To: UMN Venture Capital

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Date: March 9, 2013

RE: Market Size Opportunity for Treatment of Hypertension with Renal Denervation

With the large amount of patients worldwide with resistive hypertension and the favorable results from renal denervation treatment, the trans-catheter renal denervation device market is appealing for a new entrepreneurial venture.

It is estimated that one in four adults experience hypertension (1 billion worldwide). The number is expected to grow to 1.5 billion by 20251. Hypertension is characterized by having blood pressure above 140/90mmhg. If hypertension is not well controlled it can lead to bleeding from the aorta, chronic kidney disease, heart attack, heart failure, stroke, and vision complications2. Hypertension has shown tremendous growth from 1997 to 2009 and that trend continues today3.



Currently the standard of care is a mix of a healthy diet and exercise, along with prescription medications. While the current standard of care can greatly reduce hypertension in the majority of patients, 12% (120 million) of patients experience resistant hypertension4. These patients experience hypertension that is unresponsive to current care techniques. Until recently there was little these patients could do; however studies have shown renal denervation can reduce blood pressure levels by approximately 30mmhg systolic and 20mmhg diastolic after treatment (Figure 15). Research shows risk of mortality from ischemic heart disease or stroke doubles with every 20mmhg increase in systolic pressure or 10mmHg increase in diastolic pressure3.



Renal denervation is a minimally invasive trans-catheter procedure that uses radiofrequency to ablate the renal arteries. Currently Medtronic is on track for FDA approval in 2014. There are currently no FDA approved renal denervation devices on the market. St. Jude Medical is currently developing a renal denervation device and Boston Scientific has just entered the space by acquiring Vessix. There are several other companies in the space, but none have provided a device with a significant advantage over the competition. Large medical device companies have recently been buying up smaller companies that specialize in renal denervation for 200+ million dollars. The global market potential for renal denervation is estimated to be $2.9 billion7 by 2021 and the large medical device companies are scrambling to find new technology to gain market share. Some analysts have even argued the market potential is upwards of $30 billion if the technology was approved for non-resistant hypertension8.

There is potential for a new worldwide entrepreneurial venture to develop a minimally invasive trans-catheter renal denervation device to treat patients with resistant hypertension. The industry subsectors including physicians, hospitals, and government organizations (ex. FDA), would be engaged in the development of a novel renal denervation device.

Strong physician relationships are necessary for the venture’s success. Partnering with physicians that are experts in the field and well respected by the medical community is the best way to promote a new renal denervation device.

Typically it is rare for a new medical device venture to experience strong ROI within 5 years of starting. This is due to the costly and time consuming product development and clinical trial process required for device FDA approval. However, the renal denervation market presents a unique opportunity for new ventures with novel technology. Because the market is so big and there have been no clear industry leaders, large medical device companies are willing to spend large sums of money to acquire smaller companies in an effort to gain a competitive advantage (Boston buying Vessix for $425 million). If the new venture was acquired by a larger company, there is a strong potential for a significant return on investment in the next five years.

The best case scenario within five years is the new venture will be acquired by a large medical device company. In order for this to happen the new venture must have a novel renal denervation device that provides a significant advantage over current devices in the market. Based on historical acquisition costs, a new venture could potentially be purchased for $200-400 million.

The worst case scenario is that the company has not been acquired by a large medical device company. In five years the company will at best be preparing for clinical trial with the device. At this time, several companies will have completed clinical trials. These trials will be helpful in designing the new venture’s clinical trial which will hopefully expedite it; however the new venture device would still be several years from getting full market approval. In five years if the company has not been acquired, expected revenues are estimated to be $0. With that said, if the new venture enters the market late (10 years), even a small share of a $3 billion market could provide substantial return on investment.

1 – Rocha-Singh, Krisha J. Endovascular Today, *Renal artery denervation: A brave new frontier.* February 2012

2 - <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001502/>

3 – J.P Morgan, North American Equity Research, *Medtronic – Renal Denervation: The Next Big Thing in Cardiovascular Devices,* October 6, 2011.

4 – Geisler, Benjamin, Egan, Brent, Cohen, Joshua, Garner, Abigail, Akehurst, Ronald, Esler, Murray, Peitzsch, Jan. Journal of American College of Cardiology, *Cost-Effectiveness and Clinical Effectiveness of Catheter-Based Renal Denervation for Resistant Hypertension,* Vol. 60 No.14, 2012 P. 1271-1277

5 – International Journal of Hypertension, *Renal Sympathetic Denervation for the Treatment of Difficult-to-control or Resistant Hypertension,* Volume 2011 Artible ID

6 – J.P Morgan, North American Equity Research, *Medtronic – Renal Denervation: The Next Big Thing in Cardiovascular Devices,* October 6, 2011.

7 - <http://www.businesswire.com/news/home/20120816005133/en/Renal-Denervation-Device-Market-Grow-Dramatically-Physicians>

8 - <http://pharmaceuticalintelligence.com/2012/06/13/treatment-of-refractory-hypertension-via-percutaneous-renal-denervation/>