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MARKET TRACK

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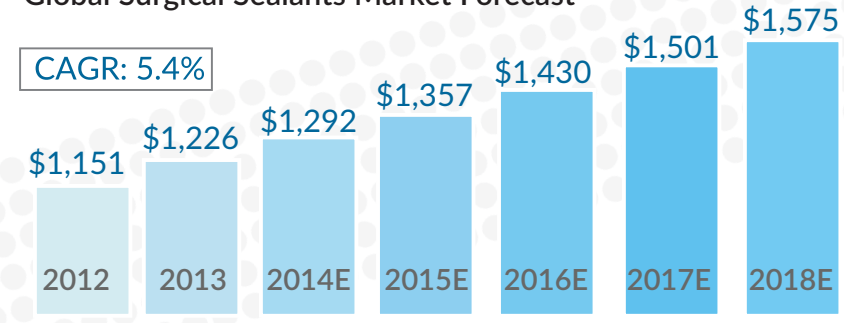
Global Surgical Sealants Market Forecast



EmpiraMed™

Maynard MASSACHUSETTS

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WHO'S BEHIND IT

Greg Erman, co-founder, President, and CEO; Dr. Neil Minkoff, Chief Medical Officer

YEAR FOUNDED

2011

UNMET CLINICAL NEED

Lack of data on how drugs and devices affect patients in the real world

SOLUTION

A software-plus-services platform to allow organizations to capture and analyze patient-reported outcomes that better measure what works in the real world and compare treatment effectiveness for targeted patient populations

FUNDING

Greg Erman

BOARD OF ADVISORS

Keith Parent (Court Square Group); Francis Campion, MD (DiagnosisOne Inc.); Richard Friedberg, MD, PhD (Baystate Health); Isabella Sledge, MD, MPH (MetaWorks); Mitch Bloom (Goodwin Procter)

EMPIRAMED: ENGAGING PATIENTS FOR BETTER DATA ON REAL-WORLD OUTCOMES

EmpiraMed offers a software platform and related services that captures real-world patient-reported outcomes not collected in clinical trials or the electronic medical record.

by WENDY DILLER

The idea for **EmpiraMed Inc.** came to Greg Erman in 2009, after he busted his knee playing tennis. An orthopedist recommended a particular procedure, but Erman couldn't find real-world evidence to evaluate it. "That's when I said to myself, 'why can't I go into a database and see what other patients who are my age and play tennis like I do think of this medical procedure he is proposing?' I couldn't find a single thing and my doc said he knew of no studies that measured patient outcomes for these procedures."

> *"That's when I said to myself, 'why can't I go into a database and see what other patients who are my age and play tennis like I do think of this medical procedure he is proposing?' I couldn't find a single thing."*
> *– Greg Erman*

Erman, a serial entrepreneur who has spent a decade or more building medical device start-ups based on technologies licensed from the Massachusetts Institute of Technology and academic medical centers, gleans his investment ideas from personal experiences combined with insights into markets and economic value uncovered through extensive interviews with potential customers and healthcare stakeholders. Three years ago, in response to the data gap he discovered while fixing his knee, he founded EmpiraMed as a software platform that captures real-world patient experiences not collected in clinical trials or the electronic medical record (EMR).

Clinical trials, by necessity, are artificially constrained. Enrollees are selected based on rigid inclusion/exclusion criteria and are studied in controlled environments that do not represent how therapies under investigation may perform in the real world, where patients with comorbidities may be exposed to other treatments. In the device world in particular, clinical trials often lack comparators, in which case there is no validated data against which to measure new treatments.

The Patient Protection and Affordable Care Act of 2010, of course, officially embedded comparative effectiveness research (CER) into the healthcare system, and FDA has been working for years to incorporate patient assessment into its preapproval reviews. Even without these government–led efforts, payor pressure has been building for more and better data from patients and comparative effectiveness studies.

Erman saw the problem, but knew little about payors, so he brought in experts who have worked in managed care: Neil Minkoff, MD, now the company's CMO, but previously a senior medical director at Harvard Pilgrim Healthcare, and Isabella Sledge, MD, MPH, an expert on health outcomes research, who is now an advisor to the company.

EmpiraMed's software program consists of three components that address shortcomings of current patient-reported outcomes (PRO) methodologies: a high burden placed on patients asked to complete traditional surveys; lack of incentives to complete them; and, partly as a consequence of these hurdles, inaccuracy and subjectivity of patient self-reported data.

The patient's experience is improved with interactive software and instruments that capture information and don't require the same level of recall from patients as traditional methods. For example, participants record notable events daily in an electronic diary. For medical devices, these likely revolve around typical side effects like pain or, for implantable devices, incidence of clotting or infection. People can much more easily record small amounts of information frequently than large amounts infrequently, points out Erman.

A toolbox of incentives motivates patients to participate. Not only are patients reminded that they are contributing to research and can share their common experiences and knowledge with each other, but they receive tangible encouragement as well.

A multitiered rewards program includes game-like giveaways, such as having participants accumulate hearts or points every time they engage with the system, which can be cashed-in for gift cards. These are similar in concept to the ubiquitous retailer rewards programs but, in order to comply with HIPPA privacy rules, merchants do not receive personal health information about individuals. About 80% of patients who are given an option to participate do so, with the studies taking an average of one year. "Compliance rates are about three times higher than traditional methods of capturing patient experience," according to Erman.

A feedback loop allows patients to see how they and others are reporting. For example, someone who injures a knee can see how other people in a certain age bracket with similar injuries are being treated, as well as the outcomes and side effects.

A third component is the set of analytics the company has built to validate the data and its accuracy. While the self-reported data does not need to be added into the EMR, both can be correlated along with other kinds of information, such as claims data to assess accuracy. In such cases, the EMR is obtained from participating healthcare providers.

The company can use the information from patients enrolled in the program to build data registries, which clients and patients – once their participation is ended – can comb for information. Multiple studies can be done based on registry data, including pre-regulatory and post-market surveillance. CER has been a hurdle for manufacturers, given the high stakes if their products fall short, but clients can ask to have it built into a study design.

The concept is straightforward, but Erman points out that the company has been able to build in competitive barriers to entry, based on years of research about implementation, privacy protection, and data reporting.

The client specifies the data it wants to collect and why, then works with EmpiraMed to develop the protocol. The studies can be run by a principal investigator in a leading academic medical center, so that they are appropriate for potential publication in peer-reviewed journals.

EmpiraMed then executes on the protocol. For medical device companies, for example, FDA is increasingly interested in PROs as part of premarket approval (PMA) trial results. In that case, EmpiraMed can collect the data, validate it and make sure it meets FDA standards. Post market, which is the bulk of the opportunity, such information could be of interest to payors and prescribers and also to regulators looking at safety. Improvements in health, reductions in costs to the healthcare system, and hospital utilization trends also can be tracked. According to Erman, "the entire study is automated in the EmpiraMed system through its unique rules-engine." Consequently, these PRO studies are more efficient to implement on a large scale.

EmpiraMed's current contracts are with biopharma clients, including **Biogen Inc.** and **Merck & Co Inc.**, but it is in talks with several medical device companies. As a former investor/owner and leader of medical device companies, Erman knows such research has not been a priority for the large device players. He believes, however, that payors will want those studies, which cannot be done without real-world patient data, and that the industry's demand for CER will grow as competition increases in therapeutic areas that were previously underserved by devices.

Erman is currently the only investor in EmpiraMed, which quickly became self-funded through revenues and has achieved profitability. The decision to forego outside capital and rely largely on a fee-for-service business model means the company is free to optimize decisions without pressure to meet outsiders' predetermined, sometimes artificial goals. On the downside, the lack of access to external investors runs the risk of constraining resources, which could hurt it if the firm has to gear up quickly to address burgeoning markets. He notes, "If the market we are in really takes off, we might need to go to investors to step on the gas further, but right now we are growing at the optimal rate based on the formation of this new category."