FIERCE Life Sciences

# FIERCE INNOVATION AWARDS

## Life Sciences Edition 2022

INNOVATION REPORT

AN EXPERIENCE FROM Questex

# Introduction

When the COVID-19 pandemic put a magnifying glass up to the healthcare system, industry innovators saw an opportunity to create dynamic solutions to help relieve weary providers, payers, patients and organizations. It took unique thinkers willing to push their creative problem solving with the best digital technology solutions to develop this year's top 5 award-winning innovations. These industry leaders are not only solving the problems of today but building digital solutions that will usher healthcare into a new era where patients can have personalized control of their health and well-being, all via a tap on the smart phone. Beyond personalization at the point of care, this year's solutions take the guess work out of treatment, prescribed medications, payment information and comprehensive maternal health—all while saving the system money.

## APPLICANTS WERE JUDGED IN THE FOLLOWING CATEGORIES:

### Clinical Information Management

Clinical information management supports decision making and ensures quality patient information at every touchpoint along the patient journey.

### Population Health Management/Patient Engagement Solutions

Health insurers and providers are seeking tools that promote behavioral changes, enhance communication and improve the patient experience.

### Financial/Operational Solutions

Healthcare organizations are seeking new ways to streamline their operations, upgrade legacy systems and increase efficiencies.

### Data Analytics/Business Intelligence

Innovative data analytics tools enable healthcare organizations to maximize performance, improve customer health and bolster efficiencies through smarter management of resources, risk assessment, quality measurement, clinical resources and predictive modeling.

### Digital/Mobile Health Solutions

Smartphones and tablets have created an intense and perpetual demand for innovative apps, solutions and services designed to engage and educate customers, save money, and enable information sharing among providers, payers and customers alike.

We invite you to read about the 2022 finalists and their transformative solutions. We encourage and support innovators bringing new ideas and solutions to healthcare as the industry addresses the rapidly-changing face of healthcare in the US.

# MEET THE JUDGES

**Rasmus Hogreffe, MSc, Med**
Vice President of DCT Innovation
Medable

**Kimberly Ha**
Founder & CEO
KKH Advisors

**Dave Hanaman**
Chief Commercial Officer
Curavit

**Colin Hayward**
Chief Medical Officer
Telix Pharmaceuticals

**Julien Meissonnier**
Vice President & Chief Scientific Officer
Catalent

**Daniel Oliver**
Co-founder and CEO
Rejuvenate Bio

**Cornell Stamoran**
Vice President,
Strategy and Government Affairs
Catalent

**Brent Vaughan**
CEO
Cognito Therapeutics

# DEVELOPING NEW MEDICINES IS SCIENCE. SCALING UP A BIOTECH FOR A SUCCESSFUL LAUNCH IS ART.

The biotech journey from lab to patient has many challenges to navigate, all while accessing funding, building an organization, and moving your product through key development milestones. As an extension of your team, Catalent has the expertise you need from helping thousands of biotech partners successfully overcome and accelerate product development obstacles across stages, indications, and modalities.

Whether your objective is to advance to the next phase or partner throughout the full drug development process, Catalent's dedicated project management and deep scientific and technical teams, combined with the broadest range of technologies and flexible-scale manufacturing platforms, will help to steer your molecule toward the best chance at therapeutic and financial success.

***Let's partner on your next journey.***

Catalent® | *WHERE SCIENCE MEETS ART.*

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# WINNERS

BIOTECH INNOVATION | SPONSORED BY: Catalent APPLIED DRUG DELIVERY INSTITUTE

## Gracell Biotechnologies

**FasTCAR Autologous CAR-T Platform**

DRUG DELIVERY TECHNOLOGY | SPONSORED BY: Catalent APPLIED DRUG DELIVERY INSTITUTE

## Lyndra Therapeutics

**LYNX drug delivery platform**

DATA ANALYTICS/BUSINESS INTELLIGENCE

## ICON plc

**OneSearch**

MEDICAL DEVICE INNOVATION

## AliveCor

**KardiaMobile Card**

DIGITAL HEALTH SOLUTIONS

## Biofourmis

**Biofourmis BiovitalsHF®**

TECHNOLOGY INNOVATION

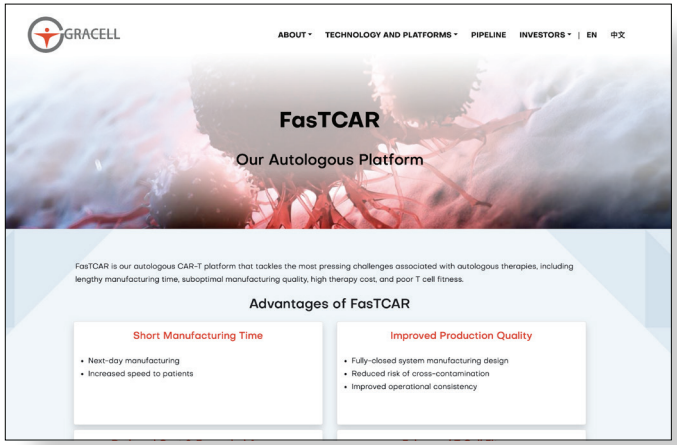
## Cytel

**Solara® Clinical Trial Strategy Platform**

GRACELL

BIOTECH INNOVATION

**CEO:** WILLIAM WEI CAO
**BASED:** SUZHOU, JIANGSU, CHINA
**FOUNDED:** 2017
**FASTCAR AUTOLOGOUS CAR-T PLATFORM**




## WHAT'S THE SCOOP:

It's been a busy year for Gracell Biotechnologies. The China-based biotech has announced multiple clinical data validating its FasTCAR autologous next-day manufacturing CAR-T technology platform as well as the potential of its lead FasTCAR candidate—GC012F—to treat multiple myeloma and B-NHL, a type of non-Hodgkin lymphoma. The platform's autologous next-day manufacturing CAR-T technology uses a patient's own T cells to produce targeted cell therapy that has a greater than 90% overall response rate. Production times using the platform have been reduced from about six weeks using conventional manufacturing to overnight, which means getting therapies to patients faster, reducing healthcare costs and improving quality of life. CAR-T cells produced by the FasTCAR platform are younger and less exhausted than what is produced conventionally and have demonstrated improved proliferation, persistence, bone marrow migration and tumor cell clearance in preclinical studies, said William Wei Cao, Gracell's Founder and Chief Executive. "We continue making big strides toward providing patients with breakthrough cell therapies and addressing incredibly pressing issues in oncology and CAR-T," Cao added. In June, the company released the latest clinical data in relapsed/refractory multiple myeloma patients that showed a 93% overall response rate and 100% MRD (minimal residual disease) negativity rate in all treated patients. It was just a year ago the FDA designated GC012F as an orphan drug. In February, Gracell said it expanded GC012F to its second indication and started a clinical trial of the treatment.

## WHAT MAKES IT FIERCE:

Its commitment to discovering and developing breakthrough cell therapies while addressing some of the pressing issues that face CAR-T such as long production time, poor cell quality, prohibitive therapy costs, and lack of effective solid tumor therapies. "In five short years since the founding of Gracell, we have developed in-house two technology platforms, a robust clinical pipeline, and dosed over 100 patients," Cao said. "We set the bar very high for ourselves and have been focusing on developing therapies that have true potential to be first-in-class and/or best-in-class."

## WHAT TO LOOK FOR:

The biotech will present the first clinical data from its newly diagnosed multiple myeloma trial with GCO12F next month. Additionally, Gracell expects to submit investigational new drug (IND) filings in both the U.S. and China, and prepare for its first U.S. study next year to evaluate GC012F in relapsed/refractory multiple myeloma. The company is also planning to advance several investigator-initiated studies, including one in China for GC503 in mesothelin-positive solid tumors. "This is the first candidate leveraging our new SMART CAR-T technology module, which uses a novel design to take advantage of the immunosuppressive tumor microenvironment." said Cao.

**DATA ANALYTICS/BUSINESS INTELLIGENCE**

**CEO:** STEVE CUTLER
**BASED:** DUBLIN, IRELAND
**FOUNDED:** 1990
**ONESEARCH**


## WHAT'S THE SCOOP:

As one of the top contract research organizations following its blockbuster $12 billion buyout of PRA Health in early 2021, ICON has been focused on innovation on a global scale by providing broader and deeper services to its customers. One of the areas the CRO leader has been addressing is the challenge of recruiting the right participants and identifying the best sites for clinical trials. “We have a myriad of innovative solutions that are truly transforming the clinical research landscape,” said Gerard Quinn, ICON’s Vice President of Innovation and Informatics. According to industry data cited by ICON, selecting under or non-performing sites costs more than $4 million a year and about 11% of sites fail to recruit a single patient. To address the problem, ICON introduced its One Search tool, which uses intuitive, integrated workflow and artificial intelligence that provides access to multiple data sources to help identify optimum trial sites the first time, and has led to a 40% reduction in time for site selection. Using industry data of capability, experience and performance records, the platform scores a potential trial site. That scoring, in turn, leads to reducing the percentage of low-performing sites from consideration, increases the percentage of studies that meet planned First Patient In goals, improves study start-up and site cycle times, and enhances efficiency in prices by reducing manual tasks. “What it’s able to do is integrate billions of data points and trillions of data connections,” Quinn said. “For the first time in the industry we now have the capability to instantaneously view/review and propose investigators and institutions from a single platform. It’s truly a game changer and what is really driving us at the moment.”

## WHAT MAKES IT FIERCE:

The clarity in knowing what the organization wants to achieve to improve the lives of patients through innovations that lead to new life-saving or life-changing treatments. “What makes us Fierce is the transformative impact we have in solving problems people didn’t think could be solved,” said Quinn.

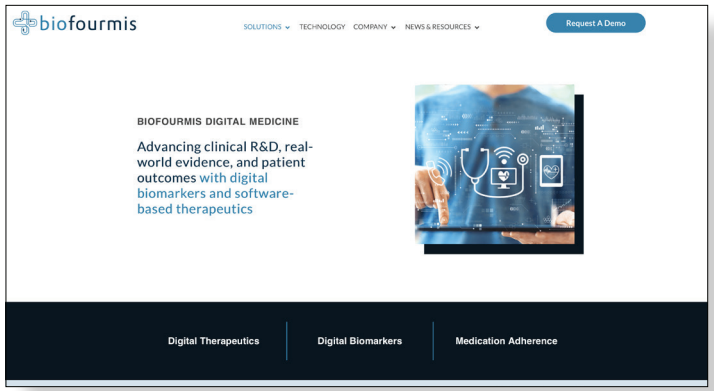
## WHAT TO LOOK FOR:

The immediate focus for the organization is to continue to utilize and expand AI capabilities in One Search in conjunction with additional data. “On a broad sense, we’re looking at new levels that will shift clinical trials in a positive way, and how we can change to reflect the changing landscape of clinical trials,” said Quinn.

biofourmis®

**DIGITAL HEALTH SOLUTIONS**

**CEO:** KULDEEP SINGH RAJPUT
**BASED:** BOSTON
**FOUNDED:** 2015
**BIOFOURMIS BIOVITALSHF®**




## WHAT'S THE SCOOP:

The goal for Biofourmis is to improve patient outcomes and reduce costs as well as the burden of care though personalized, predictive care that is supported by artificial intelligence and machine learning. The company's Biofourmis' BiovitalsHF® digital therapeutic and clinical services help clinicians provide patients with the right therapy quickly by using artificial intelligence and machine-learning driven personalized therapy. It also allows a faster analysis of a drug's efficacy. Data is collected continuously from medical-grade biosensors that track more than 20 physiology parameters. The information then creates a personalized baseline that "compares you to you" and is able to recognize a patient's patterns within 6 hours of monitoring. For example, the program can detect if a short-term fluctuation is due to a patient walking upstairs or if it's a clinically significant pattern that needs medical attention. Machine learning continually refines a patient's baseline and its predictive analytics can alert clinicians or clinical researchers to any early warning signs of an adverse event. "It can have a big impact for patients," Kuldeep Singh Rajput, Biofourmis founder and Chief Executive Officer, said. "The predictive solution enables clinical detection of a potential issue early in  patients with heart failure, and it helps guide clinicians in optimizing drug dosages and therapy while also improving adherence." Rajput said this focus is critically important because only 25% of heart failure patients are on guideline-directed medical therapy (GDMT), and only 1% of patients suffering from the disease receive optimal therapy. BiovitalsHF also digs deeper by being able detect blood sugar spikes during sleep or whether a physiological change is clinically significant or if it's simply because a patient is elevated by pillows. Rajput points out that 92% of heart failure patients have co-morbidities like diabetes and COPD so "it's important to consider all those" conditions as well. "What we have shown in clinical trials is that within three months, we can get patients on optimal guideline-directed medical therapy," he added.

## WHAT MAKES IT FIERCE:

Right to the point, it's the team Biofourmis has built. "Our people are constantly Fierce and making Fierce innovations," Rajput said. "One of the most important things in healthcare when you look at a problem is there might be large economic problems associated with it," he added. "Our team is focused on going deep on clinical needs and how they are associated with economic needs in order to drive clinical benefits that also demonstrate economic benefits."

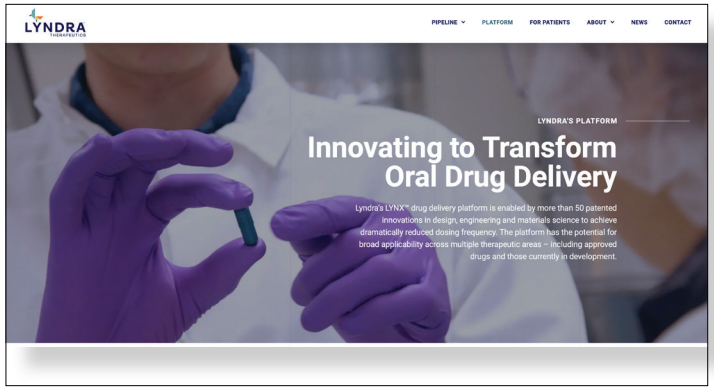
## WHAT TO LOOK FOR:

For the short- and mid-term, the company will be "very heads down" and focused on its organic growth plan, said Rajput. The areas they are focused on are to continue to manage patients in the comfort of their homes, accelerate the company's health system partnerships, and build companion therapies. "Right now it's how do we scale the business organically and also think about inorganic growth through M&A," he said.

LYNDRA THERAPEUTICS

**DRUG DELIVERY TECHNOLOGY**

**CEO:** TRISH HURTER
**BASED:** WATERTOWN, MA
**FOUNDED:** 2015
**LYNX DRUG DELIVER PLAFORM**




## WHAT'S THE SCOOP:

Pills that work beyond a 24-hour period have long been a goal of pharmaceutical companies. Not only because most people prefer taking oral medication versus an injection, but also because it could vastly improve medication adherence that would lead to better patient outcomes. It's something Lyndra Therapeutics has been working on for a while and the company's solution is the LYNXTM drug delivery platform. The drug delivery technology consists of a capsule that after traditional ingestion opens up inside the stomach similar to a flower. The arms, which are connected to a flexible core, contain the drug—or multiple drugs depending on a patient's prescription—and help maintain the system's shape in the stomach to prevent it from being excreted. The arms containing the drug soften and disintegrate when the dosing period is complete and the remaining components are then safely passed through the body. "To me, the LYNX platform delivers on the promise of every single oral therapeutic humans have been taking since they were first developed about 1500 B.C.," Trish Hurter, Lyndra's Chief Executive Officer, said. "It's designed to make long-acting oral therapies a reality -- achieving steady, consistent drug release for 7-, 14- or 28-days from a single oral dose." About 300 study participants have tested the platform and showed successful results. It was first tried with schizophrenia and bipolar disorder patients who can often struggle with medication compliance. "For people living with bipolar disorder this technology could help minimize the peaks and troughs of drug release they experience from daily pills," Hurter said, adding that eventually the platform could be used for therapies that treat heart disease and diabetes, as well as antibiotics and oral contraceptives. Lyndra is also working with the Bill & Melinda Gates Foundation for an extended (14 days) delivery system to treat malaria.

## WHAT MAKES IT FIERCE:

Hurter says it may sound a bit audacious, but the core purpose of the company is to "reinvent medicine." And to do that, she adds, Lyndra hires the kind of people who are diverse, agile learners who are up for the challenge.

## WHAT TO LOOK FOR:

The company is completing pivotal studies next year with final data expected in 2024. The goal is to have the platform on the market by as early as 2025. Lyndra is also looking to open its fully automated continuous manufacturing facility by late 2024 or early 2025 that would produce up to 25 million capsules a year.

ALIVECOR®

MEDICAL DEVICE INNOVATION

**CEO:** PRIYA ABANI
**BASED:** MOUNTAIN VIEW, CA
**FOUNDED:** 2011
**KARDIAMOBILE CARD**


## WHAT'S THE SCOOP:

AliveCor's latest personal electrocardiogram is slim enough to fit in your wallet. KardiaMobile Card—the company's latest offering in the heart monitor sector—is the size and shape of a credit card. "We all have credit cards with chips in it and this is, essentially, the same technology," Dave Albert, M.D., founder and Chief Medical Officer for AliveCor said. "It's an engineering tour de force." The device features single-lead, medical-grade detection of six of the most common types of cardiac arrhythmias including atrial fibrillation, bradycardia and tachycardia. KardiaMobile Card, which the FDA cleared in November, can withstand weather, water and other regular wear and tear, making it the company's most durable ECG offering so far. It's also accepted and sold by the Veteran's Administration. The KardiaMobile Card works by analyzing a user's pulse through two designated thumb pads. Each reading is automatically sent via Bluetooth to the user's smartphone, where it's analyzed by AliveCor's artificial intelligence algorithm. By using the device's platform on their smartphones, users can track past readings, share them with their healthcare providers, and access a comprehensive heart health report. In May, the company also launched KardiaComplete, a comprehensive heart health enterprise solution designed to improve health outcomes and reduce the cost of cardiac care. The service is available to people diagnosed with hypertension and atrial fibrillation, through their self-insured employers, health insurance plans and health systems.

## WHAT MAKES IT FIERCE:

The critical nature of their mission. "We are helping to take care of patients and their lives, and sometimes finding life-threatening conditions in a timely manner," Albert said. "That's what motivates us to be Fierce."

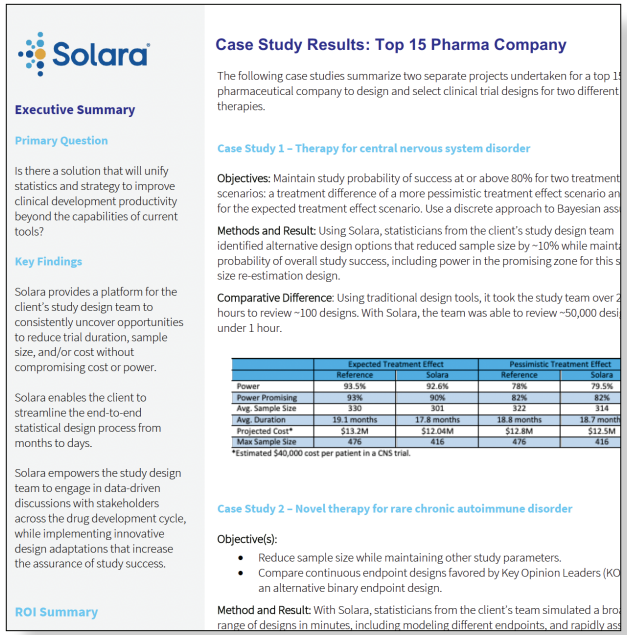
## WHAT TO LOOK FOR:

Currently servicing customers in 42 countries, AliveCor is looking to expand its offerings both in products and services. "We are looking at new devices, software, etc., in order to really implement and improve remote cardio care," said Albert.

Cytel

TECHNOLOGY INNOVATION

**CEO:** JOSHUA SCHULTZ
**BASED:** WALTHAM, MA
**FOUNDED:** 1987
**SOLARA**



Solara

**Executive Summary**

**Primary Question**

Is there a solution that will unify statistics and strategy to improve clinical development productivity beyond the capabilities of current tools?

**Key Findings**

Solara provides a platform for the client's study design team to consistently uncover opportunities to reduce trial duration, sample size, and/or cost without compromising cost or power.

Solara enables the client to streamline the end-to-end statistical design process from months to days.

Solara empowers the study design team to engage in data-driven discussions with stakeholders across the drug development cycle, while implementing innovative design adaptations that increase the assurance of study success.

**ROI Summary**

**Case Study Results: Top 15 Pharma Company**

The following case studies summarize two separate projects undertaken for a top 1
pharmaceutical company to design and select clinical trial designs for two different
therapies.

**Case Study 1 – Therapy for central nervous system disorder**

Objectives: Maintain study probability of success at or above 80% for two treatment
scenarios: a treatment difference of a more pessimistic treatment effect scenario an
for the expected treatment effect scenario. Use a discrete approach to Bayesian ass

Methods and Result: Using Solara, statisticians from the client's study design team
identified alternative design options that reduced sample size by ~10% while maint
probability of overall study success, including power in the promising zone for this s
size re-estimation design.

Comparative Difference: Using traditional design tools, it took the study team over 2
hours to review ~100 designs. With Solara, the team was able to review ~50,000 desi
under 1 hour.

| | Expected Treatment Effect | | Pessimistic Treatment Effect | |
|---|---|---|---|---|
| | Reference | Solara | Reference | Solara |
| Power | 93.5% | 92.6% | 78% | 79.5% |
| Power Promising | 93% | 90% | 82% | 82% |
| Avg. Sample Size | 330 | 301 | 322 | 314 |
| Avg. Duration | 19.1 months | 17.8 months | 18.8 months | 18.7 month |
| Projected Cost* | $13.2M | $12.04M | $12.8M | $12.5M |
| Max Sample Size | 476 | 416 | 476 | 416 |

*Estimated $40,000 cost per patient in a CNS trial.

**Case Study 2 – Novel therapy for rare chronic autoimmune disorder**

Objective(s):

- Reduce sample size while maintaining other study parameters.
- Compare continuous endpoint designs favored by Key Opinion Leaders (KO
an alternative binary endpoint design.

Method and Result: With Solara, statisticians from the client's team simulated a bro
range of designs in minutes, including modeling different endpoints, and rapidly ass

## WHAT'S THE SCOOP:

Statistical software and analytics provider Cytel's clinical trial strategy platform Solara®, which has been in the market for two years, enables simulation-guided study design and selection. With the platform, product development teams can explore millions of new trial designs that can be tested against complex scenarios they could face. It features a user-friendly interface and dynamic visualization that offers a common language and workspace to foster collaborative and data-driven discussions. "It's a big deal and can change how clinical trials are planned and designed," said Scott Gaines, Cytel's chief product officer and general manager of software. The simulation-based design helps remove some of the uncertainty inherent in clinical trials. Before Solara the number of design options that could be considered were limited as statisticians working on optimizing designs had to do so through manual input. "Now we're able to take a manual process that could take weeks and put that into days," Gaines said. "We're able to process tens of thousands of design permeations quickly, which is a huge efficiency, and saves time and costs." The platform currently boasts more than 300 users worldwide and has designed more than 200 studies covering numerous therapeutic areas. In a recent study, Solara helped a client find an optimal design that reduced study costs by an estimated $3 million.

## WHAT MAKES IT FIERCE:

Curiosity and innovation. "Those give us the courage and energy to take on risks and challenges," Gaines said. "We pair that with really deep expertise, rigor and accountability to deliver high quality products our customers trust.

## WHAT TO LOOK FOR:

Look for more growth. The company recently acquired SDS Life Science AB and SDS MedteQ AB, which added more talent to Cytel's Strategic Consulting group. It's also been expanding operations in the Asia-Pacific region. "We want to unlock the power of data so evidence-driven decisions can be made with confidence," Gaines said. "The current process is a lot of art and some science, we want that to shift to more science and less art with the help of data."

# FINALISTS

## BIOTECH INNOVATION

DNASCRIPT

SYNTAX SYSTEM

Genalyte

THE MERLIN

Senda Biosciences

SENDA ATLAS AND SENDRNA™ MEDICINES

## MEDICAL DEVICE INNOVATION

ASENSUS SURGICAL

INTELLIGENT SURGICAL UNIT™ 2.7

Avisi

ISIPLATE

CIONIC

CIONIC NEURAL SLEEVE

## DATA ANALYTICS/BUSINESS INTELLIGENCE

MEDIDATA

MEDIDATA AI INTELLIGENT TRIALS DIVERSITY MODULE

seer

PROTEOGRAPH ANALYSIS SUITE 2.0

VIAL

VIALCONNECT

## TECHNOLOGY INNOVATION

absci

ABSCI'S AI-AUGMENTED ANTIBODY OPTIMIZATION PLATFORM

Recursion

THE RECURSION OS PLATFORM

STOIC Bio
Cure People + Planet

KRAKATOA™ BENCHTOP MEDIA MAKER

## DRUG DELIVERY TECHNOLOGY

Cytonus

CARGOCYTE

SaNOtize

NITRIC OXIDE NASAL SPRAY (NONS™) BY SANOTIZE

TFF PHARMACEUTICALS

THIN FILM FREEZING TECHNOLOGY

## DIGITAL HEALTH SOLUTIONS

biofourmis

BIOFOURMIS BIOVITALSHF®

BrightInsight

BRIGHTINSIGHT® PLATFORM