enable injections

CINCINNATI OHIO

CONTACT

Michael Hooven, Founder & CEO

mhooven@enableinjections.com

YEAR FOUNDED

2010

WHO'S BEHIND IT

Founders are Michael Hooven, a co-founder of AtriCure Inc., Children's Hospital Cincinnati, CincyTech, and private investors

UNMET CLINICAL NEED

A patient-friendly way to self-administer high-volume, high-viscosity therapeutics, i.e.,many injectable biologic drugs for oncologic, rheumatological and immunological conditions and blood disorders

SOLUTION

A body-worn device capable of infusing up to 50 ml of drug, leaving patients free to go about their daily activities during the up to one hour infusion time

FUNDING TO DATE

$38 million in seed and Series A funding

INVESTORS

ORI Healthcare Fund, and Ohio-based investors CincyTech, Cincinnati Children's Hospital, CintriFuse, and Ohio Innovation Fund

ENABLE INJECTIONS:
A PATIENT-FRIENDLY DEVICE FOR THE SELF-ADMINISTRATION OF BIOLOGICS

Serving a large and growing market for biologic drugs, Enable Injections has developed a disposable auto-injector capable of delivering large volumes of highly viscous drugs, offering more comfort and convenience for patients than current devices for delivering such drugs, and potentially reducing healthcare costs by eliminating visits to healthcare facilities for drug infusions.

by MARY STUART

Michael Hooven is a 30-year veteran of the medical device industry. In his early years, he worked in product development for Johnson & Johnson's Cordis division, then at Siemens/Pacesetter and J&J's Ethicon Endo-Surgery. He went on to found Enable Medical Corp. in 1994, which was ultimately acquired by the successful atrial fibrillation company **AtriCure Inc.** Now Hooven is the founder and CEO of **Enable Injections Inc.** in Cincinnati, OH, and with a potential $10-15 billion market ahead of it, he says, "In all my years, it's one of the biggest medical device markets I've ever encountered."

Enable offers an injector that's more comfortable, doesn't have to be held during injection, and might enable weekly injections to become monthly injections.

To be fair, his company's potentially pharmaceutical-sized market is due to the fact that it serves the pharmaceutical industry. Enable Injections has developed a patient-worn device for the subcutaneous delivery of highly viscous drugs that need to be administered in large volumes, which is the case for many biologics on the market today. Indeed, Enable Injections is operating in a $209 billion global biologics market that, according to a forecast by Transparency Market Research, will grow to $480 billion by 2024.

Although a medical device company, the start-up recently raised a very large, un-device-like Series A round. In October 2016, Enable Injections raised $30 million in a round of funding led by ORI Healthcare Fund, as well as Ohio-based investors, CincyTech, Cincinnati Children's Hospital, CintriFuse, and Ohio Innovation Fund, in recognition of the enormous market opportunity. That brings the company's total funding to date to $38 million, including a seed round involving Children's Hospital, CincyTech, and selected private investors.

Acutely aware of the differences between medical device and pharmaceutical companies, Hooven assembled Enable Injection's management team by bringing in people with skills from both industries. "Our VP of quality assurance and regulatory, our VP of operations, and our VP of Corporate Development are all from the pharmaceutical industry." Coming from a background in medical devices are the VP of product development, the chief financial officer, and of course, Hooven, as CEO.

The company was founded in 2010 when Hooven, who was consulting at CincyTech, became acquainted with a technology for the painless vaccination of children, which was developed at the Cincinnati Children's Hospital. Two years in, it made sense to broaden the mission, Hooven says. "We recognized the tremendous market potential of what we are now calling "high-volume, body-worn injectors."

Many biologic drugs must be delivered in such large quantities they require patients to go to healthcare clinics for weekly infusions. Genentech Inc.'s breast cancer drug *Herceptin* (trastu-

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zumab) for example, is administered weekly (for life) via 30-90 minute intravenous infusion sessions. Other biologic drugs—for example *Enbrel* (etancercept, from Amgen Inc.) for rheumatoid arthritis—require weekly self-injections that are painful. Enable Injections aims to make both scenarios less painful and more convenient to administer with a disposable, patient-friendly, body-worn device capable of delivering up to 50 ml of drug in one session (lasting an hour or less) while patients go about their daily activities. In the *Herceptin* example, Hooven says, "You could replace a healthcare professional doing an intravenous injection at a healthcare facility with a device that allows the patient to do it themselves at home." To facilitate weekly patient self-injections, Enable offers an injector that's more comfortable, doesn't have to be held during injection, and might enable weekly injections to become monthly injections due to the device's ability to deliver large volumes of drugs.

Enable's on-body injector is about the size and shape of an *Oreo* cookie (*see Figure 1*). It attaches to the abdomen with adhesive, the patient presses a button, and the device subcutaneously infuses the drug. When all of the drug has been delivered, a button on the device pops out and the patient removes and discards the device.

Enable's customers are pharmaceutical companies, and its platform is unique in that it allows pharma companies to use their existing drug containers, which they will provide to patients along with Enable's empty injectors. Patients will follow an easy procedure to transfer the drug from its original container to the injector. There are three different transfer systems, different options designed to suit the requirements of particular biologic drugs. Option one is drug transfer by

Figure 1

Enable's On-Body Injector

Source: Enable Injections

syringe, which would be chosen if the drug needed to be administered in variable doses, or if the drug came prepackaged in a syringe, for example. The user simply empties the contents of the syringe into the injector. A second transfer system is available for drugs that come in vials. The vial is placed into the injector and the device automatically draws the contents in. Finally, a third transfer system was developed for dual vial or mixing requirements. About one third of biologic drugs are produced in powder form and need to be mixed with liquid prior to injection, according to Hooven. In this case, two vials—powder and liquid—are inserted, and the device does the rest. "We can let the pharmaceutical company use their original container, then we offer the patient a really simple way to transfer the container to the injector." That feature gives the company a leg up, Hooven believes.

Another competitive advantages lies in the reason the company was formed in the first place: reducing the pain of injection, which results from several features of the device. "First and foremost, it reduces anxiety," says Hooven, "and we have done a preliminary clinical study to show this." In some cases, it's the difference between worrying about correctly plunging an auto injector into the thigh muscle—one's own, or that of a child, for example—and holding it there for the right amount of time, and simply sticking on a cookie-shaped device and pushing a button. Second, Enable's device uses the smallest possible needle; and third, it automatically controls the flow rate. Hooven notes that some motorized syringes can cause pain when injecting large volumes of drugs because pressure starts to build up at the injection site. "Our device automatically adjusts to the pressure. As the pressure increases, the flow rate slows." This is an entirely mechanical phenomenon that relies on the difference between the input pressure from the injector and the output pressure at the injection site. Indeed, Hooven points out the injector is completely mechanical (it is not electrically powered), and very cost-effective to produce.

One final feature is electronic sensing in the device's push button, an enabler of connected health care. "It can sense and transmit when the patient is using the device, and the status of the device," information that can be transferred to a database via a mobile device

or dedicated receiver/transmitter to yield patterns of compliance and other useful information, Hooven notes.

Enable Injections' business model relies on partnerships with pharmaceutical companies. Enable will design injectors according to the specifications for a partner's particular application, with development payments made at pre-determined milestones. The pharma partner will be given exclusivity in a specific field during the development agreement. The successful conclusion of product development results in a license and manufacturing/supply agreement, whereby Enable will gain revenues from manufacturing and supplying the devices to the pharmaceutical company. To address what Hooven anticipates will be very high manufacturing volumes, Enable has entered into a partnership with Flex Medical, the largest contract manufacturer in the world.

The start-up is entering a completely new category of medical devices—body-worn injectors for biologics (for the one-time injection of the contents of the injector; as distinct from continuous infusion pumps). Early entrants include Amgen, which gained FDA approval in July 2016 for *Repatha* (evolocumab), a treatment for hypercholesterolemia and atherosclerotic cardiovascular disease, in a new on-body infuser called *Pushtronex*. While *Repatha*, as delivered traditionally, in a single-use prefilled auto injector, has to be administered every two weeks, the *Repatha/Pushtronex* product is the only drug in its class (PCSK9 inhibitors) with a monthly single-dose delivery option, giving the company a competitive advantage. Amgen also recently introduced a new delivery option for *Neulasta* (pegfilgastim), a biologic designed to reduce infection risk in cancer patients undergoing chemotherapy, now available in an on-body device called *Onpro*. Patients need to receive a *Neulasta* injection within 24 hours of a chemotherapy session. "The patient used to have to come back for the injection, but the on-body device can be applied as the patient leaves the hospital, and the device automatically injects the drug after 24 hours." Hooven notes that the patent for *Neulasta* expired in 2015, leaving room for generics to eat into the company's sales; a value-added delivery device—and the potential for a higher net selling price—can forestall some of that erosion.

In the class of on-body injectors, Hooven says the key advantage of the Enable injector is its ability to deliver a high volume of drug—up to 50 ml—while using the original drug container. The company has developed 10 ml and 20/30 ml systems "and we are not aware of any fully mobile systems [that is, the patient doesn't have to hold it during injection] that exceed a maximum volume of 3.5 ccs. We are the only game in town if you want high volume," Hooven says.

Enable has one ongoing collaboration with CSL Behring AG. Negotiations with a number of other potential pharmaceutical partners are in the works. The company will be manufacturing GMP quality clinical units early next year.

When asked what company presents a model of success for Enable Injections, Hooven points to his previous company AtriCure. "When we started AtriCure, Medtronic and Boston Scientific had 100% of the surgical atrial fibrillation market. AtriCure now has more than 60% of the market and is growing by more than 20%." Hooven notes that at AtriCure "we started with the premise that there was a different and better way to do things, while the large companies were improving upon existing devices." Enable Injections is in the same position, he says. The large companies "have been modifying existing technologies—prefilled syringes and cartridges—and we're saying, 'Hey, we think there is a better way!'"

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MedTechStrategist.com 2490 Black Rock Turnpike, #326 | Fairfield, CT 06825-2400 | ph: 480.985.9512 | 888.202.5939

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