



SOUNDVIEW  
RESEARCH

## MRI INTERVENTIONS (MRIC \$5.00)

### SEPTEMBER QUARTER RESULTS

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## 3Q2016 Results Update

MRI Interventions added another quarter to their string of consistent improved performance with their September results. As a data point it's exactly in line with the story and growth trajectory we outlined in our full report published last week (attached to this note.) We've provided links to the release below, but here is our take on the report and conference call.

All of the growth metrics continue to move in the right direction in terms of sales, number of procedures performed and margins. Operating expenses remain under careful control even with an ongoing investment cycle in new software which will be completed soon as the new version of the ClearPoint operating system is released.

One surprise was strength in sales for drug delivery applications. Drug delivery is a big opportunity for the company, but one we have not expected until future periods. Management commented that some of these orders were for use on animals. They don't contribute to the procedure count but do generate sales of the "SmartFlow" cannula. This activity is still driven by testing and trials – not approved therapies, but it may grow faster than we initially expected.

Commentary on Q4 was encouraging if not explicit. Both the performance in Q3 and our expectations for Q4 are positive and consistent with our model and intrinsic value estimate (below.)

## Conclusion

MRI Interventions continues to advance their unique and advanced solution for neurosurgery. During the last several quarters the company has executed well and delivered strong performance against both near-term metrics and longer-term opportunities like drug delivery.

At \$5.00/share, the current market capitalization of \$23M doesn't come close to reflecting the value of the business franchise and IP of MRIC. Our IV model suggests a \$22.55 share price objective. Complete coverage of the model and our assumptions behind it are included in the full report.

We remind investors that Medtronic paid \$105M for Visualase in 2014, which was in about the same amount of hospitals (45) as ClearPoint. There is at least as much strategic value in ClearPoint.

MRI Innovations Price \$5.00  
Nasdaq: MRIC IV \$22.55  
6-Nov-16 Delta 351%

Dec FY	2014	2015	2016	2017	2018	2019	2020	2021	2022
Product Revenue	\$3.4	\$4.4	\$5.8	\$7.5	\$10.8	\$15.5	\$22.0	\$30.4	\$40.0
Development Services	\$0.1	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Other Services	\$0.1	\$0.1	\$0.2	\$0.2	\$0.2	\$0.2	\$0.2	\$0.3	\$0.3
Total Revenue	\$3.6	\$4.6	\$5.9	\$7.7	\$11.0	\$15.7	\$22.2	\$30.7	\$40.3
YoY Growth		27.5%	29.1%	29.5%	43.2%	42.9%	41.5%	37.9%	31.4%
COGS	\$1.9	\$2.0	\$2.5	\$3.0	\$3.8	\$4.9	\$6.4	\$8.5	\$11.4
Gross Margin%	47%	57%	58%	61%	65%	69%	71%	72%	72%
Gross Profits	\$1.7	\$2.6	\$3.4	\$4.7	\$7.2	\$10.8	\$15.8	\$22.2	\$28.9
R&D %	92%	43%	37%	29%	20%	15%	12%	10%	10%
R&D \$	\$3.3	\$2.0	\$2.2	\$2.2	\$2.2	\$2.3	\$2.6	\$3.1	\$3.9
SG&A %	223%	182%	126%	99%	70%	52%	40%	33%	27%
SG&A \$	\$8.0	\$8.4	\$7.5	\$7.6	\$7.7	\$8.2	\$8.9	\$10.0	\$11.0
Net Operating Margin	-268%	-168%	-106%	-67%	-25%	2%	19%	30%	35%
Operating Income	-\$9.7	-\$7.7	-\$6.3	-\$5.1	-\$2.7	\$0.3	\$4.3	\$9.1	\$14.0
Taxed Operating Income	-\$9.7	-\$7.7	-\$6.3	-\$5.1	-\$2.7	\$0.3	\$4.3	\$9.1	\$14.0
Market Value Using P/E	-\$217	-\$174	-\$141	-\$115	-\$61	\$7	\$98	\$204	\$314
Cash Position		\$9	-\$1	-\$6	-\$9	-\$9	-\$4	\$5	\$19
Shares (M)	5	5	5	5	5	5	5	5	5
Period Share Price	-\$47	-\$38	-\$31	-\$25	-\$13	\$2	\$20	\$42	\$64
PV of MV 5 Years Out	\$4	\$49	\$101	\$156					
PV of Cash 5 Years Out	-\$4	-\$2	\$2	\$9					
PV MV + Cash	-\$1	\$46	\$104	\$166					
PV Value Per Share	-\$0.15	\$10.09	\$22.55	\$35.66					

MRIC	Ticker
Nasdaq	
36%	Rev Growth
\$5.00	Current Price
4.6	Shares Out
1%	Avg. Dilution
\$23	Cap (M)
\$6	Cash
\$7	Debt
0%	Tax Rate
23	P/E Multiple
15%	Discount Rate
4.1x	P/S
17.1x	IV as P/S
\$22.55	Intrinsic Value
351%	Up/Downside

## Additional Disclosures

SoundView has served as an advisor to MRI Interventions and provides strategic advisory and other services to the company including company positioning, investor communication methods and ongoing technology and market research. (see back page for more general disclosures.)



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MRI INTERVENTIONS (MRIC \$4.98)

MRI-GUIDED NEUROSURGERY

OCTOBER 25, 2016

KRIS TUTTLE & STEPHEN WAITE

## Introduction

The brain is difficult to image due to the confines of the skull. Cat scans and X-rays do a great job of imaging the bones in the head and the structure of the skull, while MRI imaging is preferred for imaging the soft tissues of the brain. As a result, operating on the brain, in a minimally invasive way, is challenging, as the soft tissues cannot be seen with clarity with typical operating room imaging methods (CT and Xray). The approach using these imaging methods consisted of making "registration marks" and bolting on restraints to firmly grip the skull and hold it in place. Even then a surgeon is basically working with what amounts to a static map and landmarks for guidance. Adding to the difficulty is the probability the brain may shift inside the skull when initial incisions are made. This shift can lead to missed targets, as the images taken earlier are no longer representative of the brain position.

MRI Interventions (NASDAQ: MRIC) has developed a surgical navigation technology called the ClearPoint<sup>®</sup> System. ClearPoint enables real-time, intra-operative MRI (iMRI)-based navigation, for more accurate targeting and placement of devices deep in the brain. There are many scientific references available but we find this quote from Dr. John Honeycutt, Medical Director of the Cook Children's Department of Neurosurgery, to be a good description of the importance of this technology: **"The ClearPoint navigation platform is the only technology that enables minimally-invasive neurosurgery under continuous MRI guidance, offering surgeons real-time direction and a direct view of the inside of a patient's brain during a procedure. MRI provides superior visualization of the brain's tissue compared to other imaging technologies."** Doctors are able to navigate in the brain with sub-millimeter accuracy with ClearPoint.

Today ClearPoint is used clinically for the placement of electrodes for deep brain stimulation (DBS) and laser ablation (LAB), as well as for biopsy and drug delivery. DBS is a leading therapy for treating Parkinson's Disease, and LAB is growing rapidly for the treatment of brain tumors and epileptic seizures. ClearPoint is FDA cleared in the US, and is used clinically in over 40 centers in the US. The number of ClearPoint

### MRIC IN A NUTSHELL

The ClearPoint system makes neurosurgery much more accurate by enabling real time MRI imaging during brain surgery. Commercial adoption is growing every quarter.

Market opportunity has two tranches – the current market opportunity is \$400M and the future (drug delivery) is at least double that for a \$1.2B total.

MRIC has a **current market capitalization of just \$23M** owing to their virtually unknown status in the investment community.

Our **IV model suggests valuation of \$22.55/share.**

**Voyager Therapeutics (NASDAQ: VYGR) just made a strategic equity investment.**

We believe that their consistent performance and market opportunity will become more appreciated.

procedures has been growing the past six consecutive quarters, and we expect this momentum to continue and even accelerate. In these categories, MRIC has a significant market opportunity of \$400M with the expansion of ClearPoint usage. Growth will be achieved in the market by increasing the utilization rate of the existing centers and adding additional ones. Since revenue is mostly from non-reusable components, the nature of the current revenue base is largely recurring.

But there is a much larger long-term opportunity evolving for MRIC and they are very well positioned for it. Specifically, there is a wave of drug therapies being developed that will need to be directly injected into specific areas of the brain. This is the core strength of the ClearPoint system, and as such, the technology is being used in nearly every relevant clinical trial going on today. Though FDA approval for such drug therapies will require time, the fact that ClearPoint is being used at the clinical trial stage means that MRIC and ClearPoint are extremely well positioned.

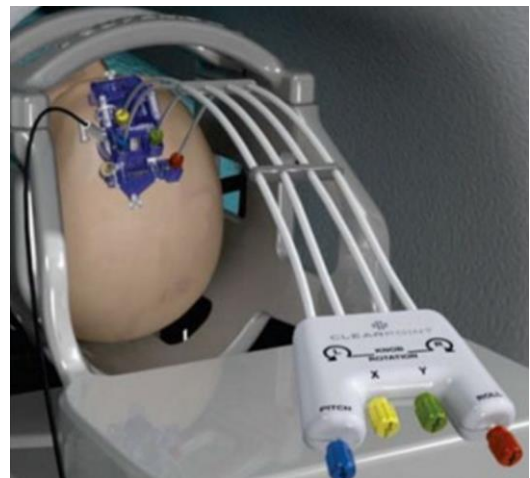
It's important to realize that their current market capitalization of \$23M is striking given their existing commercial business, intellectual property and patent portfolio, and their long-term opportunity in drug delivery.

While MRIC as a stock and a company is not yet highly visible to investors, we think it soon will be.

## What is ClearPoint and how does it work?

The best way to really understand how ClearPoint works is to spend several minutes watching the product video (link below<sup>1</sup>.) Here are the basics:

1. An initial placement of the ClearPoint SmartFrame is made using a positioning guide and the MRI images to identify the coordinates of the target area in the brain. An entry port is opened in the skull and the SmartFrame is positioned over it.
2. After placement and tightening of the SmartFrame, an attachable hand controller allows the surgeon to precisely position the target area with four degrees of freedom – X and Y, pitch, and roll. This is done with real-time imaging so the surgeon can see the position of the device, and where the trajectory is pointing.
3. What happens next depends on the procedure, but typically, different instruments are then inserted and deployed using the SmartFrame for positioning and control. After the deep brain stimulation electrodes are implanted, or the laser ablation fibers or drug delivery catheters are inserted and the therapy is deployed, the instruments are removed and the SmartFrame is detached and the entry point is closed.

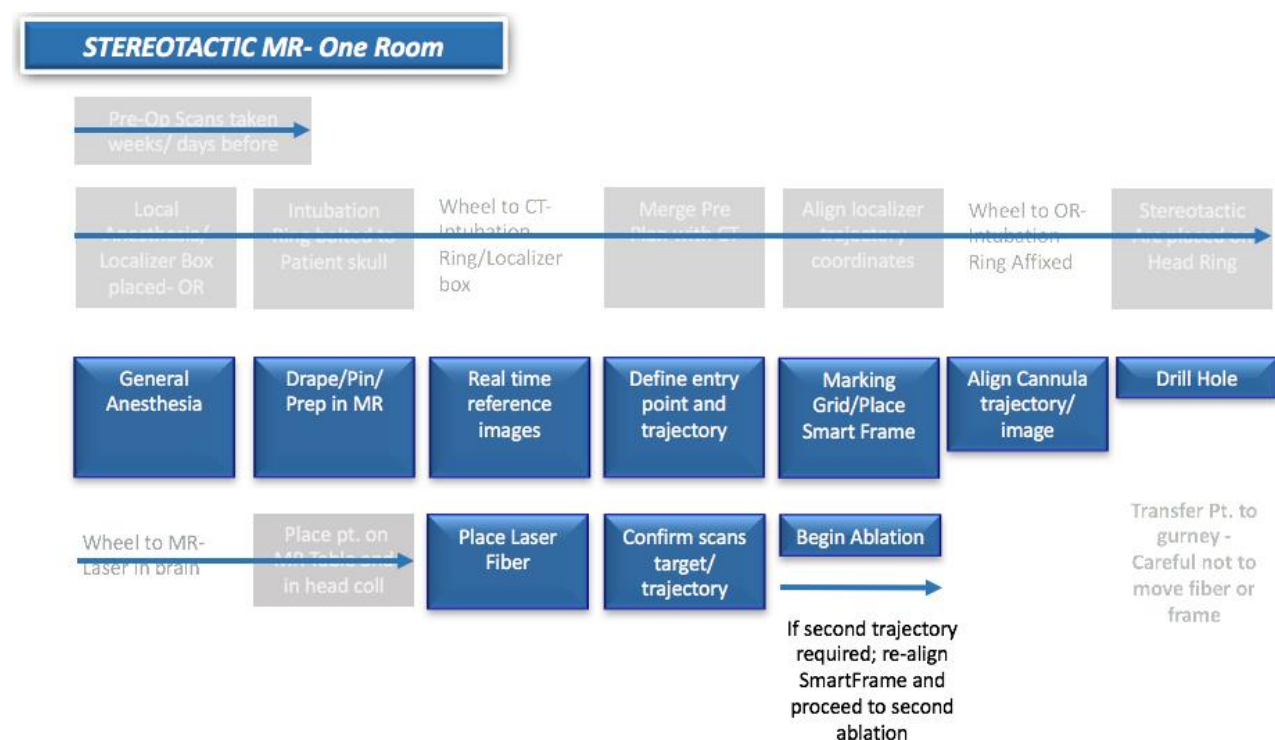


Another important aspect of the ClearPoint method, for certain procedures, is that it allows for “one room” operation, i.e., the patient does not have to be moved from the operating room to the MRI suite in the middle of the procedure. For instance, laser ablation of brain tissue must always be done inside an MRI so that the temperature of the tissue being ablated can be monitored. If traditional stereotactic guidance in

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<sup>1</sup> Visit this link for an excellent 7 minute video: [https://www.youtube.com/watch?v=IA45R\\_kvBR8](https://www.youtube.com/watch?v=IA45R_kvBR8)  
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the operating room is used to place the laser fiber, the patient will then have to be moved down the hall to the MRI suite (often to a separate floor via elevator) while under general anesthesia, and with a hole in their head. By using ClearPoint to place the laser fiber, the entire procedure can simply be done in the MRI suite, and patient transport through non-sterile hallways is avoided. This ability to perform the entire procedure in one room (“one procedure, one room”) has clear benefits, including decreased risk of infections, reduced effect of “brain shift” or brain movement between the time the brain is imaged and the surgery is performed, and much simpler workflow for the hospital staff, who do not have to worry about patient transport in the middle of a procedure. Although accuracy and real time visualization of the brain during the procedure remain the most visible drivers for switching to ClearPoint, the “one room” model is another major advantage in the laser ablation procedures that doctors and hospitals care about. We’ve included a slide here that visually illustrates the steps removed with the one procedure, one room approach for a laser ablation case.



The result of the elimination of all these steps is that patient movement through non-sterile spaces is eliminated when using ClearPoint as part of a “one room” procedure.

## Drug Delivery - Ready! Fire! Aim!

The Devil is in the details of drug delivery. The presence of the blood brain barrier, which is formed by the brain capillary endothelium and excludes from the brain ~100% of large-molecule neurotherapeutics and more than 98% of all small-molecule drugs delivered systemically (though the blood vessels), makes the delivery of therapeutic agents to cells in the brain challenging. An alternative method for delivering drugs into the brain, via direct injection under pressure, has emerged. This method is called Convection Enhanced Delivery (CED - direct injection of therapeutic agents into the brain, using continuous, low-positive pressure flow). To utilize CED for drug delivery, accurate, real-time targeting and infusion monitoring is crucial to obtaining optimum target coverage. With the intra-operative MRI imaging capability provided by the ClearPoint System, the ability to monitor and adjust the infusion during CED is

achieved. As a result, the surgeon can make adjustments during the procedure to ensure the drug is flowing into the target tissue and not escaping via other routes. Currently, seven clinical and pre-clinical studies are utilizing the ClearPoint System for delivery of a therapeutic agent directly into the brain.

Alternative methods for direct injection into the brain without ClearPoint have been shown to be ineffective. Even if a catheter appears to be well positioned, the flow of the drug into the tissue cannot be seen without the real time MRI imaging. This was illustrated in one example where a non-ClearPoint patient treated with the direct injection of a gene therapy agent died unexpectedly and surgeons were able to perform an autopsy and measure the actual penetration of the drug. **Before the autopsy, the surgeons believed that they were achieving 50% or better drug penetration into the desired section of the brain; but the autopsy proved otherwise. In this patient, the actual penetration of the drug into the target was just 14% penetration.**

In order for drug delivery to work as a therapy, in most cases it must be delivered with extremely high precision and monitored in real-time to maximize the penetration in the targeted brain tissue. ClearPoint enables both highly accurate positioning, and the ability to visualize in real time. Several programs currently underway by pharmaceutical and biotech companies are relying on ClearPoint for navigation and drug delivery throughout their trials. It's worth noting that Voyager Therapeutics (NASDAQ: VYGR) stated in their SEC filings that (emphasis added) "...we expect to continue to use the ClearPoint System in future clinical trials of VY-AADC01 **and any other of our product candidates that are injected directly into the brain.**"

Voyager recently underlined and bolded this statement themselves by making a direct investment in MRIC. During the recent PIPE financing Voyager provided a significant piece of the proceeds, to the tune of a \$2 million investment in MRIC. See the balance sheet section below for more details.

We must quickly point out that almost all of these drug delivery programs are Phase 1 studies at this point. This means FDA approval is years away at best and any or all of the active trials may fail to satisfy their end-points. That said, if any or all are approved, it will multiply the current commercial opportunity for MRIC.

In assessing the opportunity from drug delivery, our approach incorporates an additional 100,000 procedures per year using ClearPoint. With an ASP of \$7K/procedure, a \$700M annual revenue opportunity is the base case. Again we remind investors this is still years away, but trials are ongoing and many already have ClearPoint "designed in" as the preferred delivery method.

## Competitive Moat and IP

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MRIC has been at this for a long time and has invested in product development, software, procedure know-how, integration with other medical technologies, brand recognition and a large and growing patent portfolio. The advantages MRIC has today are significant and growing as the company continues to invest in these areas:

1. Even though MRI-guided neurosurgery is a more common practice today, it's still at the frontier of modern medicine. An MRI Interventions technician is present at nearly every procedure to assist, guide and learn. This sometimes-painstaking approach has enabled MRIC to introduce improvements and continue to innovate with proprietary knowledge gained from being part of the process. MRIC has been working at this for longer than anyone and built up a base of proprietary knowledge in MRI-guided surgery.



2. In many cases, MRIC has worked closely with other medical technology providers to develop integrations that enhance the results when doing a procedure. For example, MRIC has worked closely with **Monteris** at Yale to develop new ways to perform very challenging laser ablation procedures for brain tumors. ClearPoint integrates with all the major scanner platforms and subsystems.
3. Although not a consumer brand, the “ClearPoint” name is already well known and respected in the industry. As more doctors associate “ClearPoint” with accuracy in neurosurgical procedures, the value of the brand will continue to increase.
4. Patents. The patent portfolio at MRIC is considerable as seen in the graphic below. MRI-guided surgery demands innovation because the magnetic fields present require special equipment and techniques.

The MRIC patents cover a broad spectrum of MRI-related operating technology. Some of the many titles of their issued and pending patents are:

<a href="#">US8208993</a>	Imaging device for MRI-guided medical interventional systems
<a href="#">US8315689</a>	MRI surgical systems for real-time visualizations using MRI image data and predefined data of surgical tools
<a href="#">US8374677</a>	MRI-guided medical interventional systems and methods
<a href="#">US8644906</a>	Methods for using MRI-compatible patches
<a href="#">US9097756</a>	Control unit for MRI-guided medical interventional systems
<a href="#">US9192446</a>	Trajectory guide frame for MRI-guided surgeries
<a href="#">US9305365</a>	Systems, devices, and methods for tracking moving targets
<a href="#">US9314305</a>	Methods associated with MRI surgical systems for real-time visualizations using MRI image data and predefined data of surgical tools

It would be fair to say that MRIC “punches well above their weight” when it comes to IP and their patent portfolio. Investors should also appreciate how attractive that makes MRIC to partners and strategic investors.

## My Day at ASSFN

Every two years the top functional neurosurgeons (a functional neurosurgeon specializes in movement disorders) gather at an event called the American Society for Stereotactic and Functional Neurosurgery (ASSFN) Meeting. On June 19<sup>th</sup>, 2016 I spent a day in Chicago attending the event and it was a deeply challenging and enlightening experience. If I get the chance to go again, I’ll attend all three days. If you can keep up with the science, the material is amazing.

Unfortunately, the competitive nature of the industry means that doctors will not provide copies of their presentations, but I did take notes. There was also an exhibitors' area where I had a chance to talk to at least a dozen different technology vendors including Medtronic.

For example, there is an area in the brain that has long been identified to be the source of the mental illness called Obsessive-Compulsive Disorder (OCD) which is a fairly common condition. DBS is a common treatment for this illness, yet it is only 50% effective. OCD is characterized by a wide range of behaviors including obsessions with germs or contamination or compulsions like excessive cleaning or handwashing, hoarding, arranging things in a certain way, or compulsive counting to name a few.

It turns out that this area of the brain is not a homogeneous region at all. There are sub-areas that correspond exactly to the specific varieties of OCD. There is a specific small region for handwashing, for hoarding, for compulsive counting, etc. It turns out the key to more effective treatments is about more personalized functional neurosurgery. This also requires much more accurate positioning in the brain, which again is exactly what ClearPoint enables.

In another presentation that was standing room only, Dr. Veronica L.S. Chiang, MD at Yale New Haven, presented a bevy of case studies of tumor surgery using ClearPoint and Monteris laser ablation technology. What held the crowd in rapt attention was the difficulty presented by the location of the tumors inside the brain. We often think of a tumor sitting inside the brain in an area that is easily reachable with a perpendicular approach near to the surface of the skull. The reality is that tumors occur anywhere and everywhere, such as deep in the brain, down near the brainstem, near the optic nerves, and simply in places that are hard to reach and treat with accuracy.

Dr. Chiang described how she was able to "integrate ClearPoint into our practice" and how it "made [her] a faster and better surgeon." For her it was all about "3D positioning flexibility" and the ability to adjust far better than alternative systems allow. When doing laser ablation, positioning matters – given that the laser is destroying brain tissue, even a millimeter can make a big difference.

There were many conversations and scenarios discussed with different doctors. The common themes were 1) need for better accuracy, 2) need for fast and easy adjustment and positioning during the procedure, and 3) limiting the risk of infection due to moving the patient from one room to another during a procedure. It's an oversimplification of an intense conference but this conveys some of my take-away from the event.

## Competition

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ClearPoint has a superior product but faces industry characteristics that can sometimes be barriers to the adoption of new products, even when they are demonstrably superior. While we don't see anyone out there as a pure and direct competitor to ClearPoint, the fact is that the industry in general and most doctors in particular have a fair amount of inertia which slows down shifts to something new – especially when the stakes are high and the existing techniques have been around for a long time.

Looking at competition, first there are large medical device companies that serve the existing market – competitors like **Medtronic** are gigantic and are already embedded in the fabric of hospitals and operating rooms. Although their specific products may not be as accurate as ClearPoint, or do not enable real-time MRI visualization, they are perceived as being "good enough" for most surgeons.

For instance, Medtronic has a laser ablation product called Visualase which they acquired in 2014 for \$105M in cash (including an earn-out). This is one of the two laser ablation products in the market (the other is



marketed by Monteris Medical, a private, venture backed company). These products are a big improvement over cutting a hole in the skull and going in with a scalpel to excise tumors, or to surgically resect out the section of the brain from which epileptic seizures originate. While these laser ablation fibers can be placed stereotactically in the operating room (the typical Medtronic approach, which also then requires the patient to be moved into the MRI suite, with a laser fiber sticking out of his/her head), we know that ClearPoint MRI-guided surgery can provide a more accurate placement, and facilitate a more accurate ablation. Interestingly, both laser ablation products require the actual ablation to be done in the MRI suite, even if the fiber is placed in the operating room. This movement from one room to another, in the middle of surgery, is less than desirable, and the ClearPoint System enables the entire procedure to be done solely in just the MRI suite – the “one room” procedural approach described earlier.

More broadly, Medtronic has invested heavily to make the existing registration marks/MRI imaging approach work better and better. Although the “old approach” is often pictured with daunting headwear involving wires all over the place, the modern version is much more high tech. Medtronic is on their seventh generation neurosurgical navigation system and has developed multiple imaging, navigation and planning methods within it. They have also built a sophisticated software platform on which doctors are trained and use on a regular basis.

As the incumbent vendor, Medtronic understands surgeon workflow and operating planning very well. It also has invested very heavily in both the products and the software neurosurgeons rely on. Their solution has come a long way but still can’t quite match the ClearPoint system in terms of accuracy and real-time control. Finally, there is a speed issue: one data point we collected from the Children’s Hospital in Atlanta is that a procedure using Medtronic’s Visualase took 8 hours without ClearPoint and 3.5 hours with ClearPoint.

We’ve used an analogy where we’ve described the old approach to neurosurgery as working with a map and landmarks to navigate versus a modern GPS. While accurate, we admit that it’s an oversimplification because the “maps and landmarks” are getting better and more detailed.

Medtronic has taken maps and made them interactive and highly detailed. They even have things like route planning and options for the surgeon to select their route. Medtronic even facilitates the navigation and visualization of the trip. **But it’s not a real-time GPS.**

Google and Waze have taken over the market in terms of GPS. The reason isn’t better maps, but rather they provide a real time image of your progress to your destination, and provide up to the minute information to allow you to adapt to conditions as they develop. So when an accident occurs, a road is closed, a big event lets out or traffic simply backs up, new routes are identified, and you can adjust your route dynamically. Taken further, these systems can see things as they happen and not rely on static information at all. In the end, Medtronic has created a good map, but now the state of the art is a real time visualization of the route, under the best brain imaging possible – MRI.

Medtronic is the 800-pound gorilla but there are also smaller companies innovating in the space. Most of them are working on other aspects of achieving effective therapies. We all know that the robots are coming and public companies like **Intuitive Surgical (NASDAQ: ISRG)** have turned them into multiple billion dollar businesses. Intuitive Surgical isn’t about neurosurgery at all, but there are some smaller companies working on robotic methods for brain surgery. We looked at a couple of products, Neuromate from Renishaw (based in the UK) and ROSA from Medtech (based in France.)

The robot systems are designed to make the existing process better. By eliminating hand movements, robots have proven that they can allow doctors to have finer control than they could ever achieve on their MRI Interventions Report October 2016

own. However, these robotic systems still rely on frames attached to the head for reference, as well as the “interactive map” approach to navigation as described above. Fundamentally, the robots do not provide real time imaging capability like ClearPoint. In fact, they cannot be used with real time MRI visualization as the robot contains way too much metal to be near an MRI suite.

The robots are really solving a different problem than the one ClearPoint addresses. They ease the burden of accurately drilling multiple holes in the skull. For certain epilepsy diagnosis procedures, up to 20 holes for the insertion of electrodes may be necessary in order to accurately diagnose the origination site of epileptic seizures (these cases are obviously for very selected patients). They also take a different sales approach, have a different value proposition and differ in their implementation. These are large, expensive capital purchases. ClearPoint is more like an add-on to an existing technology (assuming the presence of an MRI, which we will get to). The future may indeed be robots for neurosurgery, but we are in the very early days and these examples are simply improving on the old approach of static navigation.

Finally, there is Synaptive Medical up in Toronto, Canada who combines advances in imaging, 3D mapping and planning, simulation **and** robotics to take a more sweeping approach to modernize neurosurgery. They’ve branded their system “BrightMatter” which highlights their much-improved visualization system. Their technology is very exciting, but in terms of actual use they have just sold their first system (to Indiana University) so clinical use is nascent. Although their technology does not use MRI during the procedure, and hence is not real-time, it does look like a real advance over existing, static image technologies.

## Growth Constraints

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Shifting from competition, there are some constraints with how **fast** MRIC can grow. Here are the main ones as we see them and how they are developing:

1. Limited access to MRI systems. In order to do surgery with ClearPoint it has to happen in an MRI. This has been a major issue in the past but is improving. ClearPoint can be utilized in most hospital based, diagnostic MRI systems. However, just because it can, does not mean it will. MRI suites are often designated for diagnostic use, and doing actual procedures in the MRI can be a significant change for the hospital staff. Few physical modifications are typically needed to the MRI suite, but changes in procedure and personnel practices are necessary. As we all know, changing people is a lot harder than changing facilities. Once agreement is reached within the hospital to move forward, the implementation of ClearPoint is straightforward, but reaching that agreement in the first place involves several departments and individuals within the hospital, which simply takes time.
2. Deliberate growth of intra-operative MRI suites. More hospitals are adding or building out operating rooms to include MRI. While most MRI suites focus on diagnostic use, these intra-operative suites are intentionally designed and built for use as either a diagnostic or operative suite. Installation of ClearPoint in this environment, which is already intended for operative use, is simple. However, only larger, more established hospitals are making these investments so far. Regardless, these larger hospitals also tend to be the higher volume hospitals for these types of procedures, and this trend will still help ease the historical limit on the number of procedures that can be done.
3. Doctors need to be trained, and typically an MRIC technician is on hand for each operation. As more sites are established, more doctors are trained, increasing the utilization of ClearPoint. Because operations are scheduled in advance, the MRIC technicians are able to support the volume efficiently. This could become a problem as the company scales up, but it is being addressed with

improvements to the ClearPoint software as well as standardization of procedural workflow. Well-established sites doing many procedures are becoming self-sufficient and this will continue with more high volume sites and ease-of-use improvements.

During the past several quarters MRIC has been delivering excellent sequential progress. It's sustainable and measured growth. It's also mostly recurring (or at least usage-based) in nature which provides much better visibility (and generally higher valuations).

## Management and Board

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Experienced investors in smaller companies know that the quality of the management team is perhaps the single biggest factor in how investments do over time. Anyone who takes a thorough look at MRIC products, markets and opportunities will agree that the company can generate substantial returns over the next few years, but only if management successfully executes the plan.

The company has history as a very R&D focused organization. Late in 2014, Frank Grillo was hired and became the CEO early in 2015. He led the company to raise financing, built out the management team and streamlined the company with a focus on commercial success. This included consolidating locations, eliminating a significant product line to focus on ClearPoint and rolling back unproductive or inactive sites to make sure everyone with a ClearPoint system was going to be using it.

In short, the balance sheet is cleaned up, revenues are growing 30-40% YoY and operating losses are dramatically reduced. After the most recent capital raise and a reverse split, the shares are no longer in penny-stock territory. With increased attention and trading volume we can expect institutions to become more comfortable with the company despite the very small market capitalization.

We've provided some formal background on the management team and the advisors below and we've had a chance to talk to and work with many of the senior operating managers (CEO, CFO, Marketing, & Sales) in one on one and group situations. We also have taken some time to speak with industry partners and contacts to get a better sense of the team and their culture. The overall facts about management are below, but some observations:

1. The team works well together. Our exposure is limited, but we found each area to be very on top of their own domain and working with the team to deliver results rather than second guessing colleagues or mixing up their priorities.
2. Positive characteristics we observed included honesty, integrity, conservatism and a very deliberate approach to getting things done. There's also a healthy dose of genuine intellectual curiosity in the CEO who we had a chance to watch a few times unobserved.
3. The only negative signal we picked up in our own interactions is an occasional slowness in getting some things done. This isn't a criticism per se because we know this is a very deliberate team. But I'd say that there could be just a smidge more "just get it done" in some situations.

As shown below, the management team has a wealth of experience in the right places – Intuitive Surgical, Boston Scientific, Edwards Life Sciences, and Medtronic to name the big ones.

Key Management		
Executive	Title	Prior Experience
Frank Grillo	President, CEO	INTUITIVE SURGICAL™ KYPHON BOSTON SCIENTIFIC
Peter Piferi	COO	Edwards HeartWare Cordis
Wendelin Maners	VP Marketing	Boston Scientific CSA MEDICAL
Robert Korn	VP Sales	Medtronic Codman
Hal Hurwitz	CFO	pwc ev3

Board of Directors					
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We are very comfortable with the management team and believe they are critical to the company's success. There's enough "headroom" for this team to run at least a \$100M business and we are years away from that. More importantly we think that once the shares have higher daily trading volume and the market capitalization is higher, institutional investors will be comfortable with this team.

## Reporting and Recent Quarterly Results

Quarterly reports from MRI Interventions have some specific metrics like the number of active sites and total procedures performed. Revenues are also broken down into reusable and disposable products. The latter form the basis of the "razor blade model" and grow as usage grows.

We've included the last two quarterly periods as we've seen them:

### Quarterly Results for the June Q

Reported results for Q2 continued their recent pattern: 37% revenue growth, 42% improvement in net margins) in what we expect will be continued ramp this year. Even though it's still distant we can see an inflection point when drug-delivery therapies for the brain become FDA approved. Until then, the company will continue to grow and improve their profitability.

Key takeaways from this quarterly report:

1. **Adoption continues** as physicians perform more procedures: Q2 saw a new record number of 125 procedures and during the Q&A, management commented that they did 53 in June. So, Q3 is already looking solid.

2. Growing scientific results are solidifying into a **consensus that brain procedures, especially drug delivery procedures, are going to be done with ClearPoint from MRI Interventions**. They have the pole position in this large opportunity.
3. No new installations during Q2, but a pipeline of deals in which we'll see some closed in Q3 and Q4. These are important for procedure growth longer-term.
4. Revenues of 1.1M in the quarter were consistent with our expectations and up 37% YoY. Disposable product sales were up 52% to \$1.0M. The **net loss contracted 42% YoY** to \$1.8M. And that's while the company has ramped up R&D to deliver new software functionality.
5. Recently, management has **streamlined the balance sheet, completed an offering and reverse stock split**.

A full transcript of the call is on Seeking Alpha via the link below.<sup>2</sup>

## Quarterly Results for the March Q

First quarter 2016 results demonstrated continued adoption of ClearPoint.

Some highlights from the 1Q2016 report set the stage for more work on the market, their solution, and industry position which we are undertaking right now.

1Q2016 Notes:

1. **Posted revenues were 1.4M in the quarter, up 40% YoY**. Consumables came in at \$1.1M up both YoY and QoQ. Worth noting that procedures (121) and consumables made new high water marks for the company.
2. **Revenue/procedure was up in the quarter to \$9K**. This was due to the mix of procedures and an OEM sale. The number will "bounce around" but the fact that it's higher this quarter is worth noting.
3. Gross margin was down a bit due to mix, but also because the company is now including additional costs in the COGS line to more accurately allocate costs between direct and indirect activities.
4. For the first time in a while, R&D was up as the company funds **new software development**.
5. New placements continued with **2 new placements and 3 evaluation systems installed**.

Overall results were directly on track with the company strategy of increasing procedures and disposable revenues as they add to placements and continue to gain share.

As stated during their Q2 call, we expect solid results for Q3 and to see additional sites become operational which builds pipeline for future procedure growth.

## Valuation

We've put together a few models of adoption and our traditional IV model, extended by 1 year to 5 years in deference to the healthcare industry. We remind investors that this is **our model** and may differ from management guidance. We expect to revise this model over time as the company develops, but today represents our best view of their future financials and valuation given what we know.

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<sup>2</sup> MRI Interventions Q2 ER Call Transcript Link: <http://seekingalpha.com/article/3999747-mri-interventions-mric-ceo-frank-grillo-q2-2016-results-earnings-call-transcript>  
MRI Interventions Report October 2016

As with all models, there are a few assumptions baked in (for those not familiar with our IV method, we use the same discount rate for all companies.) Here is some of the thinking behind the model:

1. We're expecting a fairly consistent linear expansion of the current business. In terms of trajectory, the number of sites should bump up by 2 or so per quarter. The average number of cases per site per quarter should expand to about 3 to 4 over the next year. We are working on some underlying models of distribution and ramp by site.
2. Gross margins will also improve over time. This is due in part to volume, but also due to increased standardization of units needed for different procedures.
3. The company has made some substantial investments in software and capacity which will allow them to increase revenues while keeping operating expenses close to flat.
4. A prior history of losses means that during the investment horizon we don't expect taxes to be due. Now that they are operating outside of the US, we may need to gradually account for taxes, but for now they are not a current expense.
5. We have applied a "20% private company haircut" to valuation based on P/E because of the very small market capitalization and low trading volume in the stock. Institutions would practically consider MRIC a private company based on their current liquidity. This is likely to change, but for now we are applying the haircut. That means a 23x P/E instead of a 28x multiple which is what we would apply to a more liquid company with the same growth rate and industry position.

As can be seen in the model below, our IV estimate for the next 12-month period is \$22.55/share. It should also be noted that MRIC is clearly a stock suited to long-term investors. They are a small company that will continue to grow steadily and ultimately offer a substantial return.

MRI Innovations      Price      \$7.00  
Nasdaq: MRIC      IV      \$22.55  
25-Oct-16 Delta      353%

Dec FY	2014	2015	2016	2017	2018	2019	2020	2021	2022
Product Revenue	\$3.4	\$4.4	\$5.8	\$7.5	\$10.8	\$15.5	\$22.0	\$30.4	\$40.0
Development Services	\$0.1	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Other Services	\$0.1	\$0.1	\$0.2	\$0.2	\$0.2	\$0.2	\$0.2	\$0.3	\$0.3
Total Revenue	\$3.6	\$4.6	\$5.9	\$7.7	\$11.0	\$15.7	\$22.2	\$30.7	\$40.3
YoY Growth		27.5%	29.1%	29.5%	43.2%	42.9%	41.5%	37.9%	31.4%
COGS	\$1.9	\$2.0	\$2.5	\$3.0	\$3.8	\$4.9	\$6.4	\$8.5	\$11.4
Gross Margin%	47%	57%	58%	61%	65%	69%	71%	72%	72%
Gross Profits	\$1.7	\$2.6	\$3.4	\$4.7	\$7.2	\$10.8	\$15.8	\$22.2	\$28.9
R&D %	92%	43%	37%	29%	20%	15%	12%	10%	10%
R&D \$	\$3.3	\$2.0	\$2.2	\$2.2	\$2.2	\$2.3	\$2.6	\$3.1	\$3.9
SG&A %	223%	182%	126%	99%	70%	52%	40%	33%	27%
SG&A \$	\$8.0	\$8.4	\$7.5	\$7.6	\$7.7	\$8.2	\$8.9	\$10.0	\$11.0
Net Operating Margin	-268%	-168%	-106%	-67%	-25%	2%	19%	30%	35%
Operating Income	-\$9.7	-\$7.7	-\$6.3	-\$5.1	-\$2.7	\$0.3	\$4.3	\$9.1	\$14.0
Taxed Operating Income	-\$9.7	-\$7.7	-\$6.3	-\$5.1	-\$2.7	\$0.3	\$4.3	\$9.1	\$14.0
Market Value Using P/E	-\$217	-\$174	-\$141	-\$115	-\$61	\$7	\$98	\$204	\$314
Cash Position		\$9	-\$1	-\$6	-\$9	-\$9	-\$4	\$5	\$19
Shares (M)	5	5	5	5	5	5	5	5	5
Period Share Price	-\$47	-\$38	-\$31	-\$25	-\$13	\$2	\$20	\$42	\$64
PV of MV 5 Years Out	\$4	\$49	\$101	\$156					
PV of Cash 5 Years Out	-\$4	-\$2	\$2	\$9					
PV MV + Cash	-\$1	\$46	\$104	\$166					
PV Value Per Share	-\$0.15	\$10.09	\$22.55	\$35.66					

MRIC	Ticker
Nasdaq	
36%	Rev Growth
\$4.98	Current Price
4.6	Shares Out
1%	Avg. Dilution
\$23	Cap (M)
\$6	Cash
\$7	Debt
0%	Tax Rate
23	P/E Multiple
15%	Discount Rate
4.1x	P/S
17.1x	IV as P/S
\$22.55	Intrinsic Value
353%	Up/Downside



## Conclusion

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MRI Interventions has a unique and advanced solution for neurosurgery that is enjoying consistently growing adoption. During the last several quarters the company has executed well and delivered strong performance against both near-term metrics and longer-term opportunities like drug delivery.

Investors who appreciate this story can see beyond the current relative small size of the business and into the two large opportunities MRIC is growing into – 1) increasing use of MRI-guided methods for neurosurgery and 2) MRI-guided drug delivery in the brain. In round numbers 1) is on the order of \$400M and 2) is double that, or \$800M.

Their company position in the industry and patent portfolio make it possible for MRIC to get a substantial share of these markets over time. There will be competition as we've outlined, but MRI-guided is and will remain clearly superior as far as anyone can see.

At \$7.00/share, the current market capitalization of \$23M we think most anyone would agree is a valuation suggesting that few, if any, investors have heard about the story. We believe that more attention will foster a bigger following for ClearPoint as a technology, MRI Interventions as a company, and MRIC as a stock.

While our IV model suggests a \$22.55 share price objective on the existing business, we know that this fails to capture a large additional component of the asset value of the company considering their brand, IP position and market potential of \$400M to \$1.2B.

If one applies the IV target, the capitalization of the company would still only be \$60M. Medtronic paid \$105M for Visualase in 2014 which was in about the same amount of hospitals (45) as ClearPoint. There is even more strategic value in MRIC than what meets the eye in our IV model.

## Acknowledgements

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We are deeply thankful to the doctors, colleagues and the company for giving us access to their time and expertise in order for us to conduct our research. During the several months we spent doing this research and meeting with doctors and hospitals, we came to understand that there is an acute sensitivity to disclosure which prevents us from listing their names here. But we can at least thank the institutions: Brigham and Women's Hospital, UCSF Medical Center, and the Emory University Hospital.

## Additional Disclosures

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SoundView is serving as an advisor to MRI Interventions and provides strategic advisory and other services to the company including company positioning, investor communication methods and ongoing technology and market research. (see back page for more general disclosures.)

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<sup>1</sup> Bloomberg, Thomson/Reuters/FirstCall, S&P Capital IQ and FactSet.