



SOUNDVIEW  
RESEARCH

## MRI INTERVENTIONS (MRIC \$2.62) BECOMING A SURGICAL PLATFORM

NOVEMBER 15, 2017  
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### Introduction

It was a year ago when we published our first report on MRI Interventions. Since that time, the company has not only continued to grow but is doing so at a faster rate and with expanding margins. All the business metrics are positive – number of centers, doctors trained, and procedures per doctor.

But the major point is that MRI Interventions (MRIC) is getting close to being a platform rather than “just a medical device company.” Platform status confers major strategic value on a company in the medical space and they are few and far between. Da Vinci from **Intuitive Surgical (NASDAQ: ISRG)** is one such example in robotic surgery. The ClearPoint system from MRI is only nascent compared to Da Vinci but it’s on the same path.

This report gets into much more detail but simply put, the ClearPoint system is used to provide **real-time** MRI imaging for neurosurgery – typically for laser ablating tumors and deep brain stimulation for epilepsy and Parkinson’s.

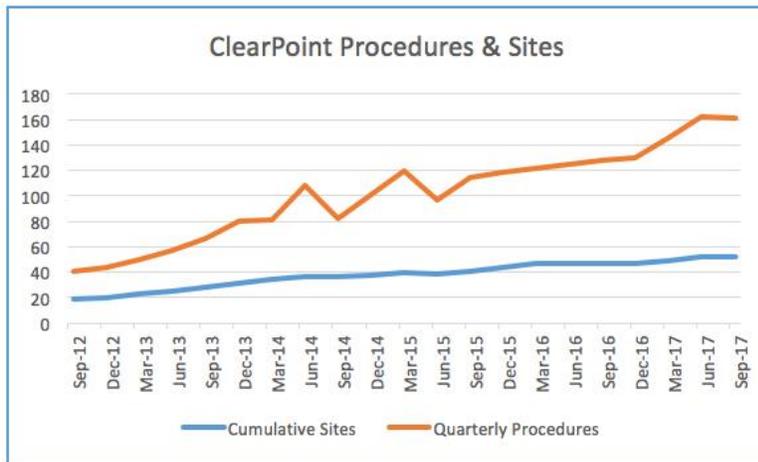
Most procedures today rely on a “fusion” of static images that use anchor points and registry marks and then overlay images from different sources. The systems do an excellent job of producing detailed images, but because these methods are based on snapshots they lose accuracy in cases where the organ can move – like the brain. ClearPoint is simply a better solution. Neurosurgeons familiar with the system tend to have the same reaction – “if I ever need something done I’ll be going to a center which is equipped with ClearPoint.”

MRIC is gaining share with ClearPoint. More systems are going in as the usage of existing systems is increasing. With run-rate revenues of under \$10M,

#### Summary Investment Points

- + Adoption of **The ClearPoint System®** brings unequalled accuracy to medical procedures.
- + Commercial success is driving **consistent 35% growth and increasing margins.**
- + ClearPoint is the **de facto method for brain drug delivery** – an emerging new market in which the FDA approval process will prescribe the use of ClearPoint.
- + A **new CEO** with a stellar track record has joined to usher in the next stage of growth and development.
- + MRIC has a **current market capitalization of just \$27M** and an enterprise value of \$23M.
- + **Shareholdings are concentrated** among long-term investors.
- + Our **IV model suggests valuation of \$17.82/share.**
- + We see **several catalysts for the shares** including a NASDAQ up-listing, ongoing drug trial updates and strong quarterly results.

MRIC has lots of room to grow in this market which is estimated to be over \$400M annually. The current installed base can already yield more than 2x the current revenue rate.



*The limitations of non-ClearPoint methods have been recently documented. In one example involving drug delivery in the brain, doctors discovered that their estimate of 50% penetration was 14% - meaning the drug didn't even have a chance of working because it wasn't put in the right place.*

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.

The ClearPoint<sup>®</sup> System 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 52 centers in the US. The number of ClearPoint 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.

Drug delivery is a major new market for ClearPoint. Several new drug therapies are being developed that 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. The drug

companies use ClearPoint for their trials which generates near-term revenue (often at higher rates per procedure) and positions MRI Interventions as the FDA-approved delivery method for those drugs upon approval.

Gene therapy has emerged in the past year as a viable method to treat previously untreatable diseases. In August the U.S. Food and Drug Administration (FDA) approved a new cancer therapy that involves genetically modifying a patient's immune cells. The agency called the decision a "historic action" because the therapy, developed by Novartis, is the first gene therapy treatment approved in the United States.

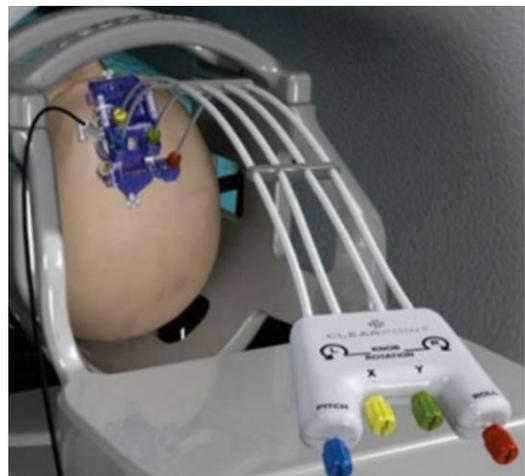
**Voyager Therapeutics is one of the leading biotechnology companies using gene therapy to develop new drugs. Their lead candidate is for Parkinson's which requires the drug to be very precisely placed in the brain. Only ClearPoint can do this successfully. To underscore how important this is for them, Voyager (VYGR) made an equity investment in MRIC.**

There are several potential near-term catalysts for MRIC stock including: NASDAQ up-listing, new CEO taking over and adding new growth initiatives to the portfolio, Voyager trial progress, and greater awareness of ClearPoint as a platform for neurosurgery and drug delivery.

## 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:

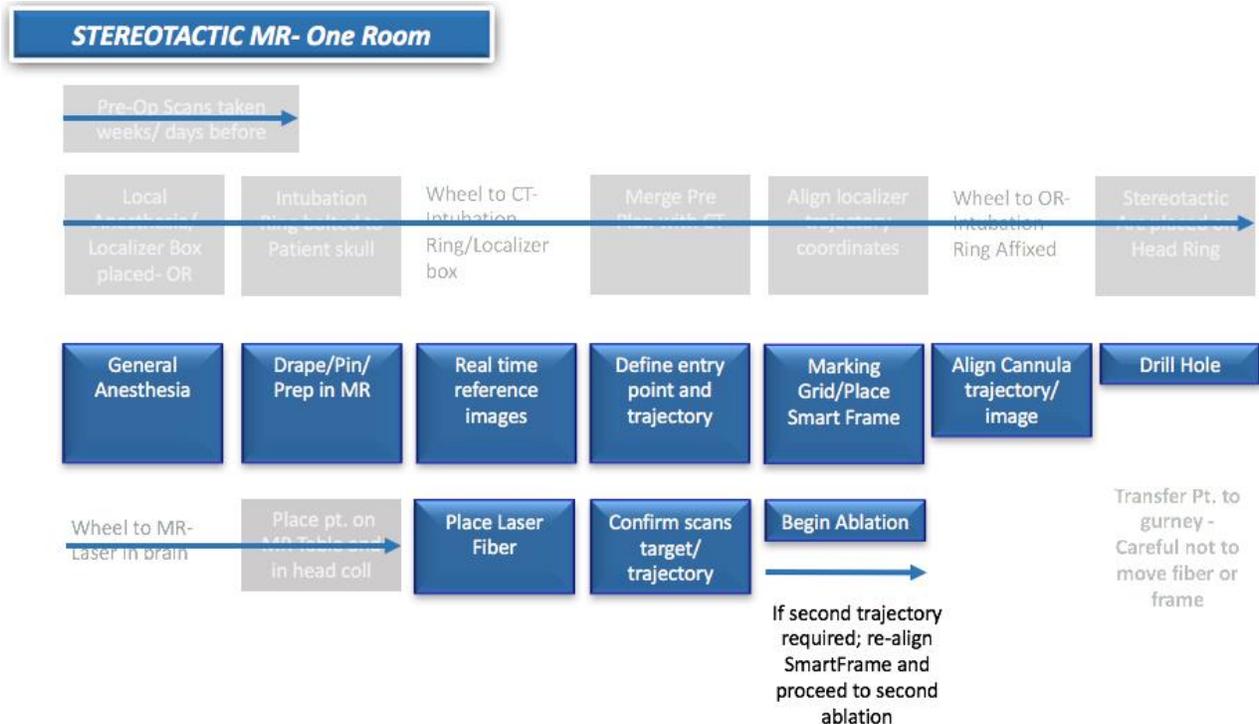
1. An initial placement of the ClearPoint SmartFrame is made using a positioning guide and the MRI images to identify the coordinates of the target area in the brain. An entry port is opened in the skull and the SmartFrame is positioned over it.
2. After placement and tightening of the SmartFrame, an 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 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

<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)

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 – Looming and Locked In

Delivering drugs in the brain is very tricky. 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 (through 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 actual penetration of the drug into the target was just 14%!**

For drug delivery to work as a therapy, 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.

To fully grasp the potential for ClearPoint, it is important to understand the FDA Approval of Interstitial Delivery of Therapeutics. **By needing to specify the payload delivery system for trial protocols, ClearPoint is tied to the approval process.** Changing device mid-clinical trial just adds a lot of variability to the program. If the sponsor has a problem, is it from the delivery device or the drug? In addition, the FDA approval of a therapeutic by method of Interstitial delivery would specify a real-time MRI imaging technology for the delivery as part of its commercial usage. Changing delivery method after a drug has been approved would create unnecessary complexities, delays, and costs.

The approval process anchors MRIC technology tightly to the therapeutic candidates without having to spend money on clinical trials and without having to market the therapeutic after the therapeutic is approved. MRIC shareholders get the upside and none of the downside of owning exposure to a basket of early stage biotech companies with cutting edge technologies.

In addition to increasing procedures at existing ClearPoint sites, any drug approvals are likely to accelerate demand for new sites because they will want to be able to administer these FDA-approved therapies. MRIC would experience "demand pull" for their units in new locations for the first time.

## Valuing the Drug Delivery Potential

In our original report, we noted that the drug delivery programs are still in the early stages – FDA-approved and reimbursed therapies are years away. We took a "swag" at the market opportunity which we pegged at about \$700M.

But we can go a step better and use a probability-weighted method to explore the potential and valuation for this part of the business.<sup>2</sup>

The following 5 companies are using ClearPoint to deliver their one-time payload to the brains as part of their clinical trials:

1. Voyager for Parkinson's disease -- Market Cap: \$360M

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<sup>2</sup> We cite MRI Interventions investor, Michael Bigger, for the use of this method and work that he has done on it. More can be found on the Bigger Capital website: <http://biggercapital.squarespace.com/about/>.

2. Medicenna for Glioblastoma Brain Tumors -- Market Cap: \$54M
3. Oxford Biomedica for Parkinson's disease -- Market Cap: \$400M
4. Lysogene for Sanfilippo Type A -- Market Cap: \$55M
5. International Stem Cell for Parkinson's disease -- Market Cap: \$7M

Voyager Therapeutics (VYGR) uses ClearPoint to deliver [VY-AADC01](#) for Advanced Parkinson's Disease. The payload consists of a gene modifying vector payload delivered one time into the putamen of the brain. The company is currently in its Phase 1. Ph1 Cohort 1 and Cohort 2 results have been published and we are now waiting for the final data on Cohort 3 which should read in Q4 2017 and complete VY-AADC01 Phase 1 study. For Cohort 3, VYGR used a posterior of the head trajectory to deliver its payload. VYGR has stated that this modification should increase the area of coverage of the therapeutic into the putamen.

VYGR intends to initiate its VY-ADDC01 Phase 2 study in late 2017 and run a Phase 3 study in parallel starting around the middle of 2018. This could lead to a PH3 readout in late 2019. This is two years earlier than previously expected from people following the company closely, and it creates a major catalyst for MRIC. We understand that this phase of the trial is getting underway.

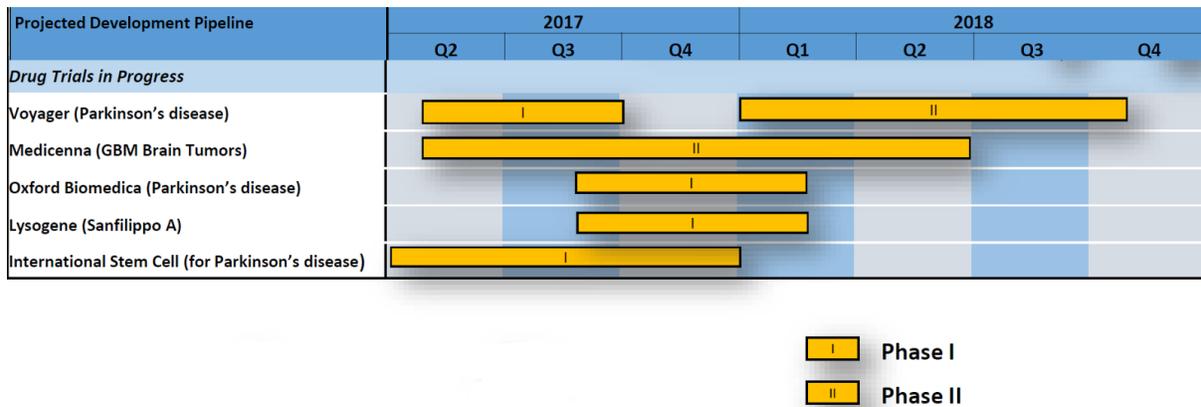
On September 2nd, 2016, VYGR made a strategic investment of \$3.8 million for a 21.04% stake in MRIC. The investment is a testimony to the value of the MRIC technology. VYGR also wanted help to ensure that MRIC had the capital necessary to support the supply of disposables for its trials. The quality of MRIC balance sheet is of the utmost importance to VYGR and any biotech companies embarking on expensive CNS drug trials. After this investment and a subsequent financing, MRIC has substantial resources to support these trials.

In 2016, VYGR performed 24 MRI guided procedures and we expect the number of procedures to increase in 2018. MRIC generates revenues from these procedures in line with its other neurosurgery activities. MRIC is in the enviable position of generating profitable business during the trial period and being in position to deliver any drugs that ultimately get approved.

## Potential Payoff Associated with the Drug Delivery Business

Clinical programs have a 10% to 50% chance of turning into a commercial drug depending on the clinical stages they are at. If you bet on 10 clinical biotech programs or more, the probability of success on a least one program is very high.

Let's derive a potential value for the MRIC Drug Delivery business. The trial pipeline looks like this:



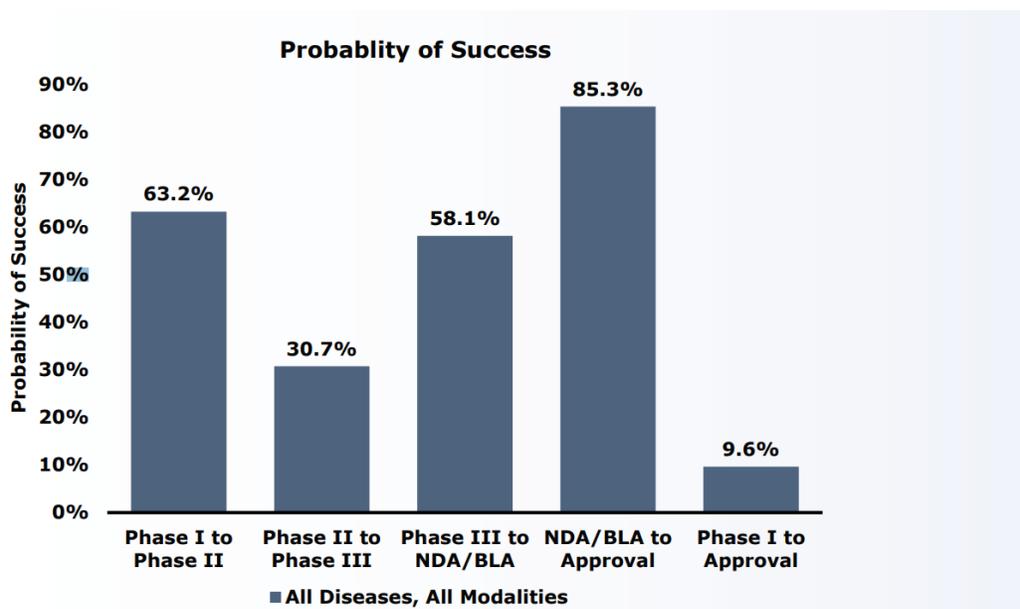
(Source: Company presentation August 2017)

Using industry data, we can derive the probability for each program to getting an FDA approval. We're using these rates based on the chart below:

- Phase I to Approval: 10%
- Phase II to Approval: 15%
- Phase III to Approval: 50%
- NDA/BLA to Approval: 85%

MRIC has computed that the annual market opportunity for the Parkinson’s drug delivery business is \$350M, and for brain tumors it’s just over \$200M.

There are three Parkinson’s trials underway but they are only in Phase 1, which gives us only a 10% probability on each one, or  $3 \times 10\% \times 350M$  or \$105M. And the probability of having 1 of 3 shots on goal hit the net is about 30%. Therefore, the current expected value of the Parkinson’s annual market opportunity is \$105 million.



(Source: [BIO Industry Analysis](#))

The brain tumor program is in Phase 2, which has a 15% chance of paying off – yielding a current expected market opportunity of  $15\% \times \$200M$  or \$30M. We assign no value to the Lysogene opportunity since it’s early and appears small. However, it’s one to leave in the “surprise bucket.”

Thus, our current expected value for the drug development market implies incremental annual revenues of \$135M. As current trials move to the next phases, this value would increase. As new trials are started, they would also contribute to this total figure. At the current 4x P/S valuation, that would equate to \$51/share. We continue to point out that these programs won’t result in approved drugs for years, but the numbers illustrate the magnitude of the value that MRI is building for future shareholders.

There are also several preclinical programs the company is aware of that would probably use ClearPoint if they enter the clinic. That would add to the expected aggregate value above. One strong possibility is the Voyager VY-HTT01 for the treatment Huntington’s Disease. Management has mentioned that they want to be the equivalent of a “biotech portfolio play”, where they have 6 or 8 or 10 shots on goal. They have 5 or so now and they are working hard to add more.

Finally, it's been pointed out that trials that have failed in the past might be possible to restart with improved targeting (they didn't use ClearPoint). This is another set of potential positive developments that we will add to our growing "surprise bucket."

## 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.
5. Being integral to clinical trials where drugs must be delivered very precisely puts MRIC in a very strong position to be the method of delivery after these drugs are approved. The incremental cost of ClearPoint is also very low compared to the likely actual cost of these drugs. There's little financial incentive to look at other solutions.

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.

## Competition

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The main competition for ClearPoint is the inertia present in the healthcare system and we have seen that begin to give way as the technology proves itself time and again.

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 procedures and by many surgeons who have “grown up” on those systems.

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 advanced. 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 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. This has been a major issue in the past, but is improving. ClearPoint can be utilized in most hospital based, diagnostic MRI systems. 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

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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 helped focus the company on commercial success by streamlining operations and raising additional growth capital.

The balance sheet is beefed up, revenues are growing 30-40% YoY and operating losses are dramatically reduced. With increased attention and trading volume, we can expect institutions to become more comfortable with the company despite the very small market capitalization.

### New CEO Announced October 9, 2017

Joseph Burnett will replace Frank Grillo as CEO on November 7<sup>th</sup>. Burnett is the GM/Business Leader for Philips' Neuro Diagnostics business. Burnett is known for his career building Volcano Corporation from 2004 through their growth as a public company until their subsequent acquisition by Philips in early 2015 for \$1.2B.

While at Philips, Burnett was instrumental in building the business there which included the \$2.2B acquisition of Spectranetics and a smaller technology buy of Electrical Geodesics for \$37M. In the course of commenting on these acquisitions, Burnett has been quoted as saying "we need more personalized and adaptive guidance tools to plan each patient's therapeutic options."

Burnett understands the market opportunity for the MRI Interventions technology and has a history of translating that opportunity into public company growth and strategic value for large acquirers. As real-time MRI becomes more mainstream, it drives usage and sales of expensive scanning equipment. Once intertwined, the large medical technology companies are likely to realize the strategic value of what MRI Interventions brings to their business.

The company has been executing well for the last two years, so it's not a turnaround situation. Burnett inherits a strong team that has the opportunity to amend and lead.

In addition to the experience Burnett brings, he will be able to leverage his network in both the industry and with investment banks, analysts, and institutional investors. He most certainly didn't take the CEO job at MRI to run a \$10M revenue organization. His aspirations and plans for the company are likely to generate new interest in both the company and the stock.

## Valuation

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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.

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 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 be steady to slightly improving. 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 20x P/E instead of a 25x 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 \$17.82/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 \$2.62  
 Nasdaq: MRIC IV \$17.82  
 15-Nov-17 Delta 580%

Dec FY	2014	2015	2016	2017	2018	2019	2020	2021	2022	MRIC	Ticker
Total Revenue	\$3.6	\$4.6	\$5.9	\$7.7	\$10.2	\$14.2	\$20.2	\$30.3	\$45.3	OTC	Market
YoY Growth		27.5%	29.1%	29.8%	32.4%	39.4%	42.3%	49.5%	49.6%	35%	Rev Growth
COGS	\$1.9	\$2.0	\$2.5	\$3.1	\$3.8	\$4.9	\$6.4	\$8.5	\$11.4	\$2.62	Current Price
Gross Margin%	47%	57%	58%	60%	63%	66%	68%	72%	75%	10.4	Shares Out
Gross Profits	\$1.7	\$2.6	\$3.4	\$4.6	\$6.4	\$9.3	\$13.8	\$21.8	\$33.9	1%	Avg. Dilution
R&D %	92%	43%	37%	41%	22%	16%	13%	11%	9%	\$27	Cap (M)
R&D \$	\$3.3	\$2.0	\$2.2	\$3.2	\$2.2	\$2.3	\$2.6	\$3.3	\$4.3	\$23	Ent Value
SG&A %	223%	182%	126%	99%	76%	58%	44%	33%	27%	\$11	Cash
SG&A \$	\$8.0	\$8.4	\$7.5	\$7.6	\$7.7	\$8.2	\$8.9	\$10.0	\$12.0	\$7	Debt
Net Operating Margin	-268%	-168%	-106%	-80%	-34%	-8%	12%	28%	39%	0%	Tax Rate
Operating Income	-\$9.7	-\$7.7	-\$6.3	-\$6.2	-\$3.5	-\$1.2	\$2.3	\$8.5	\$17.6	20	P/E Multiple
Net Interest Expense										15%	Discount Rate
Taxed Operating Income	-\$9.7	-\$7.7	-\$6.3	-\$6.2	-\$3.5	-\$1.2	\$2.3	\$8.5	\$17.6	5.1x	P/S
Market Value Using P/E	-\$193	-\$154	-\$125	-\$123	-\$70	-\$24	\$47	\$169	\$352	31.1x	IV as P/S
Net Cash Position		\$9	\$4	\$4	\$0	-\$1	\$2	\$10	\$28	\$17.82	Intrinsic Value
Shares (M)	10	10	10	11	11	11	11	11	11	580%	Up/Downside
Period Share Price	-\$19	-\$15	-\$12	-\$12	-\$7	-\$2	\$4	\$15	\$32		
PV of MV 5 Years Out	-\$12	\$23	\$23	\$84	\$175						
PV of Cash 5 Years Out	\$0	\$1	\$1	\$5	\$14						
PV MV + Cash	-\$12	\$24	\$24	\$89	\$189						
PV Value Per Share	-\$1.16	\$2.31	\$2.31	\$8.48	\$17.82						

## Conclusion

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 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 real-time MRI-guided will always be best – the only question is more about when other technologies are “good enough.”

At \$2.62/share, the current market capitalization is only \$27M. 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 \$17.82 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 be \$185M. This still leaves upside given the value of the market potential. This is also a good time to point out that while ClearPoint has a modest

upfront cost of \$100K or so, it “drags” much more revenue for makers of MRI scanners and related equipment.

## Acknowledgements

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We are thankful to the doctors, colleagues and the company management for giving us access to their expertise to conduct our research. Over several months, we met with doctors and hospitals. We also learned that there is an acute sensitivity to disclosure which prevents us from listing their individual names here. But we can at least acknowledge the institutions: Brigham and Women’s Hospital, UCSF Medical Center, and the Emory University Hospital.

## Additional Disclosures

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In the past SoundView has served as an advisor to MRI Interventions. These services concluded in October of 2016. SoundView is not a broker/dealer, investment bank or registered investment advisor. This material is provided for educational purposes only. SoundView has received fees from investors earmarked for updating our coverage of MRI Interventions and staying current on MRIC stock. (See back page for more general disclosures.)

### US-listed companies mentioned in this report:

Primary: MRI Interventions (MRIC)

Secondary: Intuitive Surgical (ISRG), Voyager Therapeutics (VYGR), Medtronic PLC (MDT), Philips NV (PHG)

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