | 10.4 | 10.4 | 10.3 | 10.2 | 10.2 | 10.1 | 10.0 | 9.9 |
| Stage I | 9.0 | 8.9 | 8.9 | 8.8 | 8.8 | 8.7 | 8.6 | 8.6 | 8.5 | 8.4 |
| Stage II | 1.1 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 |
| Stage III | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 |
| Stage II/III | 1.6 | 1.6 | 1.6 | 1.6 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 |
| Anatomical Restrictions | <u>0.5</u> | <u>0.5</u> | <u>0.5</u> | <u>0.5</u> | <u>0.5</u> | <u>0.5</u> | <u>0.5</u> | <u>0.5</u> | <u>0.5</u> | <u>0.4</u> |
| Target Population | 1.1 | 1.1 | 1.1 | 1.1 | 1.1 | 1.1 | 1.1 | 1.1 | 1.1 | 1.0 |
| Market Opportunity | \$5,580 | \$5,501 | \$5,362 | \$5,118 | \$4,832 | \$4,511 | \$4,166 | \$3,803 | \$3,471 | \$3,165 |
| Procedure Volume | | | | | | | | | | |
| Medtronic | 4,950 | 19,950 | 36,338 | 52,360 | 64,386 | 73,346 | 81,769 | 88,674 | 94,290 | 100,204 |
| Other | <u>0</u> | <u>0</u> | <u>1,913</u> | <u>9,240</u> | <u>23,814</u> | <u>44,954</u> | <u>69,655</u> | <u>96,063</u> | <u>120,005</u> | <u>139,806</u> |
| Total | 4,950 | 19,950 | 38,250 | 61,600 | 88,200 | 118,300 | 151,424 | 184,737 | 214,295 | 240,011 |
| Penetration | 0.4% | 1.8% | 3.5% | 5.7% | 8.1% | 11.0% | 14.2% | 17.4% | 20.4% | 23.0% |
| Market Shares | | | | | | | | | | |
| Medtronic | 100.0% | 100.0% | 95.0% | 85.0% | 73.0% | 62.0% | 54.0% | 48.0% | 44.0% | 41.8% |
| Other | | | 5.0% | 15.0% | 27.0% | 38.0% | 46.0% | 52.0% | 56.0% | 58.3% |
| Pricing | | | | | | | | | | |
| ASP (Euros) | € 3,700 | € 3,700 | € 3,626 | € 3,481 | € 3,307 | € 3,108 | € 2,891 | € 2,660 | € 2,447 | € 2,251 |
| Euro/USD | <u>€ 1.35</u> | <u>€ 1.35</u> | <u>€ 1.35</u> | <u>€ 1.35</u> | <u>€ 1.35</u> | <u>€ 1.35</u> | <u>€ 1.35</u> | <u>€ 1.35</u> | <u>€ 1.35</u> | <u>€ 1.35</u> |
| Average Selling Price | \$4,995 | \$4,995 | \$4,895 | \$4,699 | \$4,464 | \$4,196 | \$3,903 | \$3,591 | \$3,303 | \$3,039 |
| Revenue | | | | | | | | | | |
| Medtronic | 24.7 | 99.7 | 177.9 | 246.1 | 287.4 | 307.8 | 319.1 | 318.4 | 311.5 | 304.5 |
| Other | <u>0.0</u> | <u>0.0</u> | <u>9.4</u> | <u>43.4</u> | <u>106.3</u> | <u>188.6</u> | <u>271.8</u> | <u>344.9</u> | <u>396.4</u> | <u>424.9</u> |
| Market Revenue | \$24.7 | \$99.7 | \$187.2 | \$289.5 | \$393.8 | \$496.4 | \$591.0 | \$663.3 | \$707.9 | \$729.4 |

Source: J.P. Morgan estimates.

Table 9: US Renal Denervation Market Opportunity

| <i>in millions</i> | 2011E | 2012E | 2013E | 2014E | 2015E | 2016E | 2017E | 2018E | 2019E | 2020E |
|---------------------------|------------|------------|------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|
| United States | | | | | | | | | | |
| Population (millions) | 313.3 | 316.4 | 319.6 | 322.8 | 326.0 | 329.3 | 332.5 | 335.9 | 339.2 | 342.6 |
| Adult Population | 233.5 | 236.6 | 239.8 | 243.0 | 246.2 | 249.5 | 252.9 | 256.2 | 259.6 | 263.1 |
| % of total | 74.5% | 74.8% | 75.0% | 75.3% | 75.5% | 75.8% | 76.0% | 76.3% | 76.5% | 76.8% |
| Hypertension | 60.2 | 62.1 | 64.0 | 65.9 | 67.9 | 70.0 | 72.0 | 74.1 | 76.3 | 78.5 |
| % of total | 25.8% | 26.2% | 26.7% | 27.1% | 27.6% | 28.0% | 28.5% | 28.9% | 29.4% | 29.8% |
| Essential HTN | 51.2 | 52.8 | 54.4 | 56.0 | 57.7 | 59.5 | 61.2 | 63.0 | 64.9 | 66.7 |
| % of prevalence | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% |
| Secondary HTN | 9.0 | 9.3 | 9.6 | 9.9 | 10.2 | 10.5 | 10.8 | 11.1 | 11.4 | 11.8 |
| Diagnosed | 43.2 | 45.1 | 46.9 | 48.9 | 50.8 | 52.8 | 54.8 | 56.8 | 58.9 | 61.0 |
| % of prevalence | 84.4% | 85.4% | 86.3% | 87.2% | 88.0% | 88.8% | 89.5% | 90.2% | 90.8% | 91.4% |
| Medically Treated | 39.2 | 41.1 | 43.0 | 45.0 | 47.0 | 49.1 | 51.1 | 53.3 | 55.4 | 57.6 |
| % of prevalence | 76.6% | 77.9% | 79.1% | 80.3% | 81.4% | 82.5% | 83.5% | 84.5% | 85.4% | 86.3% |
| Controlled | 28.6 | 30.3 | 31.9 | 33.6 | 35.4 | 37.2 | 39.0 | 40.9 | 42.8 | 44.8 |
| % of Rx treated | 73.0% | 73.7% | 74.2% | 74.7% | 75.3% | 75.8% | 76.3% | 76.8% | 77.3% | 77.8% |
| Uncontrolled | 10.6 | 10.8 | 11.1 | 11.4 | 11.6 | 11.9 | 12.1 | 12.4 | 12.6 | 12.8 |
| Stage I | 9.0 | 9.2 | 9.4 | 9.7 | 9.9 | 10.1 | 10.3 | 10.5 | 10.7 | 10.9 |
| Stage II | 1.1 | 1.1 | 1.1 | 1.1 | 1.2 | 1.2 | 1.2 | 1.2 | 1.3 | 1.3 |
| Stage III | 0.5 | 0.5 | 0.6 | 0.6 | 0.6 | 0.6 | 0.6 | 0.6 | 0.6 | 0.6 |
| Stage II/III | 1.6 | 1.6 | 1.7 | 1.7 | 1.7 | 1.8 | 1.8 | 1.9 | 1.9 | 1.9 |
| Anatomical Restrictions | <u>0.5</u> | <u>0.5</u> | <u>0.5</u> | <u>0.5</u> | <u>0.5</u> | <u>0.5</u> | <u>0.5</u> | <u>0.6</u> | <u>0.6</u> | <u>0.6</u> |
| Target Population | 1.1 | 1.1 | 1.2 | 1.2 | 1.2 | 1.2 | 1.3 | 1.3 | 1.3 | 1.3 |
| Market Opportunity | | | | \$7,160 | \$7,145 | \$7,015 | \$6,802 | \$6,450 | \$6,039 | \$5,649 |
| Procedure Volume | | | | | | | | | | |
| Medtronic | | | | 2,475 | 13,275 | 23,960 | 41,930 | 64,692 | 83,561 | 105,286 |
| Other | | | | <u>0</u> | <u>0</u> | <u>5,990</u> | <u>17,970</u> | <u>43,128</u> | <u>83,561</u> | <u>128,683</u> |
| Total | | | | 2,475 | 13,275 | 29,950 | 59,900 | 107,820 | 167,121 | 233,969 |
| Penetration | | | | 0.2% | 1.1% | 2.4% | 4.7% | 8.3% | 12.6% | 17.4% |
| Market Shares | | | | | | | | | | |
| Medtronic | | | | 100.0% | 100.0% | 80.0% | 70.0% | 60.0% | 50.0% | 45.0% |
| Other | | | | | | 20.0% | 30.0% | 40.0% | 50.0% | 55.0% |
| Pricing | | | | | | | | | | |
| Average Selling Price | | | | \$6,000 | \$5,850 | \$5,616 | \$5,335 | \$4,962 | \$4,565 | \$4,200 |
| Revenue | | | | | | | | | | |
| Medtronic | | | | 14.9 | 77.7 | 134.6 | 223.7 | 321.0 | 381.4 | 442.2 |
| Other | | | | <u>0.0</u> | <u>0.0</u> | <u>33.6</u> | <u>95.9</u> | <u>214.0</u> | <u>381.4</u> | <u>540.4</u> |
| Market Revenue | | | | \$14.9 | \$77.7 | \$168.2 | \$319.6 | \$535.0 | \$762.9 | \$982.6 |

Source: CDC, NHANES, company reports, and J.P. Morgan estimates.

Table 10: Japanese Renal Denervation Market Opportunity

| <i>in millions</i> | 2011E | 2012E | 2013E | 2014E | 2015E | 2016E | 2017E | 2018E | 2019E | 2020E |
|-----------------------------|------------|------------|------------|------------|------------|----------------|----------------|----------------|----------------|----------------|
| Japan | | | | | | | | | | |
| Adult Population (millions) | 111.4 | 111.5 | 111.6 | 111.6 | 111.4 | 111.2 | 110.9 | 110.5 | 110.0 | 109.5 |
| % of total | 87.1% | 87.3% | 87.6% | 87.8% | 88.1% | 88.3% | 88.6% | 88.8% | 89.1% | 89.2% |
| Hypertension | 58.0 | 58.3 | 58.5 | 58.7 | 58.9 | 59.0 | 59.0 | 59.1 | 59.0 | 58.9 |
| % of total | 52.0% | 52.2% | 52.4% | 52.6% | 52.8% | 53.0% | 53.2% | 53.4% | 53.6% | 53.8% |
| Essential HTN | 49.3 | 49.5 | 49.7 | 49.9 | 50.0 | 50.1 | 50.2 | 50.2 | 50.2 | 50.1 |
| % of prevalence | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% |
| Secondary HTN | 8.7 | 8.7 | 8.8 | 8.8 | 8.8 | 8.8 | 8.9 | 8.9 | 8.9 | 8.8 |
| Diagnosed | 23.1 | 23.4 | 23.7 | 24.0 | 24.3 | 24.5 | 24.7 | 24.9 | 25.1 | 25.3 |
| % of prevalence | 46.9% | 47.3% | 47.7% | 48.1% | 48.5% | 48.9% | 49.3% | 49.7% | 50.1% | 50.5% |
| Medically Treated | 15.9 | 16.2 | 16.5 | 16.9 | 17.1 | 17.4 | 17.7 | 18.0 | 18.2 | 18.4 |
| % of prevalence | 32.3% | 32.8% | 33.3% | 33.8% | 34.3% | 34.8% | 35.3% | 35.8% | 36.3% | 36.8% |
| Controlled | 4.2 | 4.4 | 4.6 | 4.8 | 5.1 | 5.3 | 5.5 | 5.7 | 5.9 | 6.1 |
| % of Rx treated | 26.5% | 27.3% | 28.0% | 28.8% | 29.5% | 30.3% | 31.0% | 31.8% | 32.5% | 33.3% |
| Uncontrolled | 11.7 | 11.8 | 11.9 | 12.0 | 12.1 | 12.2 | 12.2 | 12.2 | 12.3 | 12.3 |
| Stage I | 9.9 | 10.0 | 10.1 | 10.2 | 10.3 | 10.3 | 10.4 | 10.4 | 10.4 | 10.4 |
| Stage II | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 |
| Stage III | 0.6 | 0.6 | 0.6 | 0.6 | 0.6 | 0.6 | 0.6 | 0.6 | 0.6 | 0.6 |
| Stage II/III | 1.8 | 1.8 | 1.8 | 1.8 | 1.8 | 1.8 | 1.8 | 1.8 | 1.8 | 1.8 |
| Anatomical Restrictions | <u>0.5</u> | <u>0.5</u> | <u>0.5</u> | <u>0.5</u> | <u>0.5</u> | <u>0.5</u> | <u>0.5</u> | <u>0.6</u> | <u>0.6</u> | <u>0.6</u> |
| Target Population | 1.2 | 1.2 | 1.3 | 1.3 | 1.3 | 1.3 | 1.3 | 1.3 | 1.3 | 1.3 |
| Market Opportunity | | | | | | \$8,340 | \$8,168 | \$7,785 | \$7,334 | \$6,756 |
| Procedure Volume | | | | | | | | | | |
| Medtronic | | | | | | 7,500 | 21,375 | 36,000 | 52,763 | 66,707 |
| Other | | | | | | <u>0</u> | <u>1,125</u> | <u>9,000</u> | <u>22,613</u> | <u>44,471</u> |
| Total | | | | | | 7,500 | 22,500 | 45,000 | 75,375 | 111,178 |
| Penetration | | | | | | 0.6% | 1.8% | 3.5% | 5.8% | 8.6% |
| Market Shares | | | | | | | | | | |
| Medtronic | | | | | | 100.0% | 95.0% | 80.0% | 70.0% | 60.0% |
| Other | | | | | | 0.0% | 5.0% | 20.0% | 30.0% | 40.0% |
| Pricing | | | | | | | | | | |
| ASP (Yen) | | | | | | ¥500,000 | ¥487,500 | ¥463,125 | ¥435,338 | ¥400,511 |
| Yen/USD | | | | | | <u>¥76.50</u> | <u>¥76.50</u> | <u>¥76.50</u> | <u>¥76.50</u> | <u>¥76.50</u> |
| Average Selling Price | | | | | | \$6,536 | \$6,373 | \$6,054 | \$5,691 | \$5,235 |
| Revenue | | | | | | | | | | |
| Medtronic | | | | | | 49.0 | 136.2 | 217.9 | 300.3 | 349.2 |
| Other | | | | | | <u>0.0</u> | <u>7.2</u> | <u>54.5</u> | <u>128.7</u> | <u>232.8</u> |
| Market Revenue | | | | | | \$49.0 | \$143.4 | \$272.4 | \$428.9 | \$582.1 |

Source: J.P. Morgan estimates.

Table 11: Global Renal Denervation Market Opportunity

| <i>in millions</i> | 2011E | 2012E | 2013E | 2014E | 2015E | 2016E | 2017E | 2018E | 2019E | 2020E |
|------------------------------|----------------|----------------|----------------|-----------------|-----------------|-----------------|------------------|------------------|------------------|------------------|
| Worldwide¹ | | | | | | | | | | |
| Adult Population (millions) | 711.6 | 717.1 | 722.5 | 727.8 | 733.2 | 738.5 | 743.7 | 748.9 | 754.1 | 759.2 |
| % of total | 75.3% | 75.5% | 75.8% | 76.0% | 76.3% | 76.5% | 76.7% | 77.0% | 77.2% | 77.4% |
| Hypertension | 286.1 | 290.0 | 293.9 | 297.9 | 301.8 | 305.7 | 309.6 | 313.6 | 317.5 | 321.5 |
| % of total | 40.2% | 40.4% | 40.7% | 40.9% | 41.2% | 41.4% | 41.6% | 41.9% | 42.1% | 42.3% |
| Essential HTN | 243.2 | 246.5 | 249.9 | 253.2 | 256.5 | 259.9 | 263.2 | 266.5 | 269.9 | 273.3 |
| % of prevalence | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% | 85.0% |
| Secondary HTN | 42.9 | 43.5 | 44.1 | 44.7 | 45.3 | 45.9 | 46.4 | 47.0 | 47.6 | 48.2 |
| Diagnosed | 109.7 | 112.3 | 114.8 | 117.5 | 120.1 | 122.7 | 125.4 | 128.1 | 130.8 | 133.5 |
| % of prevalence | 45.1% | 45.5% | 46.0% | 46.4% | 46.8% | 47.2% | 47.6% | 48.1% | 48.5% | 48.8% |
| Medically Treated | 94.5 | 97.3 | 100.1 | 102.9 | 105.8 | 108.7 | 111.6 | 114.6 | 117.6 | 120.6 |
| % of prevalence | 38.9% | 39.5% | 40.1% | 40.7% | 41.2% | 41.8% | 42.4% | 43.0% | 43.6% | 44.1% |
| Controlled | 61.6 | 64.2 | 66.7 | 69.2 | 71.8 | 74.4 | 77.1 | 79.9 | 82.7 | 85.6 |
| % of Rx treated | 65.2% | 66.0% | 66.6% | 67.2% | 67.8% | 68.5% | 69.1% | 69.7% | 70.3% | 71.0% |
| Uncontrolled | 32.9 | 33.1 | 33.4 | 33.7 | 34.0 | 34.3 | 34.5 | 34.7 | 34.9 | 35.0 |
| Stage I | 28.0 | 28.1 | 28.4 | 28.7 | 28.9 | 29.1 | 29.3 | 29.5 | 29.6 | 29.8 |
| Stage II | 3.3 | 3.3 | 3.3 | 3.4 | 3.4 | 3.4 | 3.5 | 3.5 | 3.5 | 3.5 |
| Stage III | 1.6 | 1.7 | 1.7 | 1.7 | 1.7 | 1.7 | 1.7 | 1.7 | 1.7 | 1.8 |
| Stage II/III | 4.9 | 5.0 | 5.0 | 5.1 | 5.1 | 5.1 | 5.2 | 5.2 | 5.2 | 5.3 |
| Anatomical Restrictions | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.6 | 1.6 | 1.6 | 1.6 |
| Target Population | 3.5 | 3.5 | 3.5 | 3.5 | 3.6 | 3.6 | 3.6 | 3.6 | 3.7 | 3.7 |
| Market Opportunity | \$5,580 | \$5,501 | \$5,362 | \$12,277 | \$11,977 | \$19,867 | \$19,135 | \$18,039 | \$16,844 | \$15,570 |
| Procedure Volume | | | | | | | | | | |
| Medtronic | 4,950 | 19,950 | 36,338 | 54,835 | 77,661 | 104,806 | 145,074 | 189,366 | 230,613 | 272,198 |
| Other | 0 | 0 | 1,913 | 9,240 | 23,814 | 50,944 | 88,750 | 148,191 | 226,178 | 312,961 |
| Total | 4,950 | 19,950 | 38,250 | 64,075 | 101,475 | 155,750 | 233,824 | 337,557 | 456,791 | 585,158 |
| Penetration | 0.1% | 0.6% | 1.1% | 1.8% | 2.8% | 4.3% | 6.5% | 9.3% | 12.5% | 15.9% |
| Market Shares | | | | | | | | | | |
| Medtronic | 100.0% | 100.0% | 95.0% | 85.6% | 76.5% | 67.3% | 62.0% | 56.1% | 50.5% | 46.5% |
| Other | | | 5.0% | 14.4% | 23.5% | 32.7% | 38.0% | 43.9% | 49.5% | 53.5% |
| Pricing | | | | | | | | | | |
| Average Selling Price | \$4,995 | \$4,995 | \$4,895 | \$4,750 | \$4,646 | \$4,582 | \$4,507 | \$4,357 | \$4,159 | \$3,920 |
| Revenue | | | | | | | | | | |
| Medtronic | 24.7 | 99.7 | 177.9 | 260.9 | 365.1 | 491.4 | 679.0 | 857.3 | 993.2 | 1,095.9 |
| Other | 0.0 | 0.0 | 9.4 | 43.4 | 106.3 | 222.3 | 374.9 | 613.4 | 906.5 | 1,198.1 |
| Market Revenue | \$24.7 | \$99.7 | \$187.2 | \$304.3 | \$471.4 | \$713.7 | \$1,053.9 | \$1,470.7 | \$1,899.7 | \$2,294.0 |

Note: Worldwide at this point includes just US, Europe, and Japan. Source: J.P. Morgan estimates.

How Long Can Medtronic Keep the RDN Market to Itself?

Given the incredible scale of the hypertension opportunity, we expect a number of companies to attempt to enter the renal denervation market over the next few years. Ultimately, the return Medtronic realizes on its Ardian investment will depend on its ability to leverage its first mover advantage into a competitive moat and prevent new market entrants. Already, more than a half dozen companies have either announced their intention to develop a RDN system or have taken steps which indicate that they plan to in the near future. Table 12 below summarizes the RDN competitive landscape as it stands today.

Table 12: Renal Denervation Competitive Landscape

| Company | Approach | Energy Source | Clinical Status | Comments |
|---------------------|-----------------------------|---------------|---|--|
| Medtronic | Intravascular | RF | CE Mark approved. US pivotal trial enrollment underway | Acquired Ardian for \$800M plus milestones in Nov 2010. Staged EU launch underway, starting in Germany. Expect FDA approval in early 2014. |
| St. Jude | Intravascular | RF | First-in-man implants completed. CE Mark trial to start imminently. | Targeting CE Mark by YE12. Expect early FIM results and system details at TCT conference in November. |
| Mercator MedSystems | Intravascular Drug Delivery | | Phase I | Developing microcatheter system for targeted intravascular drug delivery. Presented preclinical data at TCT 2010. Targeting commercialization by 2013. |
| Johnson & Johnson | Intravascular | RF | Preparing for OUS trial | Company has initiated a 200-patient Chinese RDN trial with its ThermoCool ablation catheter to study impact on heart failure, hypertension, and metabolic syndrome. Enrollment is expected to begin in November. |
| Cryomend | Intravascular | Cryo | Animals | As of 4Q10, the company was preparing to raise funds to begin first-in-man procedures. Current status unknown. |
| Kona Medical | Non-Invasive | HIFU | Preclinical | Developing novel ultrasound system for imaging and non-invasive ablation of tumors and RDN for hypertension. |
| Cryomedix | Intravascular | Cryo | Preclinical | Developing cryoblation technology for multiple applications, including tumors and hypertension. |
| Boston Scientific | N/A | N/A | Preclinical | Have expressed interest in market, but no details on approach or clinical timeline yet. |

Source: Company reports and J.P. Morgan estimates.

Of the large publicly traded companies, it appears that St. Jude is the furthest along in its efforts to develop a competitive RDN system. At its February analyst meeting, the company highlighted hypertension as one of several new cardiovascular markets it was preparing to enter in the coming years. CEO Dan Starks indicated that a) St. Jude had accumulated a significant IP portfolio and was confident in its freedom to operate within the space and b) that both device design work and initial animal studies had been completed. We expect to see first-in-man results and details on the St. Jude system itself at the TCT meeting in November. Moreover, **St. Jude's first-in-man trial, called ARSENAL, is days away from beginning enrollment.** ARSENAL is a 60 patient trial schedule for 6-month follow-up with a CE Mark submission expected to occur shortly thereafter (JPM estimate: 3Q12), followed by with the start of a US trial (JPM estimate: 4Q12-1Q13).

Elsewhere, although Boston Scientific has been vocal in expressing its interest in the hypertension opportunity, the company has given no details to date on either its approach or the status of any internal development efforts. Meanwhile, hypertension is not an area that J&J has highlighted recently, but our search of clinicaltrials.gov shows that the company is participating in a 200-patient Chinese clinical trial to

evaluate the impact of renal denervation with its leading ThermoCool ablation catheter on hypertension, heart failure, and metabolic syndrome.

Our checks suggest that one aspect of Ardian’s design that these companies may try to improve on initially is the number of ablations that are required to complete the procedure. Symplicity requires the physician to make 4-6 burns along the length of each renal artery, rotating around its circumference as they go. While we don’t view this as particularly challenging technically for the average interventional cardiologist, a multi-electrode catheter designed to create burns around the entire length of the artery with a single application could simplify the procedure.

On the private side, a number of companies are pursuing RDN technologies. Some are focused on alternative energy sources, such as cryoblation (Cryomend, Cryomedix), to create the lesions to inducing neural block. Others are exploring the potential for non-invasive approaches (Kona) or using controlled intravascular drug delivery (Mercator) to achieve the same results. We believe that each of these companies is still early in their development efforts today. However, in the wake of Medtronic’s \$800M purchase of Ardian last November, we would expect hypertension to continue to be a hot area for venture funding going forward.

It was Ardian’s intellectual property portfolio that ultimately convinced Medtronic to acquire the company instead of trying to develop its own internal system. Given the relative simplicity of the technology used in the procedure itself (ablation catheters are fairly ubiquitous for electrophysiology applications), we believe Medtronic may ultimately have to establish broad protection around the idea of ablating the renal arteries themselves to prevent a proliferation of copycat systems. Table 13 below summarizes Ardian’s IP portfolio.

Table 13: Ardian Intellectual Property Portfolio

| Number | Title | Issued |
|-----------|--|-------------------|
| 7,937,143 | Methods and apparatus for inducing controlled renal neuromodulation | July 19, 2011 |
| 7,873,417 | Methods and apparatus for pulsed electric field neuromodulation via an intra-to-extravascular approach | June 14, 2011 |
| 7,853,333 | Methods and apparatus for multi-vessel renal neuromodulation | May 3, 2011 |
| 7,756,583 | Methods and apparatus for intravascularly-induced neuromodulation | January 18, 2011 |
| 7,717,948 | Methods and apparatus for thermally-induced renal neuromodulation | December 14, 2010 |
| 7,653,438 | Methods and apparatus for renal neuromodulation | July 13, 2010 |
| 7,647,115 | Renal nerve stimulation method and apparatus for treatment of patients | May 18, 2010 |
| 7,620,451 | Methods and apparatus for pulsed electric field neuromodulation via an intra-to-extravascular approach | January 26, 2010 |
| 7,617,005 | Methods and apparatus for thermally-induced renal neuromodulation | January 12, 2010 |
| 7,162,303 | Renal nerve stimulation method and apparatus for treatment of patients | November 17, 2009 |
| 6,978,174 | Methods and devices for renal nerve blocking | November 10, 2009 |
| 5,693,570 | Process for manufacturing a programmable power generation circuit for flash EEPROM memory systems | January 9, 2007 |
| 4,726,792 | Electrical connector having electrical contacts provided with retention means | December 20, 2005 |

Source: USPTO

Ardian’s earliest work focused on using an implantable drug pump to deliver a nerve blocking agent to the renal nerves, and it was this approach that the original ‘792 patent reads on. However, the ‘570 patent issued in 2007 broadens this scope to include a number of other approaches, including both ablation of the renal nerve (claim 14) and cooling of the renal nerve (claim 15). And the ‘174 patent, issued in

2009, appears to read quite directly on the current embodiment of the technology and many of the competitive systems currently in development. Below we highlight a few of its key claims:

- 1. A method for thermally-induced renal neuromodulation, the method comprising: delivering a device to a vicinity of a neural fiber that contributes to renal function; and thermally inducing modulation of a function of the neural fiber with the device.*
- 2. The method of claim 1, wherein delivering the device further comprises delivering the device via an approach chosen from the group consisting of intravascularly, extravascularly, intra-to-extravascularly and combinations thereof.*
- 3. The method of claim 1, wherein thermally inducing modulation of a function of the neural fiber further comprises directly applying thermal energy to the neural fiber.*
- 4. The method of claim 1, wherein thermally inducing modulation of a function of the neural fiber further comprises indirectly applying thermal energy to the neural fiber.*
- 13. The method of claim 1, wherein thermally inducing modulation of a function of the neural fiber further comprises delivering high intensity focused ultrasound to the neural fiber.*
- 14. The method of claim 1, wherein thermally inducing modulation of the function of the neural fiber further comprises heating the neural fiber.*
- 15. The method of claim 1, wherein thermally inducing modulation of the function of the neural fiber further comprises cooling the neural fiber.*

We believe that the '174 patent and those that built on it give Medtronic a solid foundation on which to stand, a view which the company's own legal counsel no doubt shared to give it the confidence necessary to proceed with a deal that will likely end up costing it more than a billion dollars after milestone payments. The key question for investors is: will this matter? This is MedTech after all and, as we've seen in the past with drug-eluting stents, a viable IP position and the threat of large settlement payments down the road does not always dissuade infringement.

Another key concern is off-label use of existing devices already on the market today. As we mentioned before, ablation catheters are widely used in other settings, such as electrophysiology. Unless Medtronic can demonstrate that there is a meaningful safety advantage associated with using a system designed specifically for renal ablation, it's possible that physicians could use these other devices in RDN procedures. Indeed, the Chinese ThermoCool trial appears to be attempting to do just that. Granted, reimbursement for procedures using an unapproved device could be a hurdle and companies would not be able to actively promote the use of their products in this indication. However, we believe that this issue bears monitoring, particularly given the fact that Medtronic is currently selling the Symplicity catheter for more than \$5,000 in Europe vs. closer to \$2,500 for a typical RF ablation catheter.

Our conversations with clinicians suggest that the biggest challenge with using EP ablation catheters for RDN will be ensuring the proper amount of energy delivery, with EP catheters tending to operate at higher temperatures than Symplicity. We have heard anecdotal reports of a RDN case performed with an EP catheter that

resulted in renal artery stenosis and thrombus formation, eventually resulting in that patient losing a kidney.

Investment Thesis

Medtronic's challenge is that roughly 60% of its sales today are in businesses that over the next 3-5 years a) are unlikely to grow and b) face average annual price erosion of 4-5%. What's more, these are high-margin businesses: CRM, Spine, and Stents. And while there are potential growth drivers elsewhere within Medtronic—Diabetes, Neuromodulation, Transcatheter Valves, and Hypertension to name a few—it's hard to offset a flattish top line and significant pricing pressure on more than 60% of your business. The other 40% of Medtronic (\$6.2B in FY11 sales) would have to grow at a roughly 12% CAGR over the next three years for Medtronic as a whole to grow its revenues annually by 5%.

In light of these challenges, Medtronic is increasingly focused on (a) cutting costs and (b) reallocating resources among its businesses. The recent leadership transition is likely to accelerate these efforts, and this may ultimately be the opportunity for new CEO Omar Ishrak: given the lower top-line growth rate, cut costs and rethink spending and delivery models to boost margins. It should be noted, however, that Medtronic already has the highest margins in the sector, with gross margin at 75.4% and EBITDA at 37.3% of sales. Medtronic has also already made substantial progress at returning cash to shareholders. Over the last five years, the company bought back 108M shares and nearly tripled its dividend from \$0.39 to \$0.97. Given its US/OUS cash mix, it will be hard for the company to sustain a level of return above this without having to repatriate profits from overseas and drive up its tax rate. As such, the opportunity as we see it for Mr. Ishrak is in (1) more aggressive cost cutting and (2) some modest reshaping of the portfolio. However, with dramatic actions (like a breakup of the whole company) unlikely to create meaningful shareholder value, in our view, and no near-term fixes to the current growth issues, we prefer to stay on the sidelines until a new direction for the company has been established, and we maintain our Neutral rating.

Valuation

Our \$39 December 2012 price target values Medtronic at 10.0x our CY13 EPS forecast. This is a premium to the company's current NTM multiple of 9.2x but represents a discount to the large-cap MedTech average of 10.5x. We believe that this valuation level is appropriate given the current business challenges the company faces and its long-term growth profile, which we peg at 3-4% and 6-7% on the top and bottom line, respectively. With better upside opportunities elsewhere, we assign MDT shares our Neutral rating.

Risks to Rating and Price Target

Upside risks to our rating include (1) attempts by new management to (a) reallocate capital and (b) restructure the business in an effort to create shareholder value; (2) a re-acceleration in the company's Spine and/or CRM businesses on the back of new products or a pickup in market growth. Downside risks include (1) increased competition and pricing pressure in core end markets, in particular CRM and Spine; and (2) increased regulatory and reimbursement pressures.

Medtronic: Summary of Financials

| Income Statement - Annual | FY11A | FY12E | FY13E | FY14E | Income Statement - Quarterly | 1Q12A | 2Q12E | 3Q12E | 4Q12E |
|---|--------------|--------------|--------------|--------------|-------------------------------------|--------------|--------------|--------------|--------------|
| Revenues | 15,932 | 16,663 | 17,237 | 17,841 | Revenues | 4,049A | 4,082 | 4,115 | 4,417 |
| Cost of products sold | 3,899 | 4,100 | 4,267 | 4,426 | Cost of products sold | 1,006A | 1,004 | 1,012 | 1,078 |
| Gross profit | 12,033 | 12,563 | 12,969 | 13,415 | Gross profit | 3,043A | 3,078 | 3,103 | 3,339 |
| SG&A | 5,520 | 5,649 | 5,912 | 6,240 | SG&A | 1,408A | 1,388 | 1,387 | 1,466 |
| R&D | 1,508 | 1,519 | 1,597 | 1,679 | R&D | 371A | 376 | 374 | 397 |
| Operating Income | 5,005 | 5,395 | 5,461 | 5,496 | Operating income | 1,264A | 1,314 | 1,342 | 1,475 |
| Note: EBITDA | 5,809 | 6,210 | 6,296 | 6,353 | Note: EBITDA | - | - | - | - |
| Net interest income / (expense) | (279) | (128) | (134) | (48) | Net interest income / (expense) | (32)A | (32) | (32) | (32) |
| Other income / (expense) | (458) | (836) | (614) | (632) | Other income / (expense) | (197)A | (220) | (212) | (207) |
| Pretax income | 4,268 | 4,432 | 4,713 | 4,816 | Pretax income | 1,022A | 1,062 | 1,098 | 1,237 |
| Income taxes | 731 | 848 | 896 | 894 | Income taxes | 203A | 202 | 209 | 235 |
| Net income - GAAP | 3,642 | 3,638 | 3,869 | 3,974 | Net income - GAAP | 819A | 861 | 889 | 1,002 |
| Net income - recurring | 3,537 | 3,583 | 3,817 | 3,922 | Net income - recurring | 819A | 861 | 889 | 1,002 |
| Diluted shares outstanding | 1,082 | 1,057 | 1,035 | 1,015 | Diluted shares outstanding | 1,070A | 1,061 | 1,052 | 1,044 |
| EPS - excluding non-recurring | 3.37 | 3.44 | 3.74 | 3.92 | EPS - excluding non-recurring | 0.79A | 0.82 | 0.86 | 0.97 |
| EPS - recurring | 3.37 | 3.44 | 3.74 | 3.92 | EPS - recurring | 0.79A | 0.82 | 0.86 | 0.97 |
| Balance Sheet and Cash Flow Data | FY11A | FY12E | FY13E | FY14E | Ratio Analysis | FY11A | FY12E | FY13E | FY14E |
| Cash and cash equivalents | 2,428 | 4,931 | 3,662 | 3,617 | Sales growth | 0.7% | 4.6% | 3.4% | 3.5% |
| Accounts receivable | 3,822 | 3,872 | 3,963 | 4,057 | EBIT growth | (2.6%) | 7.8% | 1.2% | 0.7% |
| Inventories | 1,695 | 1,721 | 1,783 | 1,840 | EPS growth | 4.7% | 2.2% | 8.6% | 4.8% |
| Other current assets | 567 | 667 | 689 | 714 | Gross margin | 75.5% | 75.4% | 75.2% | 75.2% |
| Current assets | 8,512 | 11,191 | 10,097 | 10,228 | EBIT margin | 31.4% | 32.4% | 31.7% | 30.8% |
| PP&E | 2,511 | 2,559 | 2,629 | 2,722 | EBITDA margin | 36.5% | 37.3% | 36.5% | 35.6% |
| Total assets | 30,424 | 33,137 | 32,102 | 32,323 | Tax rate | 17.1% | 19.1% | 19.0% | 18.6% |
| Total debt | 9,835 | 9,835 | 7,635 | 7,085 | Net margin | 22.2% | 21.5% | 22.1% | 22.0% |
| Total liabilities | 14,456 | 14,876 | 12,825 | 12,431 | Debt / EBITDA | 1.7 | 1.6 | 1.2 | 1.1 |
| Shareholders' equity | 15,968 | 18,262 | 19,277 | 19,893 | Debt / Capital (book) | 38.1% | 35.0% | 28.4% | 26.3% |
| Net income (including charges) | 3,096 | 3,570 | 3,817 | 3,922 | Return on assets (ROA) | 11.6% | 10.8% | 11.9% | 12.1% |
| D&A | 804 | 815 | 836 | 857 | Return on equity (ROE) | 22.2% | 19.6% | 19.8% | 19.7% |
| Change in working capital | (772) | 118 | (58) | (55) | Return on invested capital (ROIC) | 13.7% | 12.7% | 14.2% | 14.5% |
| Other | | | | | Enterprise value / sales | 2.6 | 2.3 | 2.2 | 2.1 |
| Cash flow from operations | 3,372 | 4,514 | 4,423 | 4,535 | Enterprise value / EBITDA | 7.0 | 6.2 | 5.9 | 5.8 |
| Capex | (501) | (526) | (560) | (597) | Free cash flow yield | 8.6% | 12.0% | 11.6% | 11.8% |
| Free cash flow | 2,871 | 3,988 | 3,863 | 3,938 | | | | | |
| Cash flow from investing activities | (1,815) | (874) | (987) | (1,176) | | | | | |
| Cash flow from financing activities | (2,006) | (2,156) | (4,600) | (3,162) | | | | | |
| Dividends | 0.90 | 1.02 | 1.21 | 1.39 | | | | | |
| Dividend yield | 2.8% | 3.2% | 3.7% | 4.3% | | | | | |

Source: Company reports and J.P. Morgan estimates.

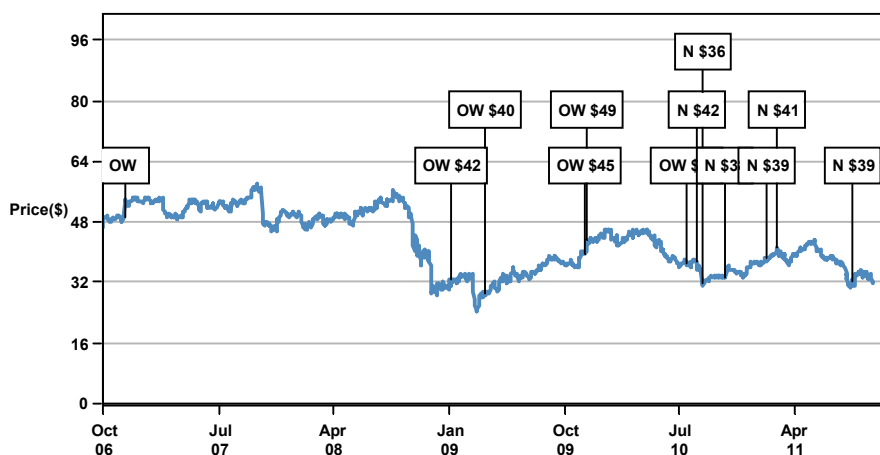
Note: \$ in millions (except per-share data). Fiscal year ends Apr

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Medtronic (MDT) Price Chart



| Date | Rating | Share Price (\$) | Price Target (\$) |
|-----------|--------|------------------|-------------------|
| 21-Nov-06 | OW | 48.95 | -- |
| 05-Jan-09 | OW | 32.58 | 42.00 |
| 26-Mar-09 | OW | 29.23 | 40.00 |
| 20-Nov-09 | OW | 39.62 | 45.00 |
| 25-Nov-09 | OW | 43.18 | 49.00 |
| 19-Jul-10 | OW | 37.09 | 44.00 |
| 09-Aug-10 | N | 37.43 | 42.00 |
| 25-Aug-10 | N | 31.87 | 36.00 |
| 15-Oct-10 | N | 33.27 | 38.00 |
| 24-Jan-11 | N | 38.51 | 39.00 |
| 18-Feb-11 | N | 41.27 | 41.00 |
| 15-Aug-11 | N | 32.03 | 39.00 |

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.
 Break in coverage Nov 21, 2006 - Jan 05, 2009.

The chart(s) show J.P. Morgan's continuing coverage of the stocks; the current analysts may or may not have covered it over the entire period.

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| | Overweight (buy) | Neutral (hold) | Underweight (sell) |
|---|---------------------|-------------------|-----------------------|
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| JPMS Equity Research Coverage | 45% | 47% | 7% |
| IB clients* | 70% | 60% | 52% |

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