

The MedTech STRATEGIST

Published by Innovation In Medtech, LLC

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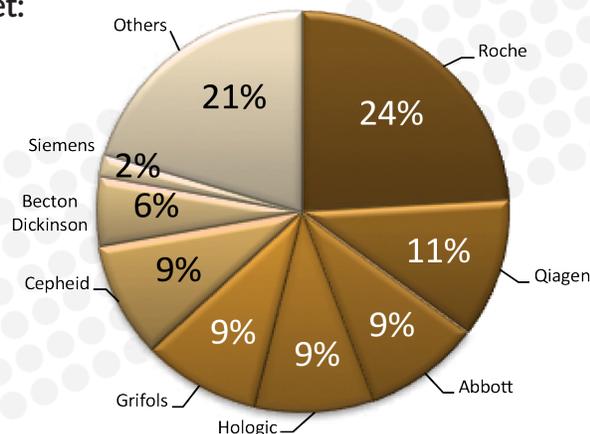
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MARKET TRACK

World MDx Market: \$5.4B

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LOWELL
MASSACHUSETTS

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YEAR FOUNDED

2011

WHO'S BEHIND IT

Cardiologist/
Electrophysiologist
Jeremy Ruskin, MD; and
Nancy Briefs, veteran
executive in the medtech
industry

UNMET CLINICAL NEED

Inefficiencies in
existing modalities for
arrhythmia detection and
monitoring that require
human over-read, add
unnecessary costs, and
complicate workflow and
reimbursement pathways
for physicians

SOLUTION

A 3-in-1 monitoring
device for all monitoring
modes and Cloud-based
proprietary analytics
platform sold on the SaaS
(software as a service)
model

FUNDING TO DATE

\$28 million up through
the Series B round

INVESTORS

Safeguard Scientifics Inc.,
Mass Medical Angels
(MA2), Excel Venture
Management, Zaffre
Investments (a subsidiary
of Blue Cross Blue Shield
of Massachusetts), and
various angels

DIGITAL HEALTH INFOBIONIC: SET TO DISRUPT ARRHYTHMIA MONITORING

Cardiac monitoring for the detection of arrhythmias such as atrial fibrillation has evolved into a fragmented and complex market with embedded inefficiencies that make monitoring cumbersome and delay diagnosis. While medical device companies to date have focused on patient-worn or implanted monitoring components, InfoBionic believes it will disrupt the market with a focus on the back-end: the Cloud-based analytics and software.

by
MARY STUART



In just two weeks, **InfoBionic Inc.** will commercialize a new HIPAA-compliant, Cloud-based cardiac monitoring platform for the detection of arrhythmias such as atrial fibrillation. The company was founded in 2011, but it's been deliberately operating under the radar until now.

A lot has happened in five years. The company has raised \$28 million to date through its Series B round with a group of investors that includes Safeguard Scientifics Inc., Mass Medical Angels (MA2), Excel Venture Management, Zaffre Investments (a subsidiary of Blue Cross Blue Shield of Massachusetts), and various angels. It has built, tested, obtained FDA clearance for, and established the clinical advantages of a new delivery paradigm and business model, which it believes, by streamlining work flow and reimbursement, will disrupt the current standard of care for arrhythmia monitoring. Half a dozen beta test sites are currently completing testing of the InfoBionic *MoMe Kardia* system, and a full commercial launch will begin at those same sites in early September.

InfoBionic was founded by four experts in their fields. Co-founder Mike Fahey, inventor of the company's core IP, is an expert in electronic health records, healthcare applications of Cloud computing, Big Data analytics, and machine learning. Fahey is currently the offering manager for Exogenous Data at IBM Watson Health. Former Chief Technology Officer Ravi Kupparaj, PhD, an expert in patient telemetry, was previously at the patient monitoring company Draeger, where he was VP, R&D, Strategic initiatives. Kupparaj is also the founder of another start-up (still in stealth mode) developing a wearable for healthcare. Cardiologist

and electrophysiologist Jeremy Ruskin, MD, was the clinical inspiration for the start-up. Ruskin is the founder and director of the Cardiac Arrhythmia Service at Massachusetts General Hospital and a professor of medicine at Harvard Medical School. These scientific founders tapped Nancy Briefs to lead the effort because of her 30-years of experience in bringing new technologies to market in the medical device industry. Briefs has played a leading role at five medtech start-ups, including Target Therapeutics, Oximetrix, Vista Medical Technologies, Percardia, and Eleme.

In 2011, when the team conceived of their new data platform, healthcare delivery was on the cusp of significant change, an upheaval wrought by payment reform and the convergence of medtech and wireless devices, sensors, databases, analytics, and Cloud-computing. Says Briefs, "We felt this new era of technology had the possibility to be based not only around clinical utility, as are all devices and healthcare IT, but also economic benefit." The company came together to build a proprietary data platform that could transform healthcare delivery by giving "anywhere, anytime access to full disclosure [minute-to-minute] data in a market for remote chronic monitoring at a lower-priced solution."

The company spent the first year filing IP around its data platform while it considered which market to target first. Says Briefs, "We wanted to disrupt a currently available market, rather than create a new one. We wanted reimbursement to be in place for the market segment. We also wanted a global market, since one of the advantages of Cloud computing is that it can scale globally very quickly."

Out of seven or eight markets for chronic monitoring that the company considered, it chose arrhythmia detection and monitoring; it's a \$3 billion global market that meets all the stated criteria, and at the same time, it's a complex and fragmented market with embedded inefficiencies that InfoBionic believes it can eliminate.

Arrhythmia Monitoring and Detection: Fragmented, Complex, and Inefficient

InfoBionic is operating in the market for ambulatory external electrocardiographic (ECG) monitoring, technology that is used to diagnose suspected arrhythmias such as atrial fibrillation (AF) and then, after treatment, to monitor the effectiveness of therapy.

AF has a great impact on healthcare costs; 2.7-6.1 million people in the US have this rhythm disorder, according to the US Centers for Disease Control and Prevention, and that number is increasing as the population ages. AF increases the risk of stroke and heart disease and is responsible for 750,000 hospitalizations and 130,000 deaths in the US each year. The CDC notes that AF costs the US \$6 billion annually. On an individual basis, patients with AF cost \$8,705 more per year than people without AF.

AF is a complicated disease to treat, as it's characterized by irregular heart rhythms caused by triggers that aren't completely understood, and patients are heterogeneous. Patients may experience symptoms, such as syncope, dizziness, and lightheadedness, or they may not. The frequency of AF episodes is unpredictable; they can occur daily, weekly, monthly, or once every six months. Diagnosing the disease is not a straightforward process either. A multi-staged pathway of diagnostic devices has evolved to try to manage the costs of various diagnostic modalities in light of their uncertain diagnostic yield over a certain time period.

The gold standard and first-line diagnostic is the Holter monitor, which patients wear for 24-48 hours as they go about their lives. The Holter collects information about every heartbeat and stores it in the device—the data is downloaded at the end of the monitoring period. Many insurance companies require that patients be tested with a Holter monitor first, simply because it's the least expensive modality, and if an

“Everyone thinks of this as a device market, but from our inception we thought about it from a data perspective.”

—Nancy Briefs

arrhythmia can be diagnosed within 48 hours, that's a cost-effective use of technology. Physician practices tend to own several of these devices, and they bill insurers for their interpretation of the studies, at less than \$100 per study. (There are several reimbursable components to ambulatory ECG monitoring: the technical component, covering the device-data collection and analytics; the set-up of the patient-worn device; and the professional component, that is, the interpretation of the results by a physician.)

If Holter monitoring is not diagnostic, the next alternatives include a 14-day Holter monitor (the *Zio* patch from **iRhythm Inc.**, which also collects and stores beat-to-beat data—see *“Wearable Technologies: What's in it for Medical Device Companies,”* The MedTech Strategist, March 16, 2016) or an event recorder, which records only an arrhythmia plus a few seconds surrounding the episode. These “events” are flagged by

the patient experiencing symptoms, who pushes a button, or are detected automatically by the systems. Event monitors do not collect beat-to-beat information, they came about as a compromise between limited device memory and the need to lengthen the test periods. They generally store up to 30 days of data, downloaded at the end of the testing period. (There are also event recorders with real-time data transmission, and these work with separate wireless devices.)

Finally, the alternative that is the most clinically efficient, in terms of the highest rate of diagnosing arrhythmias, is mobile cardiac telemetry (MCT). It's the most expensive and comprehensive option, and consists of a real-time alerting and reporting service built around data collected by the patient-worn device. MCT involves independent diagnostic testing facilities (IDTF) manned by large numbers of people who watch the data as it comes in and report to physicians events that the device algorithms flag as abnormal, in real-time. MCT is reimbursed at approximately \$1,000 per 30-day testing period by the Centers for Medicare and Medicaid Services, but physicians only get paid for the interpretation component so they only capture 5% of the global payment. Since 2014, there is a new, even more expensive option in the US market, the *Reveal LINQ* event recorder from **Medtronic plc**, which is implanted under the skin and can monitor patients for up to three years.

As noted, a patient will generally start with a Holter monitor, and if that fails to diagnose the problem, the physician offers an alternative option, and so on—a delivery model that often requires the patient to come into the practice multiple times, sometimes creating a time lag between testing periods. The current testing model is also inconvenient for physicians; it requires them to keep an inventory of multiple devices and interpret various reports that aren't standardized. Again, this system

has evolved because patients with AF are heterogeneous—heart rates don't mean the same thing from patient to patient; in one, a rate of 140 beats per minute may be just fine, in another, it's a concerning event. Symptoms vary in frequency from one patient to another, are intermittent and unpredictable, and some patients will be suspected of having life-threatening forms of the disease, requiring real-time monitoring. It's impossible for a clinician to know, going in, which type of monitor will catch the arrhythmia.

Numerous published clinical studies have shown that longer monitoring periods do uncover more arrhythmias, but here, as in medicine at large, economic considerations have shaped the way cardiac arrhythmias are currently diagnosed.

Leading with the Back-End

These were the list of problems-to-solve that InfoBionic put up on its whiteboard: for the patient, eliminate the inconvenience of multiple office visits; for the physician, allow access to full disclosure data; eliminate the headache of keeping multiple devices in inventory and interpreting various non-standardized and static reports; set up monitor-

ing times for as long as needed to obtain sufficient analysis data; and bring reimbursement and utilization under the physician's control.

The company believes it solves all of these issues in one fell swoop by focusing on the data platform, rather than the device. "Everyone has a device that does different things, but to this day, no one has developed a proprietary software on the back-end that allows you to stream beat-to-beat, full disclosure data," says Briefs. InfoBionic achieves that, she says, because of the cost advantages of the Cloud. "We moved algorithms and analytics off the devices and into the Cloud. We've created a proprietary approach, and we intend to reduce a lot of the cost inherent in today's monitoring structure, where there is a lot of redundancy between the practice and IDTF."

MoMe Kardia, which received FDA 510(k) clearance in March 2016, consists of a three-lead clinical quality monitoring device designed with a ghost display. (The Cloud-based analytics software platform received a separate 510(k) clearance in December 2015.) It's small and curved and weighs only about 4 oz. (see *Figure 1*). The device incorporates a cell phone, so it wirelessly streams data, heartbeat to heartbeat, right from the device to the Cloud; patients aren't required to carry around a second wireless device for uploading and transmitting the data. If a patient is out of the cellular coverage range, the device will store the information for up to 30 days. The minute the patient regains cellular coverage, the data automatically uploads to the Cloud.

Briefs says the device was designed to be easy to use, with the over-60 age bracket in mind (since AF is largely a disease of aging—9% of people over the age of 65 have AF). The device display has only one button; if the patient is symptomatic, he or she can push it. There are two other buttons on the device, one to look at the battery life and a button to put the device on vibrate. The display is

backlit and lights up only when there is an event worth noting, the rest of the time it's dark, so it's unobtrusive. "It is "very, very simple," says Briefs.

But the device, while simple and slick, is not the solution. "Everyone thinks of this as a device market," says Briefs, "but from our inception we thought about it from the data perspective. The company also placed its focus on the physician practice. "This is a clinical not a consumer product, and we wanted to make life more efficient and better for clinicians, cardiologists, in this case. They are the ones making the diagnosis. They and the practice are the ones that can benefit from innovation and advances in software and interactive reports."

The company worked with an IT firm called Involution Studios (in Arlington, MA) to develop an interactive interface for the cardiologist, an on-demand dashboard view called the *Mome Kardia app* (see *Figure 2*). It's an alternative to the type of static report created by other monitoring modalities. The app runs on any kind of tablet, both iOS and Android, and it aggregates patients, includes visual cues on patients requiring a closer look, and incorporates all the functionality of tablets so physicians can scroll down and look at the onset or offset of an arrhythmia. Everything is time-stamped. "Say a patient calls and says, 'I was playing tennis around 2:00 on Saturday and my heart felt like it was fluttering,'" Briefs says. "The physician can pull that patient record up and give the patient an immediate answer about what, if anything, was happening to their heart."

"We are the first company to have a proprietary platform like this," says Briefs. "A lot of innovation is happening with sensors and devices on the front-end, but the back-end is really our strong suit. We are building a data lake of information on arrhythmias."

Figure 1

InfoBionic MoMe Kardia Patient-Worn Device



Source: InfoBionic Inc.

Giving Physicians Control

What makes the system truly disruptive, is its ability to use one front-end device, for Holter monitoring, event recording, or MCT. The device can work in any monitoring mode. Because it is software- (rather than device-) based, the determination of the modality is made by the physician and that directive is implemented in the Cloud. The physician can remotely switch the patient from one modality to another until the patient has been tested sufficiently to detect patterns of arrhythmia, print off the report, and send it to the electronic health record. "Because the device uses full disclosure, we can disrupt today's IDTF with a single platform. We wanted to give all of the information, access and data—including events—back to the practice, back to the cardiologist, and we wanted the platform to be easy for the practice to use, because they enroll the patients and set them up."

InfoBionic's automated algorithms on the Cloud are able to perform what the company calls a "single-pass analysis" on the streamed data. "We give the doctor data on demand, and get rid of 60-70% of today's costs and infrastructure," as an alternative to the IDTF, which, as noted, is an expensive testing model relying on hundreds of people in brick and mortar facilities manually reading ECGs.

"This is really an efficiency play," says Briefs. "We don't need the brick and mortar infrastructure. We can scale to meet a variable number of patients each day without additional labor costs, and we can fully integrate all updates to our software to mobile devices."

Changing the Revenue Opportunity for the Practice

As noted, InfoBionic's solution operates on a software-as-a-service model. The company provides the software, data, and the device to an account for a flat fee of \$439 a month. Physicians can

use the device in whichever modality they choose on as many patients as they want. "On average, we anticipate that devices will be turned around about one-and-a-half to two times each month," says Briefs. The physician's practice does the billing and collection.

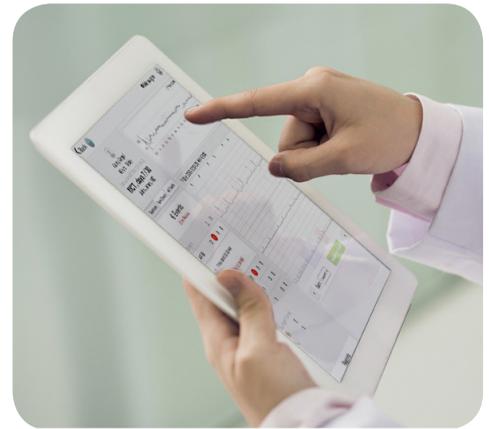
If the average revenue in the US for an MCT test is \$1,000, Briefs explains, today the physician will get, on average, \$25-30 dollars for the professional component, or about a dollar per day. But when they use *MoMe Kardia*, they'll get the technical component as well. "Instead of making \$25, they'll bill for the global fee," Briefs says. "It's a big change in the economics for them." Doesn't this model encourage the overuse of the most highly reimbursed tests? Briefs says that's not an issue because payors dictate the symptoms and requirements for each type of monitoring. "We don't think the mix between Holter, Event, and MCT is going to change at all."

Briefs notes that as healthcare moves into value-based pricing, InfoBionic is offering clinicians "the first model where anyone actually knows what their cost is going to be. Going into a contract negotiation, they know what their arrhythmia detection and monitoring costs will be and how many patients they typically monitor." Briefs reports that according to a couple of practices doing beta testing, "This alone is a huge benefit, because in the past there were so many variable costs in monitoring that they didn't know how to price some of these contracts and they lost money."

Additional benefits—for example, arriving at a correct diagnosis sooner—might be possible with the platform, but it is still very early for the company and large amounts of outcomes data won't be available until some time after full-scale commercial launch in 2017. In the first quarter of 2017, the company will be looking to raise \$20-25 million in a series C round to build out its commercial infrastructure.

Figure 2

InfoBionic MoMe Kardia Dashboard



Source: InfoBionic Inc.

A Health Information Company in a Device Segment

"This platform is different from the standpoint of efficiency and operations. We think that over time we will be able to show improved accuracy and shorter time to diagnosis, which will improve the patient experience," says Briefs.

And because the company collects full-disclosure data in a continuous data stream, it is creating another source of value. In short order, it will have a data-bank of trillions of heart beats. "We think of ourselves as a healthcare IT company, and we can now use that data to work on machine learning to improve the algorithms and also use data analytics to understand diseases and particular patients' rhythms." Briefs notes that InfoBionic asks patients for their consent to contribute their data, de-identified, to "this giant data lake that we are creating."

If successful, the company will be in a position to provide Big Data to a clinical segment—atrial fibrillation—in which much still remains unknown. That's the value proposition for the company, which is on the eve of its commercial launch. Now it just has to prove it in the marketplace. 🟡