FIERCE Life Sciences

FIERCE INNOVATION AWARDS

Life Sciences Edition 2023

INNOVATION REPORT

AN EXPERIENCE FROM Questex

Introduction

As the immediacy of the COVID-19 pandemic recedes it is clear many of the changes in the Life Sciences industry that were adopted to mitigate disruption are not only here to stay they are the building blocks for the future.

What was perceived just a few years ago as an industry slow to adopt digital technologies, novel therapies and innovative therapy delivery systems are now charging to the forefront of a health-care revolution. Artificial intelligence, machine learning and data collection has changed not only how clinical trials are conducted, but how they are designed before the first patient participant is even signed. These advances are also driving diversity in trials by identifying and recruiting patients from under-represented minority communities.

The advances are also behind serving patient needs that includes real-time monitoring of a patient's condition, alerts to physicians and clinicians of a change in their conditions and tracking their adherence to medications. The technology can also incorporate real-world data and an individual's health history to predict when an adverse medical event is likely to occur.

All of these advances have one goal that remains a constant for Life Sciences—to be patient centric. Whether it's in an organization's mission statement or demonstrated by their products, if you are in the industry your work is directed at getting the right help to the right patient at the right time, and in the most cost efficient manner possible.

This year's Life Sciences Innovation Report reflects those trends. Each year we uncover cutting edge organizations that have or are in the process of launching new technologies and services that are reinventing what it means to be focused on helping people. Each year it gets harder for our judges because there are so many more companies doing great work and making huge strides toward that goal.

Applicants were judged in the following categories:

Biotech Innovation - Championing innovation in the face of great competition. This category showcases products and service that are forward thinking and have the greatest opportunity to have an impact on the industry.

Technology Innovation - Utilizing technology to shape the industry. This category highlights products and services that are using innovative technology solutions to better serve the industry and promote innovation.

Data Analytics/Business Intelligence - Excellence in data analytics. This category recognizes greatness in business intelligence using data science, data management, and data analytics to better serve the industry.

Digital Health Solution - Forward thinking digital innovation. This category showcases the best use of digital technology and mobile apps to better serve the industry.

Drug Delivery Technology - Drug delivery technologies are shaping the industry. This category recognizes excellence and innovation in the latest drug delivery technologies.

Medical Device Technology – Innovative medical devices are a main focus of innovation given advances in materials and production. This category focuses on those advancements and what is in the device pipeline for the future.

Our expert panel of judges reviewed hundreds of applications to find the best of the best and now I am pleased to introduce you to our 2023 winners.

Rebecca Willumson
Senior Vice President & Publisher
Fierce Life Sciences

MEET THE JUDGES

Wilfredo De Jesus Monge
Founder
clinicaLea

Rebecca Willumson
Senior Vice President & Publisher
Fierce Life Sciences

Chris Jones
Chair
BrIgID Bio

Daniel Oliver
Co-founder and CEO
Rejuvenate Bio

Anna Turman
Division CIO
CommonSpirit Health

Colin Hayward
Group Chief Medical Officer
TelixPharma

WINNERS

BIOTECH INNOVATION

ELEVIDYS (delandistrogene moxeparvovec-rokl)

Sarepta Therapeutics

DRUG DELIVERY TECHNOLOGY

RaniPill HC

Rani Therapeutics

DATA ANALYTICS/BUSINESS INTELLIGENCE

BostonGene - AI-based Clinical Trials Matching

BostonGene

MEDICAL DEVICE INNOVATION

Nerivio Migraine Neuroband

Theranica

DIGITAL HEALTH SOLUTIONS

canturio™te

Canary Medical

TECHNOLOGY INNOVATION

TeleScan®

BB Imaging

SPOTLIGHT

SAREPTA THERAPEUTICS

BIOTECH INNOVATION

CEO: DOUGLAS S. INGRAM
BASED: CAMBRIDGE, MASSACHUSETTS
FOUNDED: 1980
ELEVIDYS (DELANDISTROGENE MOXEPARVOVEC-ROKL)

WHAT'S THE SCOOP:

After a long journey, Sarepta's Duchenne muscular dystrophy (DMD) gene therapy treatment Elevidys won an accelerated FDA approval in June. The one-time treatment targets the root cause of DMD in patients aged 4- through 5-years-old that despite its $3.2 million price tag is not only a game changer but a lifesaver. "We're extremely excited about Elevidys," Louise Rodino-Klapac PhD, Sarepta's head of R&D and chief scientific officer, said. "It's really been in development—and I've been with it the entire time—these past 18 years." Three clinical studies found there was meaningful and statistically significant functional improvement in patients treated with Elevidys. Additional clinical evidence showed the treatment also indicated disease stabilization, showing that patients were doing better than the previous natural course the disease would take.

WHAT MAKES IT FIERCE:

"The great thing about working at Sarepta is how focused we are," Rodino-Klapac said. "It's a relentless disease and we're working everyday for patients. We don't back down." She added, that knowing that patients are there drives the team to push very hard to get transformative therapies to as many patients as possible.

WHAT TO LOOK FOR:

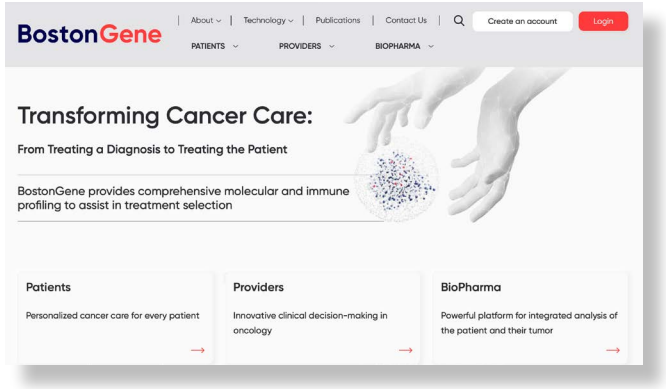
In the near-term, the company is working on broadening the label for Elevidys to treat as many patients as possible. At the same time, Sarepta is working on a number of gene therapies targeting limb girdle muscular dystrophies (LGMD) and other diseases. "We're definitely working hard to stay at the forefront of genetic medicine," she said.

SPOTLIGHT

BostonGene

DATA ANALYTICS/BUSINESS INTELLIGENCE

CEO: ANDREW FEINBERG
BASED: BOSTON
FOUNDED: 2015
BOSTONGENE - AI-BASED CLINICAL TRIALS MATCHING



WHAT'S THE SCOOP:

BostonGene focuses on cancer patients by leveraging cutting edge sequencing analysis that involves testing a patient's normal DNA in their blood as well their tumor DNA and RNA tissue. Its AI-driven Tumor Portrait platform gives a comprehensive snapshot of what is driving a tumor and pairs the information—in realtime—with information from a patient's health records as well as available drugs or clinical trials specific to their cancer in which they could take part. The platform allows physicians to make more informed treatment options that are specific to the subject's cancer. "It's the most comprehensive snapshot on what is driving the tumor," Nathan Fowler, BostonGene's chief medical officer, said. "There has been a phenomenal change in the field in the last 10 years with the cost of sequencing dropping exponentially, and there are more tools to measure the data that weren't available a decade ago." In a sarcoma trials matching study with MD Anderson Cancer Center, the platform analyzed data from 39 subjects and found more than 97 percent of the reports were eligible for at least one trial at the cancer center, and 30 different biomarker-driven clinical trials also matched. Although nobody wants to be matched with cancer being matched with the appropriate treatment is critical, Fowler said, adding that with the expected explosion of targeted drugs the need to connect patients to therapies will become even more paramount.

WHAT MAKES IT FIERCE:

The company's ability to bridge the gaps between the accumulation of the data and the ability to interrogate it. "What we've done is build a really innovative team with a very large group of biologists, immunologists and oncologists and pair them with software engineers," Fowler said. "Very few companies have the two kinds of groups overlapping, which has resulted in more than 150 patented software solutions."

WHAT TO LOOK FOR:

The company will be actively pursuing expansion in the U.S. and overseas, Fowler said. Additionally, it will be expanding its pipeline of AI solutions to include drug target applications and adverse event validation.

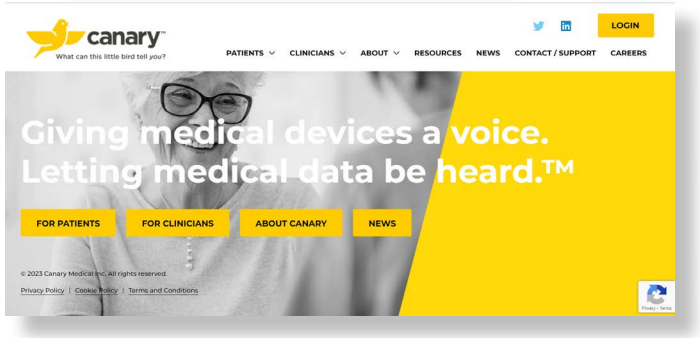
SPOTLIGHT

canary™

What can this little bird tell *you*?

DIGITAL HEALTH SOLUTIONS

CEO: BILL HUNTER
BASED: VANCOUVER, BRITISH COLUMBIA
FOUNDED: 2012
CANTURIO™TE



WHAT'S THE SCOOP:

What's smarter? Having a knee replacement or having a knee replacement that has sensors and a data platform that monitors post-operative progress that can tell if a patient is falling behind recovery expectations or is progressing according to plan? It's an easy answer for Canary Medical CEO Bill Hunter, M.D. "Historically, we've done all these surgical procedures in hospitals then we walk patients to the front door and wish them good luck," he said. "It seemed absurd to me that there might only be a follow up visit a few days or weeks later and then maybe another in a month or so." Enter Persona IQ®, a total knee replacement construct that combines Canary Medical's canturio smart stem technology with Zimmer Biomet's Persona line of patient-specific implants. Persona IQ received FDA de novo approval in 2021. Canary Medical's offering features the canturio tibial extension with a sensor, battery and antennae that autonomously monitors post-operative progress and a data analysis platform that automatically alerts health-care providers if a patient needs additional care or is recovering normally. "In the past, you would go to a clinic, and they would test your range of motion to see how you are doing," Hunter said. "Now that's done automatically every day." The data collected is likely to open more doors for the company to move from a purely diagnostic view, to serving as a predictive tool. "You don't walk the same way when you have the flu versus being late for a meeting," he said. "Right now, we're working our way through using AI to track billions of motions and look at those patterns from a predictive perspective."

WHAT MAKES IT FIERCE:

The company is bringing an entirely different way of doing things to orthopedics than what has been done in the past, that Hunter said is a much bigger change in healthcare than you might think. "It absolutely changes the way you manage the patient," he said. "People used to go home after knee surgery and not know what is going on. Now they know if they are on pace for recovery or doing too much or too little during recuperation. They go from a passenger, to being actively involved in their recovery process."

WHAT TO LOOK FOR:

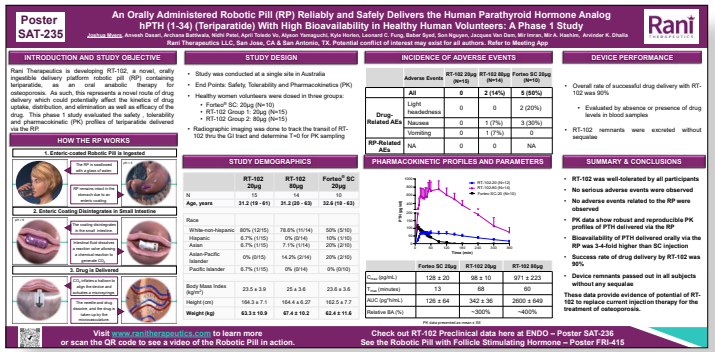
It isn't much of a technological leap to move from smart knees into smart hip and shoulder replacements. Additionally, Hunter said its existing platform could also eventually be used for spinal surgery. With respect to AI, "I feel that as this data asset grows, we'll go from identification to prediction," Hunter said. "And prediction in medicine is worth its weight in gold."

SPOTLIGHT

Rani THERAPEUTICS

DRUG DELIVERY TECHNOLOGY

CEO: TALAT IMRAN
BASED: SAN JOSE, CALIFORNIA
FOUNDED: 2012
RANIPILL HC



WHAT'S THE SCOOP:

Driven by their mission to alleviate the burden of painful injections, Rani Therapeutics developed a robotic pill, the RaniPill, that delivers biologics orally. The RaniPill's proprietary technology allows the pill to navigate through a patient's stomach and into the small intestine. Once in the small intestine, a small balloon inflates that contains a syringe that injects the medication right into the intestinal wall. It is well-established that the small intestine has no sharp pain receptors, so the patient feels no pain associated with the injection. The RaniPill innovation has the potential to expand the delivery of oral biologics to close to 100 drug candidates and can increase patient adherence to their prescribed medication.

"What we set out to do is essentially develop what is a swallowable auto-injector," Talat Imran, Rani's chief executive officer, said. The RaniPill can deliver peptides, antibodies, large proteins, and nucleotides orally. An early version of the RaniPill was limited to delivering only about 3 milligrams of a drug, so the company developed its high-capacity pill, the RaniPill HC. The difference, Imran said, is the HC class, which is undergoing non-human clinical trials, has a liquid delivery system contained in the dissolvable needle that can hold 20 to 30 milligrams.

"We have advanced our technology and can now fit about 85 percent of all approved biologics into a RaniPill," he said. "Patients hate injecting themselves, so instead of taking a large dose that way, they can take a daily pill, the RaniPill." Rani Therapeutics has conducted 15 preclinical studies that demonstrate comparable bioavailability with the RaniPill to the subcutaneous injection and has conducted two clinical trials demonstrating safety in humans, with a third clinical trial underway.

WHAT MAKES IT FIERCE:

"We're doing something no one else even thought to do that is true, fundamental disruption that affects the entire biotech industry," Imran said. "The RaniPill will advance the delivery of oral biologics and increase patient adherence."

WHAT TO LOOK FOR:

Imran said to expect a flurry of partnership activity in the next 12 to 18 months that would likely include additional funding. He said the RaniPill will likely get in front of the FDA for approval sometime in 2027.

SPOTLIGHT

theranica

MEDICAL DEVICE INNOVATION

CEO: ALON IRONI
BASED: TEL AVIV, BRIDGEWATER, NEW JERSEY
FOUNDED: 2016
NERIVIO MIGRAINE NEUROBAND

WHAT'S THE SCOOP:

Theranica's Nerivio, a prescription wearable device used to mitigate migraines, went from being a reactive approach of treating symptoms to a proactive tool for helping prevent them. Earlier this year and just a few months after submitting a new 510(k) to expand indications for the technology, the FDA cleared the device for people who experience migraines with or without aura and who are at least 12 years old. "Our mission is to provide these patients with a platform that's not only a device but a tool to manage the disease and elevate their quality of life," Alon Ironi, Theranica's chief executive, said. "You use the device (therapy) in order to reduce the frequency of occurrence and in some cases to reduce the intensity." Patients wrap the Nerivio armband around their upper arm and use a connected smartphone app to start and stop the treatment and control its intensity. Electrodes embedded in the armband emit electrical pulses to nearby peripheral nerves that trigger internal pain management mechanisms, with the resulting pain relief spreading throughout the nervous system to reach the brain. "Our overall vision was to develop a non-invasive, drug-free approach to address acute migraines," Ironi said.

WHAT MAKES IT FIERCE:

It's personal, Ironi said. For him it was his daughter who has migraines that motivated him to find a treatment. And it's personal for the Theranica team. "They really care about people with migraines and they take the extra mile or 10 miles to show they care," he said. "These are the qualities that make us Fierce—the difference here is the fire inside."

WHAT TO LOOK FOR:

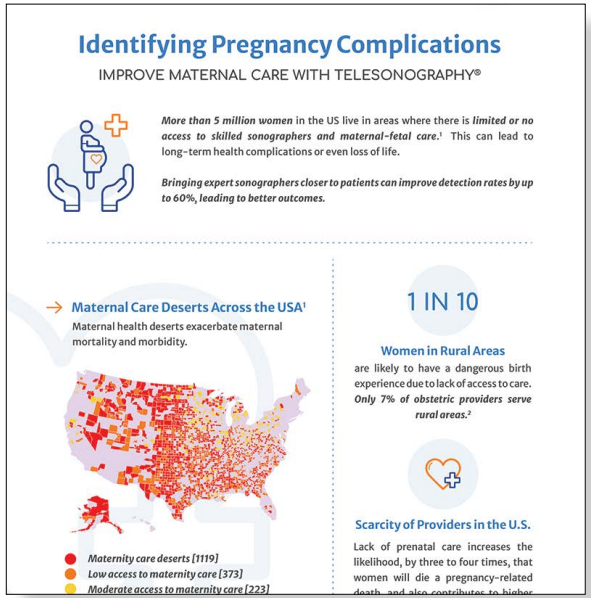
Expect the company to grow in three dimensions, Ironi said. The first is commercial, specifically growing in the U.S. with more medical liaisons and extending its coverage with health insurers, with related announcement expected in the next few months. The second dimension is geographic. Theranica is eyeing expansion beyond the U.S. and has partnered with Dr. Reddy's in India and is working to Brin the device to China and Japan. The third dimension is products as Theranica is developing a new therapy to help treat an unnamed chronic disease.

SPOTLIGHT

TeleScan®

TECHNOLOGY INNOVATION

CEO: BLANCA LESMES
BASED: AUSTIN, TEXAS
FOUNDED: 2005
TELESCAN®



WHAT'S THE SCOOP:

The mission of BB Imaging's TeleScan, a technology solution that links healthcare providers with remote sonographers to make ultrasound more accessible, is reducing maternal morbidity and mortality. About 36% of counties in the U.S. qualify as maternity care deserts. According to the Centers for Disease Control and Prevention, maternal causes of death in the U.S. grew from 20.1 deaths per 100,000 live births in 2019 to 32.9 in 2021. "There is a shortage of people in healthcare that do prenatal screening that has left many women—mom's and future mom's—out in the cold," Blanca Lesmes, chief executive of BB Imaging, said. "One of the key issues women are facing is a lack of focus on women's health. I got tired of the complacency and for the technology to catch up, so we decided software was the way to move forward." TeleScan works by having non-sonographer health-care workers upload short ultrasound videos (cine clips) to the platform, which are then reviewed by certified maternal-fetal medicine telesonographers. They produce a preliminary report for providers to review that can be accessed remotely, and patients can opt to have selected images sent to their phones. With TeleScan, ultrasounds can meet the needs of underserved areas and without requiring patients to travel long distances, endure long waits or go without care. "We feel like it's not okay for our sisters and friends not to have this prenatal service," Lesmes said.

WHAT MAKES IT FIERCE:

"We're scrappy, unafraid and able to act, that's what makes us Fierce," Lesmes said. "And the fact that we've been willing to tackle one of the key issues facing women today."

WHAT TO LOOK FOR:

Look for the company to start working with an AI model in order to extend its reach and make TeleScan more scalable on a global scale in the next two to three years. "We want women in all corners of the plant to have access," Lesmes said. BB Imaging also expects to be working with more partners and health systems to implement TeleScan. As an example, the company has been pitching to potential partners in Alaska "because there is no one in the state doing screening," she said.

FINALISTS

BIOTECH INNOVATION

JURATA'S THIN FILM TECHNOLOGY

RAREBASE

TIBSOVO® (IVOSIDENIB TABLETS)

MEDICAL DEVICE INNOVATION

IVWATCH PATIENT MONITOR AND SMARTTOUCH SENSOR

NOAH MEDICAL'S GALAXY PLATFORM

SKOUT®: IMPROVING POLYP DETECTION THROUGH COMPUTER VISION

DATA ANALYTICS/BUSINESS INTELLIGENCE

BOSTONGENE - KASSANDRA(TM) – CELL DECONVOLUTION TOOL

MEDIDATA DETECT PATIENT DATA SURVEILLANCE

SMART DATA QUALITY (SDQ)

TECHNOLOGY INNOVATION

CELL SHUTTLE (PRODUCT) OR INTEGRATED DEVELOPMENT AND MANUFACTURING ORGANIZATION (IDMO) SMART FACTORY FOR CELL THERAPIES (SERVICE)

HIGHLIGHT FOR WIPES

HUMANFIRST'S ATLAS PRECISION MEASURES PLATFORM

IGNITEDATA'S ARCHER – EHR-TO-EDC DATA TRANSFER TECHNOLOGY FOR CLINICAL TRIALS

DRUG DELIVERY TECHNOLOGY

OPTILUME

RIBOSWITCH PLATFORM

SELECTIVE ORGAN TARGETING (SORT) LIPID NANOPARTICLE (LNP) PLATFORM

DIGITAL HEALTH SOLUTIONS

FIREFLY HEALTH APP

FIREFLY HEALTH APP

VIZ ANEURYSM

FIERCE Healthcare

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