FIERCE Life Sciences

FIERCE INNOVATION AWARDS

Life Sciences Edition 2021

INNOVATION REPORT

AN EXPERIENCE FROM Questex

As COVID fades the Life Sciences see a bigger and brighter future.

As the disruption of the global pandemic begins to slowly ebb the focus of the Life Sciences industry is firmly fixed on the future and the technological advances that hold the promise of novel new treatments and the mechanics of delivering those therapies to patients.

During the crisis, the industry was nimble and efficient in responding to the challenges as well as adopting new methods that ranged from de-centralized clinical trials to digitally streamlined regulatory processes.

With those and a gamut of other lessons of the crisis learned and catalogued the industry, Life Sciences companies are busy working toward what is expected to be high-volume growth and new scientific and operational opportunities.

The widespread adoption of digital solutions in Life Sciences has generated heated interest in artificial intelligence analytics that can crunch data to help develop new therapies as well as identify potential patients. Also looming big is the expected explosive growth of the biosimilars market as many blockbuster drugs begin to come off patent in the next few years. And there is little doubt the cell and gene therapy market will continue to grow exponentially.

This year's Life Sciences Innovation Report reflects those trends and what is coming on the horizon as the industry marches ahead.

Each year we are amazed by the progress the organizations we cover have made, by what they have debuted or are planning to launch. There is no doubt they are firmly committed to improving the overall health and well-being of the industry's end user—the patient. This year was no different in the level of difficulty our judges faced in choosing winners among the many companies that are changing the healthcare landscape across the globe.

MEET THE JUDGES

Derk Arts
Chief Executive Officer
CASTOR

Dohyun Cho, Ph.D.
COO
Enzychem Lifesciences

Eric Doherty
President
BLINK SCIENCE

Daniel Erlanson, Ph.D.
Vice President of Innovation and Discovery
FRONTIER MEDICINE

Kimberly Ha
Founder and CEO
KHH ADVISORS

Dave Hanaman
CEO
CURAVIT

Colin Hayward
Chief Medical Officer
TELIX PHARMACEUTICALS

Rasmus Hogreffe, MSc, Med
Vice President of DCT Innovation
MEDABLE

Maya Fuerstenau-Sharp
Head of Marketing Advanced Therapies
SARTORIUS

Darcy Forman
Chief Delivery Officer
SCIENCE 37

Brent Vaughan
CEO
COGNITO THERAPEUTICS

WINNERS

DRUG DELIVERY TECHNOLOGY

Ivenix Infusion System

IVENIX, INC

BIOTECH INNOVATION

PROTAC® Targeted Protein Degraders

ARVINAS

MEDICAL DEVICE INNOVATION

Signatera

NATERA

DATA ANALYTICS/BUSINESS INTELLIGENCE

NB-AIR™

NUCLEUS BIOLOGICS

DIGITAL HEALTH SOLUTIONS

Universal Patient Registries

SECURE AI LABS

TECHNOLOGY INNOVATION

Plato

AVROBIO

BEST IN SHOW

BEST OUTSOURCING PARTNER

Signatera

NATERA

BEST TECHNOLOGICAL INNOVATION

PROTAC® Targeted Protein Degraders

ARVINAS

BEST NEW PRODUCT OR SERVICE

Ivenix Infusion System

IVENIX, INC

DRUG DELIVERY TECHNOLOGY

CEO: JORGEN HANSEN
BASED: NORTH ANDOVER, MA
FOUNDED: 2012
IVENIX INFUSION SYSTEM FROM IVENIX


INFUSION SPOTLIGHT

Cleveland Area Hospital

Ivenix Demonstrates Infusion Efficiency, Ease-of-Use at Progressive Critical Access Hospital

Clinicians praise Ivenix Infusion System's advanced performance in simulated environment

With a clear vision of the benefits of technology to improve patient care and a dedicated hospital team, Cleveland Area Hospital in Oklahoma delivers a level of service comparable to a hospital multiple times its size. When life hangs in the balance, residents of the Lake Area rely on the critical access facility for a full range of services in their own community.

For Cleveland Area Hospital Chief Nursing Officer Melva Bostik, a high priority is increasing clinician time at the bedside while maintaining high-quality care. A busy work environment and demanding patient population often make this difficult for the hospital's hard-working, multi-tasking nurses. Maintaining a difficult balance, Chief Information Officer Artie Lock believes technology is the gateway to the future, but at the same time must consider maintaining the hospital's financial health and vital service to the community in the face of challenging critical access reimbursements.

Both Bostik and Lock believe that building new efficiencies to make the most of staff time and automate manual tasks is crucial to meeting their goals and enhancing staff and patient satisfaction. Both also believe that technology is a crucial part of the answer—technology carefully developed and selected to meet a broad range of user needs.

The Opportunity

When offered the opportunity to be among the first hospitals to experience the benefits of the Ivenix Infusion System in a simulated user environment, Cleveland Area Hospital was enthusiastic.

"Our nurses found programming so user-friendly and intuitive that they really didn't need any instruction."

Melva Bostik BSN, RN, Chief Nursing Officer, Cleveland Area Hospital

According to Bostik, infusion pumps play a major role in a critical access hospital, often delivering a range of essential high-risk medications to patients. Yet, the complexities of most smart pumps today often hamper productivity, lead to user errors, and distract clinicians from direct patient care. They also add to operating costs by requiring more nursing time and increase the risk of errors and financial penalties. Cleveland Area Hospital believes that to build efficiency and to improve care, pumps should support ease-of-use and intuitive workflow while providing relevant infusion information at the bedside.

IVENIX

WHAT'S THE SCOOP:

Ivenix is a medical technology company with the vision of eliminating infusion-related errors that, according to the FDA, account for more than half of the 1.5 million adverse drug events reported in the U.S. each year. The Ivenix Infusion System features a large-volume infusion pump (LVP), a portfolio of administration sets, and infusion management tools and analytics aimed at improving medication delivery. The Ivenix LVP was designed with a smartphone-like user interface with visual cues and step-by-step guidance for accurate delivery of fluids, medications, and blood products. Onboard safeguards help reduce infusion errors by defaulting the nurse to the drug library, protecting against free flow, identifying incompatible medications on the pump and alerting to duplicate medications across pumps. The pumping technology focuses on delivering complex medications with measured flow that maximizes safety. Nurses do not need to manage the pump position or bag height to ensure accurate delivery. Nurses are able to spend less time on the mechanics and more time with their patients. Due to pent up demand and frustration with older technology, the company has been busy this past year ramping up production of the pumps and disposables. "Infusion therapy has lacked game-changing innovation for a long time," Robert Canfield, director of marketing for Ivenix, said. "The innovations customers are noticing are focused on solving nursing frustration with antiquated designs and eliminating error-prone steps to deliver an infusion.

WHAT MAKES IT FIERCE:

It took endurance, passion, and perseverance to break into the medical device market, but it's Ivenix's power to be disruptive that makes it Fierce. "These changes are powerful in that they have a noticeable impact on a hospital's staff and patients," Canfield said. "Disruptive is something we see every time a nurse picks up our pump and just starts programming it before we have given them our introduction."

WHAT CAN WE LOOK FORWARD TO IN THE FUTURE:

More positive disruption in the field as the company will continue to work on new innovations to keep the focus on reducing infusion-related harm. "We have come a long way in addressing frustrations nurses face every day. We are now focused on expanding our customer base while we innovate on the next infusion therapy advancements." said Canfield.

natera™

MEDICAL DEVICE INNOVATION

CEO: STEVE CHAPMAN
BASED: AUSTIN, TX
FOUNDED: 2004
SIGNATERA FROM NATERA

WHAT'S THE SCOOP:

Natera says it's just scratching the surface of its sector. It developed its Signature test that is a personalized blood test that detects minuscule traces of cancer remaining in the body after surgery. While being able to find small pieces of DNA circulating in the bloodstream as a basis of liquid biopsy tests for cancer has garnered headlines, Natera uses the same technology for a diagnostic that is aimed at monitoring the progress of transplants. In October, the company launched its genetic Prospera test for lung transplant recipients as part of its patient monitoring portfolio that includes kidney- and heart-focused versions. The test looks for donor-derived, cell-free DNA from transplanted tissues, and analyzes the genetic material for signs of rejection as well as provide a non-invasive alternative to bronchoscope biopsy tests by detecting organ injuries as well as hard-to-spot infections. The company is also focused on women's health care and offers a number of tests such as: Panorama, which uses a simple blood test to check for chromosomal abnormalities such as Down syndrome; Vistara looks for an additional 25 genetic conditions of a baby; Anora searches for possible reasons why a miscarriage occurred and how another pregnancy might be effected; and its Spectrum test can identify the healthiest embryos to use for in-vitro fertilization. "There are a lot of diagnostic opportunities out there and we are just starting to scratch the surface," Steve Chapman, Natera's Chief Executive said. "We've seen a very significant uptick in our partnerships in the clinical trial space and the adoption of our products and coverage in top medical journals has been really exciting."

WHAT MAKES IT FIERCE:

Chapman says four things make Natera stand out from their competition in a fierce way: being technology driven; backing everything up with a mountain of peer review data; focus on providing the best user experience for patients and physicians; and having great people working there. "They didn't miss a beat during COVID and that is what separated us from everyone else," he said.

WHAT CAN WE LOOK FORWARD TO IN THE FUTURE:

Chapman said Natera will continue to expand, improve and innovate its technology and focus on the three markets it currently serves—women's health, oncology and organ health. "We're excited to be in the markets we are in because there is so much to do," Chapman added. "But in oncology look for us to expand into a new segment, which is early cancer detection."

SAIL
SECURE AI LABS

DIGITAL HEALTH SOLUTIONS

CEO: ANNE KIM
BASED: CAMBRIDGE, MA
FOUNDED: 2017
UNIVERSAL PATIENT REGISTRIES FROM SECURE AI LABS

WHAT'S THE SCOOP:

Co-founded by MIT alumna Anne Kim and MIT professor Manolis Kellis, Secure AI Labs is using federated learning to create their "Unified Patient Registry" that enables a secure connection between siloed data in multiple hospitals that researchers in the real-world evidence space can use to review granular patient data without exposing sensitive information. The company addresses patient data confidentiality issues by using AI algorithms that run on encrypted datasets that remain in the data owner's system via their federated learning architecture. This enables healthcare organizations to continue to control how their data is used and allows researchers to protect the privacy of their models and search queries that can be just as proprietary as the data itself. The system creates a single access point for multiple sources of data focused on one disease as well as sources that reach across complementary endpoints. By allowing a large scale of datasets to be anonymized into aggregate insights, SAIL's technology lets researchers study rare diseases or rare subgroups of common diseases that often have small pools of relevant patient data spread out across several institutions. To get that information, researchers typically have to go door-to-door at hospitals and biobanks as well as navigate a seemingly endless trail of regulatory red tape in order to review patient databases.

"The vision of the company from the very inception was to make all datasets accessible for research without violating patient privacy," Kim said. "Today, we're working towards that vision by cutting across obstacles like complicated data moving logistics and arduous anonymization with our federated learning platform, Unified Patient Registries."

WHAT MAKES IT FIERCE:

"We're motivated to apply our technology to protect patient records in research because it's the most meaningful use of our technology that will connect more data, garner more clinical insights, all while respecting the privacy of patients," said Kim.

WHAT CAN WE LOOK FORWARD TO IN THE FUTURE:

Expect an announcement from Secure AI Labs early next year regarding preliminary results in kidney cancer research and another larger partnership. Additionally, Kim says the company is focused on expanding its technology to address other indications and diseases.

ARVINAS

BIOTECH INNOVATION

CEO: JOHN HOUSTON
BASED: NEW HAVEN, CT
FOUNDED: 2013
PROTAC® TARGETED PROTEIN DEGRADERS FROM ARVINAS

WHAT'S THE SCOOP:

Arvinas is a clinical-stage biopharma working on new therapies for treating cancer and other diseases from a different approach through its Protac Discovery Engine platform. The company's Protac degraders, or proteolysis-targeting chimeras, target and degrade disease-related proteins by using the human body's own natural protein disposal systems to breakdown and remove disease-causing proteins. The Protac system differs from inhibitors in that it finds and identifies cancer-causing proteins and destroys them, and survives to continue its fight versus inhibitors that only work if high levels are maintained in the system. With Arvinas' approach, in theory, patients will need less of the drug. "Our clinical data—across multiple indication—continues to validate our targets and has proven to be safe and effective in patients in clinical settings," John Houston, President and Chief Executive of Arvinas, said. "In addition to our oncology pipeline, we are also developing targeted protein degraders for potential use in neurodegenerative disease and other conditions." Earlier this year, Arvinas and Pfizer partnered to develop and commercialize its leading drug candidate, ARV-471, that is currently in phase 2 development for the treatment of locally advanced or metastatic ER+/HER2 breast cancer. Houston said the treatment continues to show clinical benefits in breast cancer patients with resistance to mutations and may have even broader applications for breast cancer. The company expects to initiate mono therapy and combination phase 3 studies and share data from its phase 2 VERITAC study in addition to safety date from its phase 1b IBRANCE combination study next year.

WHAT MAKES IT FIERCE:

As the first company to focus solely on targeted protein degradation, purpose is what drives Arvinas as it continues to explore innovation to bring new options to patients living with life-threatening or life-altering diseases. "We take our work seriously, and we also have fun while doing it," Houston said. "We encourage our employees to embrace the freedom to pursue innovation, think creatively, and give back."

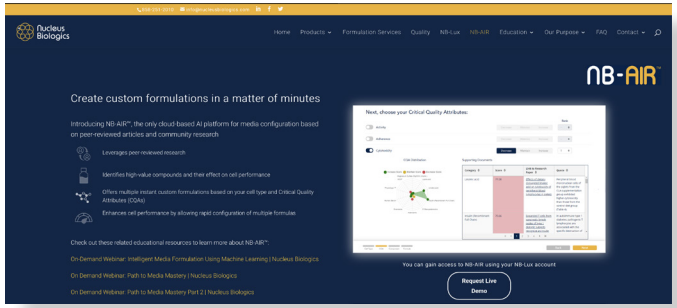
WHAT CAN WE LOOK FORWARD TO IN THE FUTURE:

Arvinas is focused on moving the first ever protein degraders into pivotal human clinical studies and being able to show successful data and get regulatory approval for a protein degrader. The company also anticipates sharing completed phase 1 dose escalation data and interim phase 2 ARDENT study for ARV-110 for the treatment of metastatic castration-resistant prostate cancer. It expects four additional INDs in the next two years. "We are excited about the progress we've made, particularly with out lead programs," Houston said. "Arvinas has a strong mix of undraggable versus 'more validated' targets, stretching across oncology, IO, and neuroscience, and we expect our progress to continue to drive some of the most significant breakthroughs in the industry."

Nucleus Biologics™

DATA ANALYTICS/BUSINESS INTELLIGENCE

CEO: DAVID SHEEHAN
BASED: SAN DIEGO, CA
FOUNDED: 2016
NB-AIR™ FROM NUCLEUS BIOLOGICS



WHAT'S THE SCOOP:

Nucleus Biologics provides custom cell-growth media, tools and technologies for the cell and gene therapy market. It has zeroed in on being able to speed the time from discovery to effective treatment by ditching old practices and product and embracing transparency by providing an ingredient list that helps streamline the regulatory process. Nucleus is also working to reduce the environmental footprint of cell culture. "Media is such a critical part in cell and gene therapy," David Sheehan, Chief Executive of Nucleus, said. "It really impacts not only how you manufacture it (a treatment) but how effective it is." Earlier this year, Nucleus unveiled the first AI research platform—dubbed NB-AIR—that optimizes cell culture formulations for cell and gene therapies. NB-AIR allows scientists to create formulas based on meta-analysis of peer-review articles that help developers improve the performance of cell therapy and reduces the time it takes to get these therapies to patients. With more than 75 million scientific publications and growing by 2.5 million more each year, NB-AIR uses a machine learning algorithm that surfs the latest peer-reviewed PubMed research in order to identify high-value compounds, concentrations and their effect on cell performance. The platform then uses a Novel Neural Network to uncover multiple media formulations that can be customized by the user. Because the user designs the media, individual ownership of the formulation's intellectual property is guaranteed, giving more control back to the scientists in order to make formulation faster than ever. "It's really about getting more transparency into the system to move discovery and scale up along quicker," said Sheehan.

WHAT MAKES IT FIERCE:

Sheehan believes that if your model is based on secrecy then you are dinosaur and probably won't survive in the pharmaceutical/biopharma world. "You can't be fearful about slaying these old business models," he said. "Our fierceness is our willingness to innovate and disrupt the current cell media model that isn't supporting the mission of our customers."

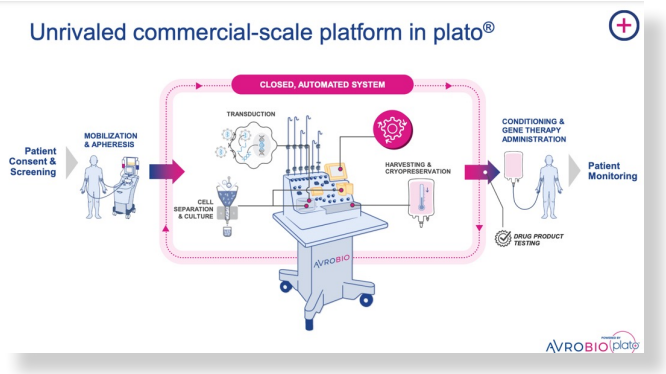
WHAT CAN WE LOOK FORWARD TO IN THE FUTURE:

Nucleus will continue to refine its current product line to streamline and speed the time to get therapies into clinics faster. The company is also taking a big step toward reducing the environmental footprint cell culture media leaves behind. "It's a big problem and we have a responsibility to reduce that footprint," Sheehan said. He added that the company will launch a product next year to address the issue.

AVROBIO

TECHNOLOGY INNOVATION

CEO: GEOFF MACKAY
BASED: CAMBRIDGE, MA
FOUNDED: 2015
PLATO FROM AVROBIO



WHAT'S THE SCOOP:

AVROBIO's goal is simple—end or reverse disease with a single dose of gene therapy. Simple and not unrealistic given what AVROBIO is accomplishing in its clinical pipeline that is currently focused on treating lysosomal disorders, including Fabry disease, Gaucher disease type 1 and cystinosis. Its pipeline also comprises preclinical programs looking at Hunter syndrome, Gaucher disease type 3 and Pompe disease.

Unlike major biopharma manufacturers, AVROBIO embraced a small-is-better approach in its proprietary plato platform, a dishwasher-sized, automated, self-contained gene therapy platform. The company spent three years developing algorithms to customize and improve output so they can deliver consistent and high-quality product in three days just about anywhere in the world in order to get treatments closer to patients. In theory, multiple units can run side-by-side in a shared clean room while producing different therapies. AVROBIO expects plato could generate up to a 60% savings on manufacturing labor because it significantly reduces quality control and testing costs as well as the expense associated with clean rooms and facilities. Recently, the company released updated safety data for AVROBIO's investigational gene therapies in Fabry disease and Gaucher disease type 1.

"It's been exciting, and in October we got our first strong safety (data) release," Geoff MacKay, Chief Executive Officer of AVROBIO, said. "With three therapies targeting lysosomal disorders already in clinical trials, we're working hard to move our three remaining programs into the clinic."

WHAT MAKES IT FIERCE:

For MacKay it's the dynamic culture of the company. "Where others have gone big building expensive, inefficient factories, we've developed an alternative," MacKay said. "I'd say we are fiercely guided by our purpose to free patients from a lifetime of debilitating disease."

WHAT CAN WE LOOK FORWARD TO IN THE FUTURE:

In addition to more clinical trials, AVROBIO is focused on its technological advantage to achieve a best-in-class platform. "We are investing heavily to continue to understand cell and gene therapy at the cell level," said MacKay.

FINALISTS

BIOTECH INNOVATION

OMEGA EPIGENOMIC CONTROLLERS (OECS)
OMEGA THERAPEUTICS

ORCA-T
ORCA BIO

PROTAC® TARGETED PROTEIN DEGRADERS
ARVINAS

DATA ANALYTICS/BUSINESS INTELLIGENCE

EVIDENCE-BASED PHYSICIAN ENGAGEMENT USING OPTIMIZERX'S AI-DRIVEN THERAPY INITIATION AND PERSISTENCE PLATFORM
OPTIMIZERX

ICON – ONESEARCH
ICON

NB-AIR™
NUCLEUS BIOLOGICS

DIGITAL HEALTH SOLUTIONS

BRIGHTINSIGHT® PLATFORM
BRIGHTINSIGHT

RESET BY PEAR THERAPEUTICS, INC.
PEAR THERAPEUTICS, INC.

UNIVERSAL PATIENT REGISTRIES
SECURE AI LABS

DRUG DELIVERY TECHNOLOGY

IVENIX INFUSION SYSTEM
IVENIX, INC.

RANIPILL
RANI THERAPEUTICS

TRUDHESA
IMPEL NEUROPHARMA

MEDICAL DEVICE INNOVATION

PROSPERA
NATERA

SIGNATERA
NATERA

XACT ACE™ ROBOTIC SYSTEM
XACT ROBOTICS® INC.

TECHNOLOGY INNOVATION

PLATO
AVROBIO

PROMAXO MRI SYSTEM
PROMAXO

SCHRÖDINGER'S PHYSICS-BASED COMPUTATIONAL CHEMISTRY PLATFORM
SCHRÖDINGER