



# Monthly Startups Index

October 2013

This report sponsored by



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## From the Editor

### The new reality for medical devices: Justify your existence

The CEO of a startup in this month's index credited his company's success in raising money to two factors. Human data about the dissolving stent and a tight budget. Kamal Ramzipoor of Amaranth Medical said those two accomplishments helped his company raise \$20 million in a series B round.

This is the new reality for device makers, both startups and established companies. Companies will have to deal with the brutal facts of healthcare in American in 2013: transparency, austerity, and wellness. Companies that can't design a product strategy that meets all those criteria will not be around for long.

#### Transparency

Just as hospitals are finding out that they can't hide behind confusing billing codes, device makers will have to accept a lot more transparency in pricing. People who can't fly to Europe for a cheap hip replacement will start looking for solutions in the states. That could be paying a doctor directly or using smart shopping web sites to find hospitals with competitive pricing. Hospitals will not take this price hit on their own; naturally they will start looking for better deals from device suppliers.

#### Austerity

Earlier this year at a med tech investing conference in Minneapolis, a hospital executive explained how he had renegotiated a contract with a group of orthopedic surgeons. In their initial deal, the group had required the hospital to provide 17 hip implants. In their own practice, the surgeons offered only two options, and so were able to turn a profit. At the next contract talk, the hospital executive changed the terms of his deal to 2 implant options instead of 17. This is only one example of cost cutting. Device makers will have to look at the problems that remain to be solved in the market and build new products to fit those needs.

#### Wellness

The goal now -- for employers and payers -- is not to pay for knee replacements but to help people stay healthy enough not to need them. Getting people to eat right and stay off the couch could reduce the need for all sorts of devices, from insulin pens to gastric sleeves. This is a long-term trend of course, but no less powerful than the short term forces working on the device industry.

Startups using lean business techniques and sticking to a tight budget will not only attract investment money. They will set the example of viability for the entire industry.

Veronica Combs  
Editor  
MedCity News



Veronica Combs, Editor in Chief  
MedCity Media

# Digital & Health IT

# Startups In-Depth: Digital & Health IT



## Would you take healthcare advice from a hologram?

By: Stephanie Baum  
October 8, 2013

The gamification of healthcare has produced some interesting approaches to troubleshooting pain points in the industry. Simulation software to train for surgeries and striking the right note with patients to ensure physical exams are free of medical jargon are just a few examples of this. Health IT startup Health Options Worldwide has launched a web-based application today called Health Intelligence, or HINT, for employer plans and individuals. It's designed to help people manage their health by reminding them of medical checkups and to help them meet fitness goals.

HINT gives users a health care risk assessment and, based on their age, sex and healthcare background, it prompts a series of reminders for users. They can choose between four personal coach profiles: a drill instructor, a young female Pilates instructor. There's also a middle-aged woman who sympathizes with users juggling family and work with health commitments squeezed in between. The fourth coach appeals to those looking for clinical feedback, said HINT co-founder and COO Clark Lagemann.

It has identified 27 activities from reminders to get a mammogram or pap smear or prostate cancer screening to taking a walk, going for a run or take a walk and check out the fall foliage.

Lagemann said although the tool will be free for consumers the business model is aimed at small and medium-sized businesses. It's designed to help them manage their employee health and who might not have the resources

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**Company:**  
Health Options Worldwide

**Founder/CEO:**  
Joe Carabello

**Website:**  
<http://www.healthoptionsworldwide.com/>

**Twitter:**  
@getmyHINT

# Startups In-Depth: Digital & Health IT

## Health Options Worldwide (Continued)

for a more expansive program. The idea is that by encouraging people to be more proactive with their health and getting regular checkups will catch potential health problems earlier and lead to fewer missed workdays.

Some believe people are more receptive to medical advice if it comes in the form of an avatar or hologram or fictional character because it comes across as “less judgey.” Next year the company plans to release smartphone apps.

# Startups In-Depth: Digital & Health IT



## Polaris, ARCH Venture Partners put \$15M behind launch of deCODE genetics spinoff NextCODE

By: Deanna Pogorelc  
October 23, 2013

Sequencing the genome is one thing, but applying the data produced from that process to clinical care is a whole other thing.

A new startup called NextCODE Health has launched with \$15 million and a license to use the genomics platform of deCODE genetics to develop sequence-based clinical diagnostics.

deCODE, a once-bankrupt Icelandic company now owned by Amgen, has spent years working to combine data from modern DNA sequencing techniques with medical and genealogical data to uncover links between genes and disease.

NextCODE will leverage deCODE's technology in working with physicians and geneticists to improve their abilities to make clinical use of patients' genetic data without having to invest in IT infrastructure. Genomics could potentially be applied in clinical care to assess patient risk for specific illnesses, diagnose disease and select the most effective treatments.

In its announcement today, NextCODE said it's already working with Queensland University in Australia, Boston Children's Hospital and Newcastle University in the U.K.

The new company also said it's secured \$15 million in Series A financing from Polaris Partners and ARCH Venture Partners, the same pair of investors that

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**Company:**  
NextCODE Health

**CEO:**  
Hannes Thor Smárason

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N/A

# Startups In-Depth: Digital & Health IT

## IRISense (Continued)

bought deCODE out of bankruptcy in 2010.

Here's how it describes its analysis process:

“Raw sequence data is run through a pipeline that combines the GOR infrastructure, access to deCODE's substantial knowledge base including public and proprietary reference sequence data, and systems for genome analysis and interpretation. NextCODE's Clinical Sequence Analyzer (CSA) facilitates rapid confirmation of mutations through visualization of raw sequence data in

real time, providing greater transparency than existing systems and enabling users to validate their findings with speed and confidence. This clinically intuitive interface enables users to quickly identify and confirm possible mutations, collect disease-causing mutations into a custom database, and generate printable summary reports for physicians.”

Hannes Smarason, deCODE's former CFO and executive vice president of business and finance, will serve as CEO of NextCODE.

# Startups In-Depth: Digital & Health IT



## Could selfies someday replace the finger prick for testing blood sugar?

By: Deanna Pogorelc  
October 17, 2013

Bloodless glucose monitoring: many have tried, none have succeeded. At least yet.

There's no question why the diabetes community would want to ditch the daily lancet and test-strip routine for a cheaper, more convenient method of monitoring blood sugar levels.

In his lab at University of Toledo, bioengineering professor Brent Cameron has spent years studying ways to use light to non-invasively measure blood glucose. Medical device company Freedom Meditech, which developed an ophthalmic medical device that would enable eye care professionals to screen patients for diabetes during routine exams, licensed some of his technology several years ago.

Now a Toledo-based startup called IRISense LLC is in the early stages of commercializing more of his research in the form of a smartphone app that would predict blood glucose levels based on images of the eye.

But why the eye, rather than the fingertip or the earlobe? There's glucose in the aqueous humor, a transparent, gelatinous fluid between the cornea and the iris, and there's also no skin in the way, explained CEO Brent Cousino. There is, however, a small delay between glucose levels in the blood and glucose levels in the aqueous humor that seems to be about five minutes.

**Company:**  
IRISense LLC

**CEO:**  
Brent Cousino

**Website:**  
<http://irisense.net/>

**Twitter:**  
N/A

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# Startups In-Depth: Digital & Health IT

## IRISense (Continued)

But that doesn't seem to be causing too much trouble. Cameron developed an algorithm to estimate glucose levels in the aqueous humor based on changes in the shape of the iris captured by a cellphone camera. The idea behind IRISense is that it will develop an app that users would first have to calibrate by manually entering blood glucose levels. Then, they would take a picture of their eye whenever they need a blood sugar reading. Their readings would be displayed and automatically stored over time.

The company, which was spun out of University of Toledo and is owned by UT Innovation Enterprises, has developed a beta app that captures the images needed to apply the algorithms, and has tested it in a cohort of 17 people, Cousino said. Next, it needs to automate the image capture process and further refine the algorithm. That will involve a second study — this one led by a

primary investigator who's an endocrinologist, he said.

Ideally, a strategic partner or potentially some angel investors would follow that study. Since the eventual goal is to replace current testing methods, the app would also need FDA approval.

Using the eye to measure glucose isn't a new idea. Fovi Optics and Oculir are among the companies that have tried, and failed, to commercialize eye-scan devices for glucose monitoring, either because they were not accurate or not practical. Cousino certainly isn't naive to that, or to the fact that there are a number of other companies taking different approaches to non-invasive monitoring, too.

"We've looked at the competing products and we know what's out there," he said. "We still feel good about what we've got."

# Startup Activity: Digital & Health IT

## **MedWhat wants to counteract bad online health advice with ‘personal medical assistant’ – Oct 1, 2013**

MedWhat has built a smarter solution to searching for medical information online. Founder Arturo Devesa said it has been called “Siri for Health” or “Dr. Google”

<http://bit.ly/15JgL37>

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## **Developers building apps for Doximity’s newly released API – Oct 1, 2013**

Doximity, commonly referred to as a “Facebook-for-doctors,” has released an API and announced that more than 50 developer partners are building applications on it.

<http://bit.ly/1brCmBr>

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## **Cloud storage firm Box challenges developers to build apps for patient education – Oct 2, 2013**

Box offers a HIPAA-secure, mobile-accessible, content-sharing platform. The company claims it’s doubled its sales in the healthcare industry and expanded its customer base, which includes GlaxoSmithKline, Johns Hopkins Medicine and Alere, since April.

<http://bit.ly/15IPWRT>

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## **SimplyInsured gets \$750K to help small businesses choose health insurance plans – Oct 2, 2013**

SimplyInsured has closed \$750,000 to help small businesses navigate the changing landscape of costs, taxes, fines, and regulations surrounding health insurance. The Y Combinator-backed company has built a number of online tools to help small businesses figure out which plans are right for them.

<http://bit.ly/19X4ZU2>

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## **Cohealo raises \$1.5M to help hospitals get the most from their medical equipment - Oct 4, 2013**

Boca Roton, Fla.-based Cohealo isn’t a traditional medical device company. Instead, the team has developed a set of technology tools to help hospitals fully utilize their most expensive assets: medical equipment.

<http://bit.ly/GDgR6T>

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# Startup Activity: Digital & Health IT

## **Social network platform designed to help hospitals collaborate on health IT issues** – Oct 8, 2013

A new social network to connect staff inside and outside their health systems wants to help them collaborate on health IT and other issues these groups face. The launch of Next Wave Connect has come less than a month after Next Wave Health initiated the cloud-based infrastructure to support it.

<http://bit.ly/15kvy7a>

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## **The unhealthy side of tech: Silicon Valley Syndrome** – Oct 8, 2013

“Personal posture trainer” startup LumoBack released the results of a study today that examined “Silicon Valley Syndrome,” the physical and mental health symptoms that arise from spending WAY too much time sitting in front of a computer screen.

<http://bit.ly/15kvy7a>

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## **Quantified self startup Lark is quietly raising \$3.6 million** – Oct 8, 2013

A Form D filing reveals that the mobile health startup, Lark Technologies, has raised \$3.1 million from six investors and could continue raising another \$450,000. The device tracks sleep time and patterns and can be purchased alongside additional sleep coaching services.

<http://bit.ly/17TFcyG>

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## **SaaS company giving patients direct access to lab results raises \$1M** – Oct 9, 2013

Luminate Health, which graduated from Blueprint Health’s accelerator program earlier this year, offers a software-as-a-service platform that helps patients understand their lab results and is designed to save time on physicians’ communications with patients.

<http://bit.ly/19zdlkc>

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## **Fitbit Force packs in more features than Flex** – Oct 10, 2013

The Fitbit Force (\$130) packs in all of the features from the company’s first wristband, the Fitbit Flex, but it adds in an altimeter to track the stairs you’ve climbed and a tiny display that shows time and other information.

<http://bit.ly/1cA5Wbc>

# Startup Activity: Digital & Health IT

## **Mhealth startup deepens patient literacy app experience for medical professionals** – Oct 16, 2013

When Orca Health CEO Matt Berry set out to develop apps to improve health literacy, he saw them as a useful tool to stimulate interactions between physicians and patients.

<http://bit.ly/1ap7FtG>

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## **Hula unzips a new way to create a personal sexual health record** – Oct 17, 2013

A startup working to make sex safer and more informed has changed its name, launched an app and raised almost \$1 million. Qpid.me is now Hula. Founder and CEO Ramin Bastani said that his company is building a database of STD testing centers around the country.

<http://bit.ly/1aRI0eA>

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## **Glow and MyFitnessPal partner to integrate data, increase pregnancy odds** – Oct 17, 2013

Healthcare startup Glow today announced its first partnership, which is with MyFitnessPal. With this integration, the idea is that the nutrition and fitness data curated from MyFitnessPal can be incorporated into Glow's database to help better calculate when a woman has the best chance of getting pregnant.

<http://bit.ly/1cZafgh>

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## **Startup Endomondo logs 20M users, makes fitness social, and turns a profit** – Oct 17, 2013

Endomondo has reached 20 million users for its fitness app that is socializing exercise. In a time where there are plenty of fitness apps available, Endomondo has stood out because of its sharing ability.

<http://bit.ly/1hZC2uZ>

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## **Diabetes app developer WellDoc attracts institutional-level investment from Super Angels**

– Oct 21, 2013

WellDoc has gotten high-level investments for an app that includes a medication adherence component, provides real-time transmission, and captures and stores patients' blood-glucose levels.

<http://bit.ly/181Smpr>

# Startup Activity: Digital & Health IT

## **Physician finder app identifies specialists by user insurance plan, raises \$2.6M** – Oct 22, 2013

With such a big market in the U.S., entrepreneurs sense opportunity and an appetite for experimentation. BetterDoctor sees its invitation-only service as a way to ensure that users get a better experience.

<http://bit.ly/196MYpE>

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## **Wellbe snags \$1.4M to build step-by-step digital roadmaps through hospital episodes of care** – Oct 22, 2013

A digital health startup working with hospitals to help their patients navigate through an episode of care has loaded up with \$1.4 million from investors in a Series A round. Madison, Wisconsin-based Wellbe Inc. creates software called Guided Carepaths that essentially acts as a virtual navigator for patients undergoing joint replacements or sports medicine surgeries.

<http://bit.ly/1acuOmw>

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## **Startup gets \$5.7 million investment to provide secure group messaging for doctors** – Oct, 23 2013

Cureatr has just nabbed \$5.7 million in financing, a sizable first round for a health technology startup that provides a secure group messaging solution for doctors, which is fully HIPAA compliant, meaning it protects the privacy of patients' most sensitive health information.

<http://bit.ly/1aG9qTp>

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## **Web startup Prevently launches with a 4-pillar approach to engaging people in their wellness** – Oct 25, 2013

The beta version of Prevently.com is launching today with the goal of "making the world a healthier and more connected place." It's planning to do that with a four-pillar approach to engaging people in their wellness.

<http://bit.ly/1dsicuL>

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## **Silicon Valley startup raises \$3M to crunch EMR data** – Oct 28, 2013

A med-tech startup called Kyron has closed \$3 million in funding, according to an SEC filing. Kyron is based in Silicon Valley, Calif., and boasts an impressive team of founders. Kyron's data scientists are analyzing data from electronic medical records to generate new insights, such as the latent associations between medical conditions.

<http://bit.ly/1hfvVVC>

## Startup Activity: Digital & Health IT

**This robot has 4 wheels, 1 “eye” & the potential to be a learning tool for autistic children –**  
Oct 29, 2013

Jalali Hartman, founder of ROBAUTO, said existing robots aren't accessible to most children with autism because they're so expensive. ROBAUTO is designing a device that is says will cost a few hundred dollars and will be simple and durable enough for use at home.

<http://bit.ly/196chrL>

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**Startup unveils a wearable device it says can count calories – but it doesn't actually exist yet –**  
Oct 30, 2013

Rather than using an accelerometer to count steps, AIRO says it uses heart rate monitoring to track exercise, calories burned and stress levels. But to paint a more complete picture of health, it goes a step further.

<http://bit.ly/17tmsc3>

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# Pharma & Biotech

# Startups In-Depth: Pharma & Biotech



## Virginia startup hopes to bring personalized cancer treatment to stage 4 patients

By: Lindsey Alexander  
October 8, 2013

While many point to genetic testing as the major breakthrough for personalized cancer treatment, a startup in Virginia thinks that's only a third of the equation.

"Genes tell you what could be and proteins tell you what is," Perthera Co-Founder and CEO Dendy Young said. "There's one more nuance: proteins may be active or inactive, so you really need in effect three different tests to put a picture together of what's going on."

Because of this, Perthera focuses on not only genetic testing, but also proteomic testing to come up with personalized cancer treatments for patients. Though it's useful to know the details of the genes, it's more useful to know what proteins are in the cell and most useful to know what proteins are active in the cell, Young said. "It's important to know which pathways are open, which proteins are active—if you use a drug that targets that protein that is active, that's a much better chance if drug-delivery is effective."

The startup claims to be the "only company that safeguards biopsy quality for analysis and takes into account proteomics, genomics and your past medical history."

Perthera uses this information to create a report for stage-four cancer pa-

Continued on next page ▼

### Company:

Perthera

### CEO/Co-Founder:

Dendy Young

### Website:

<https://perthera.com/>

### Twitter:

@Perthera

# Startups In-Depth: Pharma & Biotech

## Perthera (Continued)

tients. That report includes the assessment of genes, proteins and clinical history. It's reviewed by a panel of oncologists who identify clinical trials the patient could join and send it on to the physician and patient.

"We don't care what's right for the patient as long as there's something that's right for the patient," Young said. If the patient goes forward with a treatment his insurer doesn't cover, Perthera sends the insurance company documentation of why the treatment should be reimbursed.

"We can tell a patient there is a right drug for you and it's XYZ. There is a right drug for you but it's not yet FDA-approved but it's in a trial. We can get you into that trial if you want us to." Or, of course, there is currently no effective treatment for the patient's cancer. "It's one (scenario) we hope never to run into."

So far, the company has served more than 50 patients, and hopes to reach 100 patients by the year's end. The goal is to ramp up to being able to serve thousands of patients a month from one location, serving patients all over the world.

"We don't take a patient away from his home setting, from his home oncologist, from his home, from his house, from whatever—we allow him to stay there," Young said.

Personalized medicine is a hot buzz phrase right now in healthcare, but personalized cancer treatment is perhaps one of the areas that offer the most obvious and largest benefits. Personalized cancer treatment has potential for huge, life-saving benefits for individuals—finding the right experimental treatment, the right plan of care, the right drug based on the specific make-up of his cancer.

Perthera started out targeting oncologists because they're the people who dispense chemo drugs, Young said, and though many are interested, they want more data, which the company and others like it are working

to provide. Now the company is expanding its scope and marketing to patients as well.

"Because if I had cancer, if I were about to get chemo, I would want to know what chemo they were giving me and whether or not it would work with me," he said.

Many of the company's competitors, which include universities and Genomic Health, only do either genomics or genetic testing on a tumor (not proteomic testing). Companies such as Applied Proteomics, which is on the cutting edge of proteomics diagnostics, have seen success—recently closing a \$28 million Series C round.

Young said one of the things that sets Perthera apart is its focus on getting the perfect tissue sample. The company gathers tissue in a very specific way—actually having a team in the collection suite—and only uses recently collected tissue samples, or as the company website puts it, "the patient's tumor today."

"We're dealing with current tissue that's properly handled and properly managed," Young said. "We can't rely on a biopsy from three months ago. We feel strongly enough about that, we put someone in the operating theater with the patient to collect that sample."

In time, he said, they may be able to train clinicians at certain hospitals to collect the samples. But until then, Perthera insists on this method because the company is "much more persnickety" than other labs.

While personalized cancer treatment has the attention of many medical experts, oncologists and patients, it struggles for reimbursement dollars. The full Perthera treatment costs under \$6,000 out-of-pocket, Young said. (Not astronomical for a medical bill, but certainly making it a hard-to-get option for many.)

"Payers are a conservative lot," Young said. "Frankly, the choice of spending money on multiple rounds of chemo versus spending it just once on the right thing seems to make imminent sense."

# Startups In-Depth: Pharma & Biotech



## RNAi firm raises \$5M to develop and deliver drugs that turn off disease-causing genes

By: Deanna Pogorelc  
October 21, 2013

**Company:**  
Arcturus Therapeutics

**CEO:**  
Joseph E. Payne

**Website:**  
<http://www.arcturusrx.com/>

**Twitter:**  
N/A

Just a few years ago, several big companies abandoned their RNAi drug development efforts, finding it difficult to deliver drugs that use the RNAi method for silencing genes. Recently, though, the market seems to be on the rebound.

A San Diego startup developing a siRNA drug delivery system for the orphan disease market is further evidence of that. To expand its team and work toward choosing a lead clinical candidate next year, Arcturus Therapeutics has just rounded up \$5 million from angel investors in Canada, Japan and the United States.

RNA interference is a technique that uses small snippets of RNA to silence a cell's expression of genes and viruses that cause disease. Arcturus is developing a lipid nanoparticle drug delivery system that leverages small interfering RNA, which can bind to specific messenger RNA molecules and increase or decrease their activity. It's using that system to develop a pipeline of new therapeutics for orphan diseases, beginning with a rare liver disease.

Since its \$1.3 million seed round closed early this summer, the company has licensed a portfolio of Marina Biotech's unlocked nucleic acid technology.

Two former employees of Nitto Denko, Joseph Payne and Pad Chivukula, started Arcturus earlier this year. It's one of 18 life sciences companies located at Janssen Labs, an innovation center in San Diego that provides startups access to wet labs and research and administrative equipment.

Global Industry Analysts estimates that the market for RNAi technologies, with leaders like Alnylam Pharmaceuticals and Silence Therapeutics, will reach \$4 billion by 2017.

Continued on next page ▼

# Startup Activity: Pharma & Biotech

## **Startup Clintrax Global negotiates contracts to help expedite clinical trials** – Oct 4, 2013

The Raleigh startup, co-founded and led by a former director of legal affairs at giant contract research organization PRA International, has a single-minded focus: negotiating contracts with doctors' offices, hospitals and other health-care providers that participate in clinical trials.

<http://bit.ly/1cdP1Lg>

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## **\$14M round for 'cross-kingdom vaccine' maker will fund trials in prevention of yeast infections** – Oct 4, 2013

NovaDigm will be able to test its hypothesis thanks to a new 14 million Series B from RusnanoMedInvest, a \$380 million fund in Moscow, Russia, and Domain Associates.

<http://bit.ly/1aaTc5H>

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## **Dual Therapeutics forms to develop new cancer therapeutics discovered at Mount Sinai** – Oct 9, 2013

Dual Therapeutics will develop new treatments for prostate cancer, lung cancer and acute lymphoblastic leukemia, according to an announcement today from BioMotiv.

<http://bit.ly/1c09AIC>

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## **Ready for a growth spurt, Mobius Therapeutics lands \$3M for eye surgery drug kits** – Oct 10, 2013

What Mobius has done is take the drug mitomycin c, which ophthalmologists have been using for years off-label, and package it into a standard dosage kit that can be stored at room temperature for up to 24 months.

<http://bit.ly/180ExeQ>

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## **Pharmacist wants to crowdfund \$25K for OTC gel that stops a nosebleed in one minute** – Oct 18, 2013

A startup with University of Wisconsin ties has launched a \$25,000 Indiegogo campaign to bring over-the-counter nosebleed relief to patients with a topical gel that claims to stop the nosebleed in one minute.

<http://bit.ly/15QUTGi>

# Startup Activity: Pharma & Biotech

## **To advance treatment for post traumatic stress disorder, biotechnology firm raises \$2.2M – Oct 18, 2013**

A biotechnology company developing a way to treat PTSD has raised \$2.2 million, according to a Form D filing with the U.S. Securities and Exchange Commission.

<http://bit.ly/19PyacX>

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## **FDA approves Iroko's NSAID formulation to reduce cardiovascular risk – Oct 18, 2013**

The U.S. Food and Drug Administration has approved Iroko Pharmaceuticals' drug Zorvolex to treat mild to moderate acute pain in adults, according to a company statement.

<http://bit.ly/1gEvbX2>

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## **Late stage gene therapy for inherited blindness part of Children's Hospital spinout – Oct 22, 2013**

Spark Therapeutics is advancing the work of CHOP's Center for Cellular and Molecular Therapeutics. The center was set up in 2004 as a center for gene therapy translational research and manufacturing. CHOP is giving it \$50 million to advance its genetic therapies.

<http://bit.ly/16pWXHC>

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## **Startup's proposal for Alzheimer's drug success adds new science to old, failed trials – Oct 23, 2013**

Alzheon launched today with a plan to scoop up abandoned drug candidates to which it thinks it can apply recent advances in the understanding of Alzheimer's disease and new diagnostic and prognostic tools to refine the drugs and target them toward more specific groups of patients.

<http://bit.ly/166wlsY>

# Medical Devices & Diagnostics

## Startups In-Depth: Medical Devices & Diagnostics



### Startup builds better diagnostic and prognostic tests as one step toward better ALS treatment

By: Deanna Pogorelc  
October 1, 2013

It might not seem like a fitting name for a medical company – or at least one that you’d expect – but Iron Horse Diagnostics actually makes a lot of sense.

The name comes from baseball great Lou Gehrig, nicknamed “The Iron Horse.” He died from amyotrophic lateral sclerosis (ALS), one of the neurodegenerative diseases the startup thinks it can help diagnose earlier.

The one-man, Scottsdale, Arizona company is developing a series of protein-based biomarkers to function as diagnostic and prognostic tests for the disease, which affects nerve cells in the brain and the spinal cord. Because ALS has non-specific symptoms that could also be indicative of other diseases, it’s difficult to diagnose.

There’s also no cure for ALS, but Robert Bowser, professor and chairman of neurobiology at Barrow Neurological Institute, said the interventions available to help manage the disease tend to work better if they’re administered sooner. One FDA-approved drug, riluzole (Sanofi-Aventis), for example, has been shown to slow progression of the disease in clinical studies. Typically, the disease is fatal within five years of diagnosis.

Bowser is also founder of Iron Horse Diagnostics, and he said that the company has just secured a pharmaceutical partner to validate its two ALS tests. “We’ve already performed studies in 23 centers in the U.S. where samples were collected and shipped to the lab,” he said. “The overall accuracy of the

**Company:**  
Iron Horse Diagnostics

**President/CEO:**  
Robert Bowser, Ph.D.

**Website:**  
<http://ironhorsedx.com/>

**Twitter:**  
N/A

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# Startups In-Depth: Medical Devices & Diagnostics

## Iron Horse (Continued)

test was 93 percent.”

Next, he’s gearing up to run another 300-subject prospective study at six more sites. The lab-based tests look for levels of proteins called pNfH and complement c3, which Bowser and fellow researchers have identified as being important components of the disease. One test uses a patient’s cerebrospinal fluid, and the other uses a blood sample, he said.

Down the line, he hopes to develop additional prognostic assays that would be used to monitor ALS progression and gauge the effectiveness of new drugs in clinical trials. In the meantime, Iron Horse is also working on a blood biomarker that would allow earlier and more confident diagnosis of traumatic brain injury.

Before launching Iron Horse in 2012 with technology he developed as a faculty member at the University of Pittsburgh, Bowser co-founded a drug development company called Knopp Biosciences. That Pittsburgh-based company is developing drugs for ALS and in 2010 signed a licensing deal with Biogen Idec. Earlier this year, though, the drug failed to prolong life or slow loss of muscular function in people with the disease in a Phase 3 trial.

Supported so far by an SBIR grant from the National Institutes of Health and some private funding, Iron Horse is seeking funding for clinical trials.

# Startups In-Depth: Medical Devices & Diagnostics

## LIM: Innovations™

### California startup to streamline mom-and-pop prosthetic sockets with new medical device technology

By: Lindsay Alexander  
October 8, 2013

#### Company:

LIM Innovations

#### Founder/Co-Founder:

Andrew Pedtke

#### Website:

<http://www.liminnovations.com/>

#### Twitter:

N/A

LIM Innovations, a California-based healthcare startup that has created an innovative prosthetics socket, aims to close out its first round of funding—\$1.5 million—by the end of October. So far the company has raised \$450,000 in convertible notes, with more pledged from strategics and undisclosed investors. The company also recently won MedTech Idol, a competition sponsored by WSGR, among others.

Despite the company's growth, CEO and Co-Founder Andrew Pedtke didn't intend on entering the healthcare startup sector. At all.

"I fell into it. I never really expected to go into business at all. I was just minding my own business as a surgical resident at UCSF," he said. He'd been disappointed by the expensive iterative medical device technology, and talking to a surfing buddy in prosthetics, CIO and Co-Founder Garrett Hurley, was excited by potential innovation in that field.

"If you can put a car on Mars, you can change this industry in the right way," he said. He compared the current model for producing such as a socket to an outmoded craft.

"Think of going to a cobbler to make you a wooden shoe. Over the next month, he whittles you a wooden shoe, and it doesn't change. It doesn't accommodate the fact your foot changes size and shape," he said. It doesn't have laces, it doesn't breathe, it's labor intensive, he added.

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# Startups In-Depth: Medical Devices & Diagnostics

## LIM (Continued)

LIM, while obviously a play-on-words with “limb,” also stands for “Life is motion” and “Less is more.” Those goals—mobility and simplicity—have driven the innovative product design at the company. Pedtke said four clinical needs grew the development of the sockets:

1. “No.1: Amputees need more comfortable sockets.”
2. “They need something that they can adjust or gives the user empowerment—meaning they can work with it, change it to accommodate their changing limb shape and size.”
3. Moisture management solutions in a combination of materials and design. Toward this end, the startup is at work to make liners that have wicking properties and also a valve expulsion system to remove water.
4. “Overall access to the socket needs to be better.”

That final clinical need is the one LIM arguably is best-equipped to meet. Getting a patient a prosthetics socket

that fits takes about a month. LIM is able to get a socket that fits well to a patient in about a day.

The product allows for variability by being adjustable, making the overall fitting quicker. It also allows the patient to adjust for comfort during the day. It works like this: “Roll out a liner, lock it into a socket, adjust the top part, adjust the bottom part and go.”

Future milestones include completing a 10-patient trial for a user-feedback study, which will help cement product design; fill out its IP portfolio; and clear regulatory and pricing matters, Pedtke said. Though the company will roll out its above-knee product first, Pedtke said the company plans on moving to below-the-knee innovation next and finally products for upper extremity amputee patients.

Because it’s a Class-1 FDA device and it’s not particularly expensive to make, Pedtke said the prosthetic knee socket device should see its commercial launch in September 2014.

## Startups In-Depth: Medical Devices & Diagnostics



### Device moves continuous oxygen saturation monitoring from the fingertip to the wrist

By: Deanna Pogorelc  
October 14, 2013

**Company:**  
Oxitone

**Founder/Co-Founder:**  
Leon Eisen

**Website:**  
<http://oxitone.com/>

**Twitter:**  
N/A

Fitbits and Nike FuelBands are great in that they have opened up a huge market for wearable self-tracking devices, but in medicine, taking that concept a step further is what's really going to save lives, according to Leon Eisen, founder and CEO of Oxitone Medical.

Oxitone is developing a clinical-grade, wrist-worn device that continuously monitors a patient's heart rate and O<sub>2</sub> saturation and detects changes that could indicate early signs of hypoxemia, or less-than-safe levels of oxygen in the blood. These are especially important metrics for patients with COPD and congestive heart failure, Eisen said, which are the first two markets the company is going after.

Typically, clinicians use a fingertip pulse oximetry device to monitor at-risk patients. But that's problematic in that wearing a device clipped on the finger for long periods of time is uncomfortable and unrealistic for everyday use. Oxitone's device takes the same approach as those devices, but uses a different configuration of optical sensors and electronics so that it can measure O<sub>2</sub> saturation at the wrist rather than at the fingertip.

A small screen on the device, which at this point is a functional prototype and is undergoing miniaturization, displays a user's oxygen level and pulse rate. Meanwhile, that information is also transmitted to the cloud through a mobile device. If a person's O<sub>2</sub> levels drop below a certain level, Oxitone automati-

Continued on next page ▼

# Startups In-Depth: Medical Devices & Diagnostics

## Oxitone (Continued)

cally sends out alerts to pre-identified family members or caregivers and a trained agent, who could then call for emergency responders.

“Our goal is to make preventative alerts, not just reactive,” Eisen said.

The company tested the accuracy of the device at a hospital in Israel and found that, in about 300 tests, it was able to measure oxygen saturation within an error of +/- 3 percent, or within the FDA’s requirements, he said.

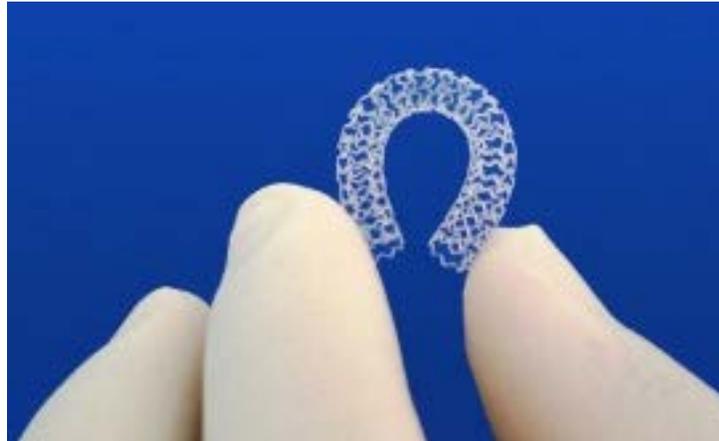
The initial version of the device will retail for about \$200 and could be on the market by 2015 if the company can

raise the \$3 million it thinks it needs to get through the remaining steps, including 510(k) FDA clearance.

To help it get there, Oxitone is participating in a three-year entrepreneurship program run by StartUp Health and GE. Eisen pitched at the startup challenge at the Medical Innovation Summit Monday.

Eventually, Oxitone imagines that the device would also monitor a more thorough set of biometrics including sleep patterns and activity patterns, to give responders and clinicians a more complete picture of a person’s condition. It would also reach other markets, like severe sleep apnea, and include a provider interface that would allow a clinician to keep tabs on the patient.

# Startups In-Depth: Medical Devices & Diagnostics



## Human data + tight budget earn dissolving stent company \$20M in VC money

By: Lindsey Alexander  
October 16, 2013

**Company:**  
Amaranth Medical

**CTO:**  
Kamal Ramzipoor

**Website:**  
<http://amaranthmedical.com/>

**Twitter:**  
N/A

Amaranth Medical, a medical device company with roots in California and Singapore, has raised \$20 million for a series B round. The money will support continued development of the company's bioresorbable scaffold (a dissolving stent) technology and the CE Mark approval process. General Manager and Chief Technical Officer Kamal Ramzipoor compared the stent to a cast. "The cast is only needed for the time the body needs to heal, then it can go away."

New investors DCP Management of Singapore and VenStar Capital joined repeat investors Bio\*One Capital, Charter Life Sciences and PhillipCapital to complete the round. (Much of the funding is from Singapore.)

"Among the recent advances in interventional cardiology, we believe that the development bioresorbable scaffolds is one of the most significant," Fred M. Schwarzer, managing partner of Charter Life Sciences and chairman of the Amaranth board of directors, said in a release.

"Ultimately, once we have the CE Mark approval, the U.S. is the next natural step," Ramzipoor said. On entering the U.S. market he added, "We may do it ourselves or we may partner with one of the existing large companies."

The next generation for the technology at Amaranth? A drug-eluting version. Elixir Medical received CE Mark approval for such a device (although it takes a year to dissolve) earlier this year. It's not just startups that have taken an

Continued on next page ▼

# Startups In-Depth: Medical Devices & Diagnostics

## Amaranth Medical (Continued)

interest in this space. Many of the top medical device companies in the heart space are at work to create strong dissolving stent technology. Abbott (ABT) has led the bioresorbable stent space and its ABSORB scaffold has been CE Marked since 2011. It launched the product internationally last year.

Ramzipoor said what sets Amaranth's technology apart from competitors is its stent platform is as strong as a metallic stent, more flexible and fully bioresorbable. Because of this and the product's "full conformability," he said, recoil and downward movement aren't an issue. It even potentially could take away the need for patients'

use of blood thinners. He said the next generation of bioresorbable scaffolds will start dismantling after three to six months.

As for raising such an impressive amount of venture capital for a medical device in a withering funding environment, Ramzipoor said having human data to approach investors with, as well as running the company on a "a very tight budget," made Amaranth stand out.

"Investors look at how the funding is managed and how it can be stretched. That gives them a sense of security, if you will."

# Startups In-Depth: Medical Devices & Diagnostics



## PurThread weaves high-tech fabric to keep the ick out of hospital curtains

By: Stephanie Baum  
October 15, 2013

A veteran of the pharmaceutical industry and biotechnology entrepreneur has a new venture — microbe-resistant textiles for hospitals.

Lisa Grimes, the CEO, says PurThread Technologies is taking a different approach than most textile companies in this sector. Instead of treating the clothing and fabric after they are produced, it adds the protective coating at the beginning of the process with the thread.

Clothing and curtain surfaces are one way bacteria can be transmitted to vulnerable patients. The idea is to reduce hospital-acquired infections, which add up to \$34 billion in healthcare costs.

Its chief technology officer Stephen Foss, a textile industry veteran, founded the company in 2009. As a board member of the Dana Farber Cancer Institute, he learned of the urgency of the problem of hospital-acquired infections.

The company based in Durham, North Carolina uses silver salts — a raw material — as part of its anti-microbial protection. Although it's not the only company that uses silver for its anti-microbial benefits, the silver salts are mixed with a resin in a molten state. It has worked with University of Iowa's microbiology lab to test the efficacy of its technology.

Grimes told MedCity News that the advantage to embedding this treatment at the beginning of the fiber production process rather than dipping fab-

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**Company:**  
PurThread Technologies

**CEO:**  
Lisa Grimes

**Website:**  
<http://purthread.com/>

**Twitter:**  
@PurThread

# Startups In-Depth: Medical Devices & Diagnostics

## PurThread Tech (Continued)

rics later in the process is it extends the anti-microbial benefit through the life of the fabric. It produces scrubs, privacy curtains, blankets and sheets.

Grimes acknowledges that there are lots of entrepreneurs and other companies working with hospitals at different touch points to combat hospital-acquired infections. One startup developed an air filtration system while others have focused on changing behavior of hospital staff. But its technology is passive and requires no training, said Grimes.

Privacy curtains are another area where the company has worked to be innovative, particularly with making them easier to change. To that effect, it developed a zipper at the top.

Although Grimes doesn't come from a textile background, she and some colleagues bring a pharmaceutical and biotech perspective to the problem of hospital-acquired infections so she sees it as a good fit. Before Grimes joined PurThread, she led a clinical trial management company, InSite Clinical Trials, which was acquired by UnitedHealthcare.

Anti-microbial protection isn't the only area where the

company is focusing its textile design efforts. The push to make hospitals a little more aesthetically pleasing to put patients at ease while maintaining a sterile environment has proven a challenge. But PurThread has developed a line of privacy curtains for patient rooms that are pretty atypical for hospitals (pictured) in response to demand.

Grimes said while it's interested in partnering with other companies, it wants to have a collaborative relationship. It wants to maintain the integrity of its brand.

The company is also looking at protecting other surfaces inside and outside of the healthcare industry. "I'm excited about looking at developing prototypes of leading-edge fashions that are also highly functional."

There are a few startup companies in this space. One is Vestagen Technical Textiles. Earlier this year it raised \$8.3 million in a Series A to apply for medical device clearance from the U.S. Food and Drug Administration and launch the line of products. Another, Aries Medical Textiles, is led by Adam Greenspan and resides in the Philadelphia-based University City Science Center incubator space.

# Startups In-Depth: Medical Devices & Diagnostics



## Crowdfunding a diaper-shaped ice bag for damaged testicles

By: Stephanie Baum  
October 28, 2013

A new medical device company thinks it has an innovative approach to help with the recovery process for penis and scrotum injuries. It's raising \$75,000 on crowdfunding website "B a Med Founder" to advance its Epiditi scrotal ice pack with the helpful catchphrase, "Cool the Jewels!"

Short Hills, New Jersey-based Gallen Technologies said its device is designed to reduce post operative trauma, such as twisting of the scrotal sac as well as complications of swelling, bruising, inflammation, hemorrhaging, pain and like diseases of the scrotum and penis, according to the website. The company sees its device as a more sophisticated alternative to ice packs or bags of frozen peas.

Funding will be used for manufacturing, marketing outreach to the medical industry and sales from its website. It's also launching a TV ad campaign for consumers. So far it's raised \$2,500 from eight donors.

The B-a-Medfounder crowdfunding website claims to be the only one focused on medical devices. It's domiciled in Cyprus and is led by Sedat Barokas, the CEO and Daniel Yachia, the chief medical officer.

Although crowdfunding supporters see it as a great way to expand the number of potential investors in startups, there is some concern that incautious investors will allocate funds to companies without due diligence.

Two other companies listed on the site include a catheter-like device and another device for pelvic floor reinforcement, both from Israel.

### Company:

Gallen Technologies

### CEO:

Mike Gallen

### Website:

<http://www.gallentechnologies.com/content/index>

### Twitter:

@GallenTech

# Startup Activity: Medical Devices & Diagnostics

## **NIMH grants \$1.8M to company that aims to lower cost of molecular imaging with PET** – Oct 2, 2013

Sofie Biosciences announced it will receive a \$1.8 million Phase 2 Small Business Innovation Research grant from the National Institute of Mental Health to be paid out over three years.

<http://bit.ly/1dmrRAp>

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## **Is this the future of personalized diagnostic devices? Nanobiosym clinches Nokia prize** – Oct 2, 2013

A Boston-based nanotechnology incubator Nanobiosym developed a device and app to make the process of diagnosing a condition less costly and faster in a move that could shake up the diagnostic industry. Its Gene Radar device can analyze a blood sample, saliva or other bodily fluid using a nanochip placed into a mobile device.

<http://bit.ly/1f22JIt>

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## **California team hopes to modernize the standard of care for postpartum hemorrhage** – Oct 2, 2013

InPress Technologies, a California-based device startup, has an ambitious plan to solve a potentially fatal problem for pregnant women around the world.

<http://bit.ly/GzIWMh>

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## **FDA grants Neuros Medical IDE approval for clinical trial of pain management tech for amputees** – Oct 10, 2013

Neuros Medical, a Cleveland-based medical device company, received an FDA investigational device exemption approval to begin a clinical study on its technology for intractable limb pain management for amputees.

<http://bit.ly/1g9Toc6>

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## **No catheter, no cuff: FDA clears Sotera Wireless' continuous noninvasive blood pressure technology** – Oct 12, 2013

Sotera Wireless announced the FDA has given 510(k) clearance to its continuous non-invasive blood pressure (cNIBP) technology, a new feature of its ViSi Mobile patient monitoring system.

<http://bit.ly/17sgrFE>

# Startup Activity: Medical Devices & Diagnostics

## **St. Jude Medical acquires mini, leadless pacemaker technology with Nanostim buy** – Oct 14, 2013

St. Jude Medical (STJ) announced it has acquired Nanostim, Inc., a California-based early-stage medical device company focused on leadless pacemaker technology, for \$123.5 million.

<http://bit.ly/1cklJbl>

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## **Atlanta device company lands \$11M to launch smart materials orthopedics technology** – Oct 14, 2013

MedShape, Inc., a medical device company, announced it closed an \$11 million funding round that will go toward a full-market launch of the Eclipse Soft Tissue Anchor. It is a shape-memory, soft-tissue repair device that allows surgeons to attach tendons, ligaments or soft tissue to bone.

<http://bit.ly/18eM6yS>

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## **Startup uses 3D scanner to build customized ostomy pouches** – Oct 17, 2013

The kit uses a 3-D scanner to produce customized devices, as stoma size can vary. Users download a companion app, point the phone at their stoma and it automatically uploads the images to a 3D printer for customized production.

<http://bit.ly/16SJZAI>

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## **Close look at 23andMe founder and what genetic testing means for adoptive parents** – Oct 19, 2013

What began as an assignment to investigate and profile 23andMe Founder and CEO Anne Wojcicki took a personal turn for one adoptive parent and Fast Company contributor.

<http://bit.ly/16XALD8>

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## **Startup kicks off crowdfunding campaign for noninvasive glucose meter** – Oct 25, 2013

Socrates Health Solutions has gone to Indiegogo to crowdfund \$125,000 for its noninvasive glucose meter technology, the Companion, by Nov. 12. The healthcare startup has Dallas roots as part of the Health Wildcatters incubator. The campaign will help push the device through an FDA 510(k) clearance path.

<http://bit.ly/1aisdWf>

# Startup Activity: Medical Devices & Diagnostics

## **EndoChoice wins FDA 510(k) clearance for gastroscope with wider field of view – Oct 31, 2013**

EndoChoice, an Atlanta, Ga.-based healthcare startup, announced its received 510(k) clearance for its Fuse Gastroscope. Its not the first positive FDA device approvals news the company has gotten this year either.

<http://bit.ly/1dUm2Nr>

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## **Nasal drug delivery treatment for polyps begins enrollment for Phase 3 trial – Oct 31, 2013**

A few months after licensing its drug delivery platform for migraine treatment to Avanir Pharmaceuticals, OptiNose is shifting its focus to nasal polyposis. The condition affects up to 4 percent of the population, about 12 million people, and produces polyps in the nasal cavity, which can impact quality of life. It has begun enrolling for the first of two Phase 3 clinical trials.

<http://bit.ly/19gzlnO>

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## Most Popular Startups This Month

A list of the five startups that got the most attention from readers on MedCityNews.com.



### 1) IRISense LLC

Could selfies someday replace the finger prick for testing blood sugar?

Bloodless glucose monitoring: many have tried, none have succeeded. At least yet.

In his lab at University of Toledo, bioengineering professor Brent Cameron has spent years studying ways to use light to non-invasively measure blood glucose.

*Read more:* <http://bit.ly/1cZT2Dt>

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### 2) Kinsa

Smart thermometer was the favorite at Cleveland Clinic & StartUp Health's venture challenge

The smart thermometer tracks the spread of human disease by mapping it using mobile tools, starting with a smart-phone-enabled thermometer and app. The company's low-cost thermometer attaches to a smartphone and uses the device's electronics to determine a person's temperature.

*Read more:* <http://bit.ly/192SAjO>

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**3) HealthSpot** The after-hours doctor visit of the future arrives in Ohio... *Read more:* <http://bit.ly/1aDG9i8>

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**4) Oxitone** Device moves continuous oxygen saturation monitoring from the... *Read more:* <http://bit.ly/1cCKDCY>

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**5) Glooko** FDA clears Glooko's mobile diabetes management system for... *Read more:* <http://bit.ly/17vurOu>

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# EXPERTS IN HEALTH MEDICAL MARKETING

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