



FAMILY OFFICE INSIGHTS

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Peer Insights

R E P O R T

Q&A with John McMahon of Mitre Medical CEO

Principal Series:

Mitre Medical has entered the largest cardiovascular opportunity for medical devices (>\$30B by Wells Fargo). Mitre provides a simpler, safer innovation that benefits surgeons, patients and hospitals. There have been more than \$3B in strategic acquisitions in this space in the past 5 years.

This is the team's fifth start-up and all previous companies have been acquired with exit value in excess of \$600m. The company has excellent 1-year results from its first series of patients in Europe and is raising capital to begin to treat US patients in its FDA approved clinical trial – a major valuation inflection point for the company.

Mitre is eliminating the need for open heart surgery for patients with functional mitral regurgitation (FMR) and at risk of heart failure. Stopping and opening the heart for the present standard of care is implicated in doubling the risk of AFib and tripling the risk of neurological complications including stroke.

The most common cardiovascular surgery is the coronary bypass procedure. Bypass patients also have FMR 30% of the time, and the presence of significant FMR doubles the 5-year mortality rate in these patients. Patients and surgeons would choose a safe and effective FMR treatment patients to

be performed at the same time as their bypass procedure. Unfortunately, adding the present standard of care, mitral annuloplasty, triples the risk of neurological complications including stroke, doubles the risk of AFib and adds three days to the hospital stay to the bypass procedure. The result is less than 4% of bypass patients have their FMR treated at the same time.

We fill the needs of patients, surgeons and hospitals with a simpler, safer and more effective option for FMR. In our initial clinical study using our Mitral Touch, we have treated FMR without the need for open heart surgery. We are raising money to bring this product through the FDA approval process.

Functional MR is driven by an enlarged heart, specifically the left ventricle. When it enlarges, it deforms its associated mitral valve, which begins to leak. This is known clinically as mitral regurgitation (MR). The surgical correction of this valve was developed over 40 years ago and requires open heart surgery to restore the geometry of the deformed mitral valve from inside the heart. This standard of care does nothing to treat the underlying cause of left ventricle enlargement, which is why the FMR returns in 30% of patients at 1 year.

The inventors of our Mitral Touch were cardiac surgeons who realized that if you could change the geometry of both the mitral valve and the left ventricle from the outside of the heart, you could have a simpler and safer procedure and a more effective device. We have confirmed our Mitral Touch can treat the mitral valve without stopping the heart, and for the first time, reduce the left ventricle as well. This was demonstrated by the outstanding results from our initial clinical trial in Europe.

Our company, Mitre Medical, is a team of medical device entrepreneurs that operates as an extension of Research and Development for global publicly traded MedTech companies. Our CEO has 4 previous start-ups which all have been acquired for a total of >\$600M in exit value. Our team includes world-leading researchers in cardiac surgery, including Michael Mack, MD of Baylor and Isaac George MD of Columbia Presbyterian in New York City.

We are raising \$12M in equity capital to bring this product to US patients as soon as possible, through our recently FDA approved Feasibility Study. So join us as we transform the standard of care in FMR patients by eliminating the need for open heart surgery, while providing the potential for an excellent return on your investments at the same time.

We believe that if our first 10 US patients have similar outcomes to our European patient experience that a structured deal is within reach.

[Join us for a private Family Office Insights Webinar featuring Mitre Medical Corp.](#)

A medical device start-up that is eliminating the need for Open Heart Surgery.

July 2nd, 2020 • 2:15-3:15 PM Eastern

Investors Only Please



Mitre Medical



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What are the history of acquisitions in the mitral valve space?

Below are some of the more prominent acquisitions in the mitral valve space. The acquirers have been aggressive, with none of the below technologies having treated US patients prior to the exits.

2015 – Edwards Acquires CardiAQ – “The purchase price is up to \$400 million, including \$350 million in cash at closing, and the remainder payable upon achievement of a European regulatory milestone.”
<https://www.edwards.com/ns20150710>

2015 Medtronic Acquires Twelve - “Medtronic has agreed to pay up to \$458 million for Twelve including \$408 million at closing and \$50 million on achievement of CE Marking.”
<https://global.medtronic.com/xg-en/about/news/press-releases/Y2015/R2081800.html>

2017 – Edwards Acquires CardioBand prior to treating US Patients
“The purchase price of Valtech is \$340 million in stock and cash at closing, with the potential for up to \$350 million in additional pre-specified milestone-driven payments over the next 10 years.”
<https://www.edwards.com/ns20161128>

2017 – Edwards Acquires Harpoon - “Edwards paid \$100 million in cash for Harpoon at closing on Dec. 1. In addition, there is the potential for up to \$150 million in pre-specified milestone-driven payments over the next 10 years.”
<https://www.edwards.com/ns20171206>

2018 – Boston Scientific Acquires Millipede “Boston Scientific initially entered into an investment and acquisition option agreement with Millipede in January 2018. It purchased \$90M in existing and newly-issued Millipede shares, with the option to acquire the company's remaining shares for \$325M at closing, with a \$125M payment becoming available upon achievement of a commercial milestone.”
<https://news.bostonscientific.com/2018-12-27-Boston-Scientific-Exercises-Option-to-Acquire-Millipede-Inc>

2019 – Edwards Acquires Mitralign signs Structured Acquisition for Corvia -
“Edwards has invested \$35 million in an exclusive right to acquire Corvia Medical, Inc., the developer of the world's first transcatheter device designed to treat heart failure with preserved or mid-range ejection fraction.”
<https://www.edwards.com/ns20190311>

What is Mitre’s differentiation in the market space?

We are expanding the surgical market for Functional MR patients to include the large volume of presently under-treated patients by providing a safer, simpler procedure and a more effective device.

For example, there are ~190,000 coronary artery bypass procedures in the US each year and 30% (>50,000 patients) also have clinically significant functional MR, which is an independent risk factor that can double 5-year mortality. Surgeons add treatment for their FMR in less than 10,000 of these patients because the standard of care requires a technically demanding open heart procedure with known risks of stroke, AFib and extended hospital stays. This leaves >30,000 FMR patients leaving the operating room undertreated.

Surgeons would treat these patients immediately if they had a safer, more effective device.

The standard of care device only treats the mitral valve and not the left ventricle. Recent clinical trials have shown that to reduce hospitalizations and increase survival you must impact the geometry of the left ventricle.

Our Mitral Touch will immediately provide the >30,000 under-treated patients a beating heart option that includes supporting the left ventricle to improve their outcomes and reducing their hospital stays without the risks of open heart surgery.

Are there additional growth markets for the Mitral Touch?

Absolutely.

Our FDA approved clinical protocol involves treating patients already in the operating room that also have functional MR. This is a well-documented unmet clinical need for surgeons and patients and is described as a concomitant market.

There are 10x more patients in the US with heart failure and healthy coronaries. The majority of these patients have FMR as the primary cause of their heart failure. This large patient population is the main driver in the early and extensive acquisitions in the space as companies make bets on technologies that can help the heart failure patients who have failed medical therapy and have FMR.

These patients represent a stand-alone procedure. Those with enlarged ventricles presently have poor prognosis and no therapeutic option, and they are not presently referred to the cardiac surgeon.

With successful clinical data, the heart failure specialists that manage these patients will want to refer their patients for the Mitral Touch stand-alone option. We are already presenting the clinical data to date at Heart Failure conferences. A subsequent clinical study would be needed to confirm the efficacy in these patients.

This patient population is 10x the existing bypass + FMR surgical market. We want to be there for them as well.



John McMahon of Mitre Medical

John MacMahon is a serial entrepreneur trained in the discipline of BioDesign. John has spent his career in early-stage medical device start-ups. He has invented and/or brought through first clinical studies devices to treat acute heart attacks, mitral valve repair, hypertension and stroke prevention.

These start-ups have cumulative exits in excess of \$600M. As founder and CEO of Kerberos Proximal Solutions (sold to Fox Hollow Technologies), as COO for Maya (sold to Covidien) and as the General Manager of Europe for Claret (sold to Boston Scientific) John has built teams that balance Silicon Valley engineering with front-line clinicians from around the world for the benefit of patients' lives.

The impact of these technologies has been exemplary, with clinical studies of two devices reporting the most effective peer-reviewed results in their fields. Currently, the Sentinel from Claret Medical remains the only FDA approved device for stroke prevention during aortic valve replacement known as TAVR. The acquiring company, Boston Scientific, is enjoying first mover position in this important field.

Currently as CEO of Mitre Medical, John is leading a team dedicated to transforming the treatment of heart failure by cardiac surgeons. The Mitral Touch provides a minimally invasive beating heart option to treat the heart as a unified structure. This requires treating both the mitral regurgitation and left ventricular dilation with a single device.– An elegant and disruptive approach that addresses the fundamentals of heart failure without the need for open heart surgery.

Mr. MacMahon studied Physics as an undergraduate at University of California, Santa Cruz, where he won the UCSC Chancellor's Award for his research on synthetic aperture radar imaging. He attended graduate school at Stanford University, where he studied Biomechanical and Electrical Engineering. He shared a Whitaker Fellowship from Drs. Dennis Carter and Tom Andriacchi in orthopedic biomechanics. His career path was determined when he attended the course Medical Device Start-Up 101 Seminar, sponsored by Wilson Sonsini and Dr. Paul Yock.

The program was the precursor of Stanford BioDesign. John continues to support the next generation of Medical Device entrepreneurs in this program as well as advisory and mentoring roles for Enterprise Ireland, Kauffmann Foundation and Singularity University.

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Alert & disclosure: *The Coronavirus (COVID-19) has now been identified in New York City. During the outbreak of the virus, in order to protect the health of our friends members and staff. Family Office Insights, BavelasGroup LLC and all affiliates is following the recommendations of the CDC and suggest you do the same. Affected individuals should limit their exposure to everyone including fellow members and staff.*

Affected individuals include members, non-members, guests, general population and staff who exhibit Coronavirus symptoms (including but not limited to fever, cough and shortness of breath), may have been exposed to the Coronavirus, or who have recently traveled to countries affected by the Coronavirus. Limiting exposure may include self-quarantining, avoiding common areas, and limiting close contact with others as much as possible.

All are also encouraged to continue to engage in everyday preventative actions, including covering coughs and sneezes with a tissue, washing their hands often with soap and water for at least 20 seconds (or using hand sanitizer), and cleaning frequently touched surfaces and objects daily using a regular household detergent and water. We DO NOT assume or accept any responsibility for the negligence or any action or inaction of anyone. As is our standard policy, we will with pleasure reschedule any service with best efforts issuing FOI services credit only. Please note it is your choice to participate or interact in any way with anyone and is your choice alone and you assume the responsibility thereof. Family Office Insights, BavelasGroup and/or an affiliates or assigns does not offer or give medical, financial or investment advice, or offer or suggest or recommend securities or any other invest for sale or otherwise, and is not a broker dealer. Anyone considering deployment of capital will likely be well served by seeking advice from a qualified professional. I love you.

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