# BARDA DRIVe Portfolio Companies

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# About the Research Analyst

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Susan obtained a Master's degree in Library Science (MLS) from UNC Chapel Hill in August 2012 and a Master's of Management in Clinical Informatics (MMCi) from Duke University in August 2018. While at UNC, she worked as a library intern with the Environmental Protection Agency Library in RTP. Prior to that, she graduated from the University of Mississippi with degrees in English and French and minors in mathematics and chemistry.

# Note about authorship

All sources, such as Pitchbook Venture Capital database, are fully cited in the footnotes. Because of the nature and intended use of this report by the client and to save time, much of the text in this report was extracted directly, word-for-word, from the cited sources without the use of quotation marks. In other words, we are not claiming authorship of this information. Notes from the analyst are typically formatted in italics and/or highlighted. Anything summarized or re-written by the analyst is cited as such, to show that distinction.

# Contents

# Executive Summary

To date, BARDA DRIVe has provided funding to thirteen entities. Cytovale, Emory University, Immunexpress, InnaMed, Prenosis, Qvella and Sepsis Alliance have received funding through the Solving Sepsis track, while Biobeat, Empatica, EnLisense and Spire have received funding through the ENACT track. Enesi Pharma and Janus-I Science have also received funding through another track.

The companies funded through the ENACT focus are developers of wearable sensors of biomarkers (cytokine levels) or bio-signals (heart rate, breathing variability, changes in body heat, etc.) through sweat or movement. Spire has raised money through multiple funding rounds and has products on the market. EnLiSense's products are still in development and they do not have a profile in Pitchbook venture capital database, but have received funding from the National Institute on Alcohol Abuse and Alcoholism (NIAAA) in 2017. The federal funding that EnLiSense and Spire have received have been from either NIAAA or the National Institute on Drug Abuse (NIDA). Biobeat has received funding from several venture investors and has a relationship with several accelerator or incubator groups such as Plug and Play Tech Center. Empatica is based on technology out of MIT and has received funding through venture groups as well as crowdfunding.

The companies funded through the Solving Sepsis focus have distinct products. InnaMed provides a rapid blood test for a sepsis-associated biomarker. Prenosis develops algorithms to help doctors predict the progression of sepsis in a patient. CytoVale develops low-cost diagnostics that use microfluidics, high-speed imaging, computer vision and machine learning to test blood samples for changes that occur when a person is getting sick. InnaMed has received funding from several incubator and VC groups, while Prenosis has raised money from incubator groups and venture competitions as well as the NSF and CDC. CytoVale has received funding from various sources including venture capital groups, agencies like NSF and companies like Becton Dickinson (BD). CytoVale has also been included in several notable incubator/accelerator programs, including Breakout Labs and Google Developers Launchpad. While InnaMed and Spire are in separate BARDA DRIVe focus areas, they have both received assistance through Y Combinator, an accelerator based in Cambridge, MA. Qvella has developed a rapid pathogen identification platform and leverages Predigen Inc.'s gene signature analytical power to help develop the intended assay for the early diagnosis of sepsis. Predigen is a spinout of Duke University. Qvella has received several rounds of VC funding, including funding from Hatteras Venture Partners. Immunexpress has developed a product that rapidly evaluates a set of patented gene-expression biomarkers from the patient's blood and has also received VC funding. Emory University is using machine learning to predict sepsis in patients. Shamim Nemati at Emory University has received funding in the past on this topic from NIEHS and state groups. Sepsis Alliance is a nonprofit that is launching a sepsis education and training initiative called the Sepsis Institute.

The other companies funded are Janus-I Science and Enesi Pharma. Janus-I Science will develop a sample-to-answer workflow that uses nanopore sequencing to accurately identify unknown pathogens in patient specimens, while Enesi Pharma has developed ImplaVax® formulation and needle-free system enables solid dose implants containing vaccines to be delivered quickly and painlessly under the skin with ease. Neither of these companies have any funding listed in Pitchbook, though they do both have several previous partnerships with other companies and government organizations in the US and UK.

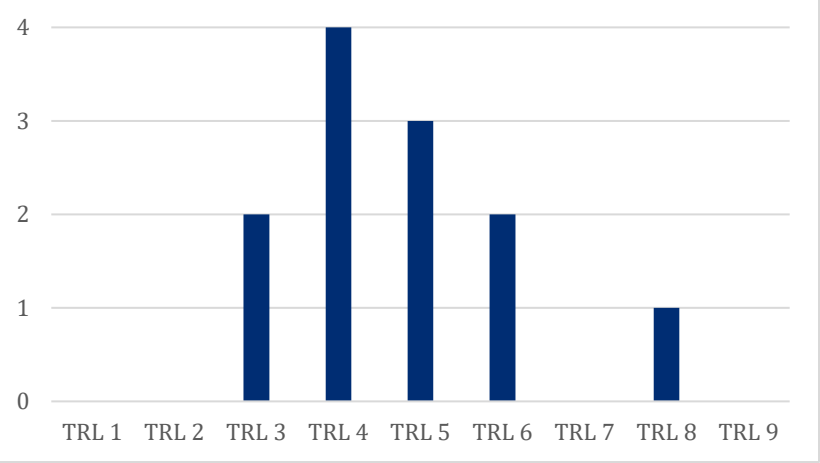
# Overview of Cost Sharing

Most of the companies are incurring around a 30% cost share, excluding Immunexpress at 77%, CytoVale at 46% and Empatica at 45%. There is not much information available around what the cost share is covering; for most companies, it is stated that the cost share is going towards "development costs" according to the BARDA press releases.

| Portfolio Company | DRIVe Investment | Cost Share | Total | Cost Share |
|---|---|---|---|---|
| Spire | $62,200 | $26,660 | $88,860 | 30% |
| InnaMed | $200,000 | $85,750 | $285,750 | 30% |
| Prenosis | $749,000 | $322,552 | $1,071,552 | 30% |
| EnLiSense | $550,909 | $236,104 | $787,013 | 30% |
| CytoVale | $749,000 | $648,200 | $1,397,200 | 46% |
| Biobeat | $599,000 | $355,800 | $954,800 | 37% |
| Emory University | $699,376 | $348,400 | $1,047,776 | 33% |
| Empatica | $251,454 | $205,734.98 | $457,189 | 45% |
| Immunexpress | $744,739 | $2,458,929 | $3,203,668 | 77% |
| Qvella | $692,236 | $296,673 | $988,909 | 30% |
| Sepsis Alliance | $427,248 | $195,000 | $622,248 | 31% |
| Enesi Pharma | $689,863 | $294,227 | $984,090 | 30% |
| Janus-I Science | $710,619 | $304,560 | $1,015,179 | 30% |
| **Total** | **$7,125,644** | **$5,778,590** | **$10,904,965** | **53%** |

# TRL Distribution

The graph below shows the distribution of the portfolio companies by Technology Readiness Level (TRL).[1]




TRL 3: Qvella, Janus-I Science
TRL 4: Innamed, Prenosis, Empatica, EnLiSense
TRL 5: Cytovale, Immunexpress, Enesi Pharma
TRL 6: Emory University, Spire
TRL 8: Biobeat

[1] Note that the Sepsis Alliance does not have a TRL and therefore is not included.

# Solving Sepsis Company Profiles

## Cytovale

http://cytovale.com/
San Francisco, CA
Number of employees: 5-15
Year founded: 2013
Award date: 11/14/2018
TRL 5 – Product Development

### Products

Cytovale's low-cost diagnostic holds the potential to provide the quick information emergency room healthcare providers need in the critical first hours and days of this often-deadly disease.

The Cytovale technology takes advantage of advances in microfluidics, ultra-high speed imaging, computer vision, and machine learning to rapidly quantify immune cell dysregulation from a blood sample in minutes. It uses deformability cytometry to measure immune cell changes, like inflammation and other changes that occur when a person is getting sick.

### Previous funding[2]

- The company raised $7.25 million of Series B venture funding from Baidu Ventures, Blackhorn Ventures and Breakout Ventures on July 1, 2018, putting the company's pre-money valuation at $25 million. Pactolus Ventures also participated in the round.
- The company joined Google Developers Launchpad in October, 2017. The startups "get what Google deftly described as 'equity-free support,' and access to Google mentors, community engagement as well as datasets and testing environments for prototyping, as examples."[3]
- The company received $2.97 million of grant funding from U.S. Department of Health and Human Services and National Science Foundation in September 2016.
- The company received $25,000 of grant funding from Becton, Dickinson and Company (NYSE: BDX) on April 6, 2015. This was in partnership with Breakout Labs. [4]
- The company raised $4.3 million of Series A venture funding from NetScientific, IT-Farm Corporation and undisclosed investors on June 10, 2014, putting the pre-money valuation at $8.1 million.
- The company raised an undisclosed amount of venture funding from Breakout Labs and Dolby Family on November 15, 2013

### Strategic partnerships

- Cytovale has partnered with various academic institutions and healthcare systems on their publications, including UCLA, California NanoSystems Institute, Louisiana State University, Baton Rouge General Medical Center

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[2] Retrieved from Pitchbook.
[3] Google powers up AI, machine learning accelerator for healthcare. November 1, 2017. https://www.healthcareitnews.com/news/google-powers-ai-machine-learning-accelerator-healthcare
[4] Breakout Labs and Becton, Dickinson and Company Partner to Provide Capital and Expertise to Biomedical Startups. April 6, 2015. https://www.businesswire.com/news/home/20150406005695/en/Breakout-Labs-Becton-Dickinson-Company-Partner-Provide

### Cost share
DRIVe and Cytovale are committed to a public-private partnership, with DRIVe contributing $749,000 of the total $1.397 million project cost. Cytovale will cover the remaining development costs for this phase of development as a part of a cost share.

## Emory University

http://nematilab.info/
Atlanta, GA
Award date: 1/22/2019
TRL 6 – System Integration and Testing

### Products
The BARDA DRIVe Solving Sepsis initiative is partnering with Emory University to further validate an interoperable machine learning software for early prediction of sepsis in hospital intensive care units that will provide physicians with actionable information. The project will leverage a multicenter consortium (Emory University School of Medicine, Massachusetts General Hospital, University of California San Diego School of Medicine, and Atlanta's Grady Health System) for retrospective validation utilizing a secure cloud architecture and will also execute a prospective deployment of the real-time predictive algorithm.

The deep learning algorithm currently in use in the Emory Healthcare system processes high-resolution vital signs and laboratory measurements in real time to produce prediction scores and has the potential to warn health professionals of the impending development of sepsis in patients 4 to 6 hours in advance.

Leveraging the Google Cloud Healthcare API and the Google Cloud Platform, the Emory team will optimize the software platform and undertake a prospective cloud-based implementation study, for a multi-site evaluation and validation, with an eventual goal of seeking FDA clearance as software as a medical device (SaMD) for early prediction of sepsis. The device, which would allow for detection of early signs of sepsis and the corresponding leading causes via a deep learning-based multi-dimensional time-series analysis approach, could improve clinicians' situational awareness and potentially save lives.

### Previous Funding
- Dr. Shamim Nemati is listed as PI on an NIEHS grant titled "Deep Learning and Streaming Analytics for Prediction of Adverse Events in the ICU" from 2015-2019.
- Dr. Shamim Nemati is listed as Co-PI on a $300,000 NSF grant titled "Leveraging Heterogeneous Data Across International Borders in a Privacy Preserving Manner for Clinical Deep Learning" from 2018.
- Dr. Shamim Nemati is PI on a $39,982 Pilot Grant through Georgia Clinical & Translational Science Alliance titled "Real-Time Identification of ICU Patients at Risk for Sepsis Through Big Data."
- May 1st, 2018 The Georgia Tech Pediatric Technology Center awarded funding to PIs Shamim Nemati (Emory), Gari Clifford (Emory), Kevin Maher (CHOA), and Wilcox, to pursue a new project focused on preventing bloodstream infections through interpretable machine learning: "A FHIR-Enabled Interpretable Deep Learning Platform for Timely Prediction of Central Line-associated Bloodstream Infections."

### Strategic Partnerships
The Nemati Lab at Emory often partners with researchers and clinicians at Emory Healthcare as well as The Clifford Lab at Emory University and Georgia Institute of Technology, led by Gari Clifford.

### Cost Share
DRIVe and the research consortium will work in partnership, with DRIVe contributing $699,376 of the total $1.04 million estimated project cost. The consortium institutions will fund the remaining development costs.

## Immunexpress
http://www.immunexpress.com/
Seattle, WA
Number of employees: 15
Year Founded: 2006
Award date: 1/31/2019
TRL 5 – Product Development

### Products
Immunexpress is a Seattle-based molecular diagnostic company committed to improving outcomes for patients suspected of sepsis. Immunexpress' SeptiCyte™ technology rapidly quantifies, directly from whole blood, specific molecular RNA biomarkers from the patient's own immune system – the 'host response'. SeptiCyte™ LAB, recently cleared by the FDA, is the first of its kind in using the host immune system to differentiate systemic inflammatory response syndrome (SIRS) and sepsis.

Immunexpress SeptiCyte™ technology is a precision diagnostic tool that evaluates a set of patented gene-expression biomarkers from the patient's blood. The tool is being designed to use mathematical algorithms to differentiate sepsis and infection negative systemic inflammation and identify whether the sepsis infection is viral or bacterial.

### Previous Funding
- The company is in the process of raising $20 million of Series C venture funding from undisclosed investors as of January 4, 2018. The round is expected to close August 31, 2018.
- The company raised $27.23 million of venture funding from undisclosed investors. The date of this was not disclosed.
- The company raised $12 million of venture funding in a deal led by Debiopharm Innovation Fund on March 5, 2014. The company intends to use the funds to advance development of the Immunexpress SeptiCyte® technology and bring one of its late-stage sepsis diagnostic products through to market.
- The company received AUD 982,707 of grant funding from Commercialisation Australia on February 18, 2014.

## Strategic Partnerships

- **Biocartis**
  In January 2018, Immunexpress announced a partnership with Biocartis to develop and commercialize a fully automated SeptiCyte™ LAB test for use on the Biocartis' sample-to-answer real-time PCR Idylla™ platform.
- **MARS Sepsis Consortium**
  2011 – present: The MARS Sepsis Consortium is a prospective observational cohort study designed to produce molecular information relevant to sepsis diagnosis and management. Immunexpress is a full partner in the collaborative Consortium. The Consortium recruited 8,603 critical care patients with signs of Systemic Inflammatory Response Syndrome (SIRS) across two tertiary hospitals in the Netherlands: the Academisch Medisch Centrum (AMC) in Amsterdam, and the University Medical Centre Utrecht (UMCU). Immunexpress is continuing collaborative sepsis clinical research at both study sites. (Clinicaltrials.gov identifier: NCT01905033)
- **Seattle Children's Hospital**
  2013 – present: The Genotypes and Phenotypes in Pediatric SIRS and Sepsis (GAPPSS) study is a collaborative pilot study at the Seattle Children's Hospital between Professor Jerry Zimmerman and Immunexpress. Immunexpress and the Seattle Children's Research Institute are jointly funding this study. (Clinicaltrials.gov identifier: NCT02728401)
- **Intermountain Health Care**
  2013- present: Intermountain Healthcare acted as the coordinating trial and data collection site for the FDA clearance studies of SeptiCyte™ technology, including the on-site real-time studies, and has a long history of interaction with Immunexpress. This collaboration has resulted in multiple papers and publications ranging from assay performance trials through to health econometric modeling.
- **University College London Hospital**
  2011 – present: University College London and Immunexpress continue to collaborate in prospective observational cohort studies including in pneumonia, immunocompromised sepsis patients, UTIs, and on validation of gene expression biomarkers for bacterial and viral sepsis.

## Cost Share

DRIVe and Immunexpress are committed to a public-private partnership, with DRIVe contributing $744,739 of the total $3.2 million estimated project cost, and Immunexpress funding the remaining development costs. Immunexpress will leverage its prior experience of developing its FDA-cleared product (SeptiCyte™ LAB) to develop this new sepsis diagnostic on the Biocartis Idylla™ platform.

# InnaMed

https://www.innamed.com/
Philadelphia, PA
Number of employees: 4
Year founded: 2016
Award date: 9/28/2018
TRL 4 – Optimization

## Products

Developer of a smart, at-home blood testing device designed for the early detection of deterioration and automation of therapy in chronically ill patients. The company's device utilizes patented DNA-driven assay

technology, aptamer reagents and signal processing hardware, enabling rapid, ultra sensitive blood testing at the home.

InnaMed will develop its proprietary electrochemical proximity assay (ECPA) technology to rapidly test blood for the sepsis-associated biomarker, a recently identified peptide that has shown increased sensitivity, specificity and prognostic ability compared to currently used sepsis indicators. The ECPA platform will be combined with analytics to determine a "sepsis score" to triage and monitor patients. InnaMed products are currently available for investigational use.

The company has one publication indexed in PubMed.

### Previous funding[5]

- The company raised $735,000 of venture funding from Arab Angel, Data Collective, and Matadero Ventures on March 20, 2017. GWC, Cheng Hu, Dong Hai, and Dorm Room Fund and other undisclosed investors also participated in the round.
- The company joined Y Combinator as part of the Winter 2017 class on March 20, 2017 and received $120,000 in funding
- In January 2017, the company joined California Institute for Quantitative Biosciences
- In May 2016, the company joined Boomtown HealthTech Accelerator on May 23, 2016 and received $20,000 in funding. Wharton Venture Initiation Program also participated in this round.
- The company received $10,000 of grant funding from Publicis Groupe on an undisclosed date.

### Strategic partnerships

- InnaMed co-authored a study in 2018 with NeoVentures Biotechnology of Ontario.
- Their website claims that they are partnering with "payers, health systems, skilled nursing facilities and pharmaceutical companies" but I haven't been able to find any news articles naming specific entities.
- InnaMed was a finalist in the 2016 Accenture HealthTech Innovation Challenge.

### Cost share

DRIVe and InnaMed are committed to a true public private partnership, with DRIVe contributing $200,000 of the $285,750 estimated project costs. InnaMed will fund the remaining development costs.

## Prenosis

http://www.prenosis.com/
Formerly known as ElectroCyt
Chicago, IL
Number of employees: 6-13
Year founded: 2014
Award date: 9/27/2018
TRL 4 – Optimization

[5] Retrieved from Pitchbook.

## Products

Prenosis' ImmunoMatch™ technology uses machine learning algorithms trained by its proprietary dataset (NOSIS) which combines critical biological information with existing electronic medical record data, to perform intelligent patient matching. With technology to predict how a sepsis patient's condition will progress, doctors can determine more quickly what is needed to improve outcomes over the continuum of sepsis care.

Prenosis is developing analytic systems that may help doctors predict the progression of sepsis in a patient. With DRIVe funding, Prenosis will develop a precision-medicine technology that could transform the clinical management of sepsis.

The first product, planned for early 2019 release, is a platform agnostic software system for use in Emergency Departments, in-patient populations, and ICUs. The second product, a combined handheld device with accompanying analytics, will be released by early 2021.

The company has one publication indexed in PubMed and co-founder Rashid Bashir has a few additional publications that are not affiliated specifically with Prenosis.

## Previous funding[6]

- The company received $ 704,525 of grant funding from National Science Foundation in 2018: SBIR Phase II: Point of Care Device for High Frequency Stratification of Patient Populations at Risk of Sepsis.
- The company received $150,000 of grant funding from CDC in 2017: Point of Care Device for Reducing Overuse of Antibiotics in Potentially Septic Hospital Populations.
- The company received $150,000 of grant funding from National Science Foundation in 2017: SBIR Phase I: Point of Care Device for High Frequency Stratification of Patient Populations at Risk of Sepsis.
- The company raised $1.5 million of angel funding from undisclosed investors on September 7, 2016.
- The company received $5,000 of grant funding from VentureWell on July 13, 2016.
- The company received $10,000 of prize money from Technology Entrepreneur Center as a part of 14th Annual Cozad New Venture Competition on June 14, 2016.
- The company raised $65,000 of angel funding from undisclosed investors on March 18, 2016. The deal also includes an undisclosed amount of convertible debt financing.

## Strategic partnerships

- Prenosis is a spinout of University of Illinois and Carle Foundation Hospital in Urbana, IL.

## Cost share

DRIVe and Prenosis are committed to a true public-private partnership, with DRIVe contributing $749,000 of the total $1.07 million estimated project cost. Prenosis will fund the remaining development costs.

[6] Retrieved from Pitchbook.

# Qvella

https://www.qvella.com/
Carlsbad, CA
Number of employees: 30
Year Founded: 2009
Award date: 2/11/2019
TRL 3 – Feasibility Demonstration

## Products

Qvella is a molecular diagnostics company founded in 2009 by a group of scientists and engineers with the goal of dramatically reducing time to results in bacteriology. The company aims to revolutionize how sepsis management is practiced by significantly cutting costs and saving lives. Qvella's Field Activated Sample Treatment (FAST) technology utilizes a novel sample prep technique that enables rapid detection of infectious agents and host response biomarkers from whole blood.

The BARDA DRIVe Solving Sepsis initiative is partnering with Qvella Corporation of Carlsbad, California, to develop ground-breaking technology to diagnose infection in patients suspected of sepsis with assay results in 60 minutes. The new host response diagnostic system leverages Qvella's FAST-ID™ pathogen identification platform based on revolutionary new approaches to rapid sample processing and nucleic acid isolation and amplification directly from whole blood. The Qvella project combines the company's diagnostics technology and expertise with Predigen Inc.'s gene signature analytical power to help develop the intended assay for the early diagnosis of sepsis.

## Previous Funding

- The company raised $20 million of Series B venture funding in a deal led by RA Capital Management, Sands Capital Ventures, Kensington Capital Partners, Whitecap Venture Partners on December 4, 2017. Hatteras Venture Partners and BioMérieux also led the round. The funds will be used to conduct clinical trials, to support on-going research and development and to facilitate team expansion and manufacturing scale-up.
- The company raised $20 million of Series A venture funding in a deal led by RA Capital Management and Whitecap Venture Partners on October 14, 2015. Hatteras Venture Partners, Sands Capital Ventures and Sands Capital Management also participated in the round.
- The company raised an undisclosed amount of venture funding from Whitecap Venture Partners on June 23, 2015.
- The company received $539,000 of grant funding from The Health Technology Exchange's Investing in Business Innovation Initiative on May 11, 2012. This funding will accelerate the commercialization of Qvella's bacteria testing platform, resulting in improved patient care and reduced healthcare costs.
- The company received $2.5 million of financing in a deal led by The Health Technology Exchange on January 20, 2012. Other undisclosed investors also participated. The funding will support the development of the company's whole blood sample preparation and bacterial ID system.

## Strategic Partnerships

Qvella leverages Predigen Inc.'s gene signature analytical power to help develop the intended assay for the early diagnosis of sepsis. Predigen is a spinout of Duke University, led by Ephraim Tsalik.

### Cost Share
DRIVe and Qvella are committed to a public-private partnership, with DRIVe contributing $692,236 of the total $988,909 estimated project cost. Qvella will fund the remaining development costs.

## Sepsis Alliance

https://www.sepsis.org/
San Diego, CA
Number of employees: 20
Year Founded: 2004
Award date: 1/29/2019
TRL N/A

### Products
Sepsis Alliance is the leading sepsis organization in the U.S., with expertise in developing educational materials for professionals and for the public, reaching more than 3 million patients and providers each year. Sepsis Alliance is working in all 50 states to save lives and reduce suffering by raising awareness of sepsis as a medical emergency. In 2018, Sepsis Alliance launched It's About TIME™ , a national initiative to create broader awareness of sepsis and the need for urgency in seeking treatment when there are signs and symptoms present.

To educate healthcare providers on recognizing the signs of sepsis across the continuum of care, DRIVe and Sepsis Alliance, one of the nation's leading sepsis organizations, launched a sepsis education and training initiative called the Sepsis Institute.

The Sepsis Institute will provide high quality, evidence-based education and training on the recognition, treatment and management of sepsis to healthcare professionals. The Institute will develop and house new webinars and training modules created for a range of healthcare providers including primary care and urgent care practitioners, nursing staff and emergency medical services personnel.

### Previous Funding
Sepsis Alliance receives funding from a variety of sources including private donations, grants, and sponsorships, for example, a $30,000 grant in 2018 from the Del E. Webb Foundation to produce Sepsis: First Responders, a training video designed for 2.7 million first responders in the United States.

### Strategic Partnerships
Sepsis Alliance lists National Sponsors on their website including:

- EKFMF
- ThermoFisher Scientific
- Biomerieux
- Edwards Life Sciences Foundation
- Merck
- Accelerate Diagnostics
- La Jolla Pharmaceuticals
- Beckman Coulter

### Cost Share
DRIVe and Sepsis Alliance are committed to a establishing a public-non-profit organization partnership, with DRIVe contributing $427,248 of the total $622,248 estimated project cost to establish the Sepsis Institute and develop educational content. Sepsis Alliance will fund the remaining development costs.

# ENACT Company Profiles

## BioBeat

https://www.biobeat.cloud/
Petach Tikva, Mehoz HaMerkaz, Israel
Number of employees: 10-20
Year founded: 2012
Award date: 12/10/2018
TRL 8 – Pivotal Clinical Studies and Regulatory Approval

### Products
Biobeat's Wrist Watch is an FDA-cleared monitoring device that continuously measures blood pressure, heart rate, heart rate variability, oxygen saturation, respiratory rate, stroke volume, cardiac output and index, systemic vascular resistance, sweat, skin temperature, and more. With funding from DRIVe, Biobeat will further develop the technology to track bodily changes that signal the user has potentially been exposed to an influenza virus or other pathogen.

Biobeat's technology is based on reflective photoplethysmography, a low-cost technique to detect blood volume changes in the smallest blood vessels of human tissue and often used non-invasively to make measurements at the skin surface. The data is recorded and analyzed to produce alerts and recommendations of clinical significance. This also potentially allows prediction and early warning before severe physiological emergencies occur. Information can be transmitted via the cloud to a cell phone application or database

### Previous funding[7]
- The company raised $3 million of venture funding in a deal led by Oxford Sciences Innovation on August 14, 2018. White Cloud Capital, IQ Capital Partners, Future Positive Capital, and inovia Capital also participated in the round. The new investment will support the company as they focus on delivering their cutting-edge wellness solutions to a global audience.
- The company joined Plug and Play Tech Center as a part of its Batch 4 of Health & Wellness Accelerator on March 21, 2017.
- The company raised $2.28 million of venture funding in a deal led by White Cloud Capital Advisors and Oxford Sciences Innovation on April 22, 2016. Samsung NEXT Ventures, AXA Strategic Ventures and IQ Capital Partners also participated in this round.
- The company raised $299,000 of Seed funding from Raptor Group, Slow Ventures, Italian Angels for Growth and other undisclosed investors on November 1, 2014, putting the company's pre-money valuation at $2.25 million.

[7] Retrieved from Pitchbook.

- The company received an undiclosed amount of grant funding from the UK's Innovation Agency on June 27, 2013.
- The company raised $750,000 of seed funding from ENIAC Ventures, Zhen Fund and K5 Ventures on May 1, 2013. 11 individual investors also participated in this round.
- The company raised seed funding from BE Great Partners, Zynik Capital and individual investor: Nadeem Kassam, Cantora and other undisclosed investors on May 15, 2012.

### Strategic partnerships

Biobeat lists their clients on their website, including

- Ministry of Health (Israel)
- Tel-Aviv Sourasky Medical Center
- Tri-logical Technologies Ltd.
- Rambam Health Care Campus
- Medison
- Amgen
- Magen David Adom
- Femi Premium
- Israel Defense Forces
- GE Healthcare
- Elbit Systems
- D-MARS (Desert Mars Analog Ramon Station, Israel)
- U.S. Department of the Air Force
- The Chaim Sheba Medical Center at Tel Hasomer

### Cost share

DRIVe and Biobeat are committed to a public-private partnership, with DRI contributing $599,000 of the total $954,800 project cost. Biobeat will provide the remaining development costs.

## Empatica

https://www.empatica.com/
Cambridge, MA
Number of employees: 65
Year Founded: 2011
Award date: 1/24/2019
TRL 4 - Optimization

### Products

Empatica Inc. is an MIT Media Lab Spin off that develops wearable smartbands that utilize machine learning and an intricate combination of biosensors to unlock the physiology of your health. Their Embrace smartband is the first FDA-cleared, wrist-worn wearable to be cleared in the field of epilepsy for its seizure monitoring and alerting capabilities. Embrace detects patterns in motion and physiological signals that may be associated with generalized tonic-clonic seizures, and immediately alerts caregivers; these signals include electrodermal activity, rotational speed, skin temperature, and high sensitivity motion detection.

The project builds on Empatica's Embrace2, a battery-powered wristband FDA-cleared as a medical device for use by people suffering from epilepsy. Embrace2 technology measures multiple indicators related to

physiological parameters. Embrace has also been approved in Europe as a medical device to monitor seizures and alert since April 2017. Currently Embrace2 uses advanced machine learning to monitor physiological parameters, detect unusual patterns that may be associated with convulsive seizures, and immediately notify users and caregivers.

The Empatica device will be among those tested in the upcoming DARPA/BARDA Prometheus Influenza In-the-Home Clinical Studies to evaluate health signatures that can predict pathogen exposures prior to symptoms.

### Previous Funding

- The company raised EUR 5 million of Series A venture funding in a deal led by Innogest on April 1, 2017. Endeavor Global and Invitalia Ventures also participated in this round.
- The company raised $500,000 of angel funding via crowdfunding platform Indiegogo on January 21, 2015.
- The company joined Polihub on an undisclosed date.

### Strategic Partnerships

Clients listed on the company's website include

- Danny Did Foundation
- Epilepsy Foundation
- Massachusetts Institute of Technology
- Boston Children's Hospital
- NASA
- Sunovion

### Cost Share

DRIVe and Empatica are committed to a public-private partnership, with DRIVe contributing $251,454 of the total $457,189 project cost. Empatica will provide the remaining development costs.

## EnLiSense

https://enlisense.com/
Allen, TX
Number of employees: 2-10
Year founded: 2014
Award date: 9/14/2018
TRL 4 - Optimization

### Products

EnLiSense's Wearable Point-of-Need SWEATSENSER Dx Platform is an easy-to-use, cost-effective sensor technology (i.e. No needles, No punctures) offering real-time, continuous reporting from passively expressed sweat with no external stimulation and works with varying skin types and varying environments for early warning of changes to body's physiological state.

EnLiSense's non-invasive SWEATSENSER diagnostics (Dx) Platform could become an easy-to-use wearable sensor to quickly detect or rule out infections. The sensor, which may resemble a wrist-watch, works by

detecting and tracking multiple biomarkers, including cytokine levels in sweat; these levels may be an early warning of changes in the body.

The SWEATSENSER could be used in a hospital setting or in the community to identify an influenza infection or other illness related to chemical, biological, radiological, or nuclear disasters.

Currently, EnLiSense does not sell their product and it is still in development.

EnLiSense has authored or co-authored 16 publications in PubMed since September 2015.

### Previous funding

- None listed in Pitchbook
- Received $242,389 from National Institute on Alcohol Abuse and Alcoholism (NIAAA) in 2017 for project, "AWARE (A wearable awareness with real-time exposure): rapid wearable alcohol diagnostics"

### Strategic partnerships

- UT Dallas (technology spun out of UT Dallas through Dr. Shalini Prasad).

### Cost share

This EnLiSense and DRIVe announcement is a true public private partnership with DRIVe providing just over $550,900 and EnLiSense picking up a share of the cost.

## Spire

https://spire.io/
San Francisco, CA
Size: 25 employees
Year founded: 2013
Award date: 9/20/2018
TRL 6 – System Integration and Testing

### Products

Developer of a fitness sensor designed to monitor sleep, stress, and activity. The company's sensor is wearable that tracks both physical and psychological fitness to lower stress and increase productivity, enabling users to lead a healthy life and improve their performance.

The Spire Health Tag is a small washable device that attaches to clothing to monitor and report activity and detect changes in the body. The device can send messages to the user's cell phone to report findings and alert the wearer to real-time bio-signals, like heart-rate and breathing variability, changes in body heat, stress levels, and other changes in the unique health signature of the user. It is designed to be easy to use, can be worn while the person sleeps, and does not need to be recharged.

Currently the Spire Health Tag is available for consumer health and wellness use, including to help monitor sleep, stress and activity. Now with funding for DRIVe, Spire will further develop the product, aiming for U.S. Food and Drug Administration (FDA) 510K clearance. FDA clearance is required to ensure medical devices are safe and effective before they can be marketed for clinical applications.

Spire is backed by 7 years of research from Stanford's Calming Technology Lab, their consumer products are sold globally in Apple Stores, and their Spire Health Platform is in use by Fortune 100 medical device companies, large apparel retailers, and health professionals worldwide.

### Previous funding[8]

- In 2018, Spire received $209,276 from the National Institute on Drug Abuse (NIDA) for the project, "A clothing-adhered wearable to monitor biomarkers of cognitive/emotional state and deliver just-in-time behavioral interventions."
- The company graduated from Y Combinator as a part of the Winter 2015 class and received $120,000 in funding on March 24, 2015.
- The company raised funding from Tigerlabs Health, StartX and Dan Sutera on an undisclosed date.
- The company raised an undisclosed amount of convertible debt financing from Scrum Ventures on October 28, 2014.
- The company raised $100,000 of seed funding from Scrum Ventures, Lee Linden and Rock Health on August 21, 2013. Mayo Clinic, University of California, DN Capital, San Francisco, Bert Navarrete also participated in the round.

### Strategic partnerships

In 2018, Spire partnered with Swim.com to design a smart swimsuit.[9]

### Cost share

Spire and DRIVe, as a true public private partnership, are sharing costs to increase the chances of success. The total project cost is $88,860, with the DRIVe contributing approximately $62,200 and Spire funding the remaining costs.

# Other Company Profiles

## Enesi Pharma

www.enesipharma.com
Abingdon, Oxfordshire, UK
Size: 10-20 employees
Year founded: 2017
Award Date: 4/10/2019
TRL 5 - Demonstration

### Products

Enesi Pharma has developed ImplaVax® formulation and needle-free system enables solid dose implants containing vaccines to be delivered quickly and painlessly under the skin with ease.

[8] Retrieved from Pitchbook.
[9] https://www.wareable.com/sport/spire-smart-swimsuit-release-date-price-specs-5577

The ImplaVax® technology comprises three main components:

- A single precision-engineered solid dose Universal Vaccine Implant (UVI) containing the monovalent or multivalent vaccine or vector construct together with its associated excipient matrix that confers its mechanical strength and stability
- A separate, disposable unit dose cassette pre-loaded with a single solid UVI
- A handheld spring-powered actuator (single or multi-use)

This project will involve analytical and pre-clinical evaluation of novel ImplaVax®-enabled solid dose implant formulations of known influenza vaccines in standard animal models. In-vitro tests will include evaluation of mechanical strength and surety of implantation. In-vivo testing will assess comparative immunogenicity and dosing regimens. Performance of solid dose implants versus placebo and active control vaccine delivered by needle and syringe will also be measured. The overall aim is to generate evidence to support the further evaluation of solid dose presentations as a potential alternative method of vaccination in a future pandemic response.

## Previous Funding

No previous funding is listed in Pitchbook.

## Strategic Partnerships

- **University of Oxford** – In April 2019, Enesi announced that they entered into a collaborative agreement to create and test a solid dose vaccine against plague. The collaboration will leverage Enesi's ImplaVax® needle-free technology and a proprietary vaccine against the bacteria causing plague (Yersinia pestis) developed by OVG, based on a ChAdOx adenovirus vector.[10]
- **GeoVax** – In January 2019, GeoVax and Enesi announced a collaboration to develop solid-dose needle-free vaccine formulations utilizing GeoVax's novel MVA-VLP vaccine platform in combination with Enesi's ImplaVax® device and formulation technology. The collaboration is expected to include development of thermostable solid-dose needle-free vaccines for a variety of infectious diseases and evaluation of the potential to generate improved vaccine responses with simplified administration and reduced storage and distribution costs.[11]
- **Public Health England** – in October 2018, Enesi entered a research and development collaboration with Public Health England (PHE), an executive agency of the UK government's Department of Health and Social Care. The collaboration is focused on the development and evaluation of a novel solid-dose formulation of a number of PHE's proprietary vaccine candidates including anthrax recombinant protective antigen (rPA) and Crimean-Congo hemorrhagic fever (CCHF) for delivery via Enesi Pharma's ImplaVax needle-free technology.[12]
- **Sementis** – In November 2018, Sementis and Enesi announced a collaboration focused on the development and evaluation of solid dose versions of Sementis' lead peanut hypoallergy vaccine and their single vectored chikungunya/Zika vaccine candidates for administration via Enesi

[10] https://www.prnewswire.com/news-releases/enesi-pharma-and-university-of-oxford-collaborate-to-target-plague-with-a-novel-implavax-enabled-adenovirus-based-solid-dose-vaccine-300826499.html
[11] https://www.geovax.com/component/easyblog/entry/2019/01/02/geovax-and-enesi-pharma-to-collaborate-on-development-of-multiple-vaccines-administered-by-implavax-a-novel-needle-free-vaccine-delivery-platform.html?Itemid=101
[12] https://www.thepharmaletter.com/in-brief/brief-enesi-pharma-collaborates-with-public-health-england-on-solid-dose-vaccine-for-emergent-threat-pathogens

Pharma's ImplaVax® technology. ImplaVax is an innovative and proprietary needle-free solid dose implant and device technology for subcutaneous vaccination.

- **Walter Reed Army Institute of Research** – In September 2018, Enesi entered a CRADA with WRAIR, ocused on the development of a robust and stable solid-dose formulation of WRAIR's Shigella flexneri 2a artificial Invaplex (Sfl2a InvaplexAR) vaccine for delivery via Enesi Pharma's ImplaVax® technology.

### Cost share

BARDA and Enesi are committed to a public-private partnership, with BARDA DRIVe contributing $689,863 of the total $984,090 estimated project cost. Enesi will fund the remaining development costs.

## Janus-I Science

https://jiscience.com/
Vista, CA
Size: 5-10 employees
Year founded:
Award date: 4/15/2019
TRL 3 – Feasibility Demonstration

### Products

Janus-I Science will develop a sample-to-answer workflow that uses nanopore sequencing to accurately identify unknown pathogens in patient specimens, and importantly, would be available for use right where patients need it for fast answers. Integrating the steps involved will simplify the workflow of sequencing-based diagnostics and provide faster, actionable results.

The project leverages Janus-I Science's end-to-end sample preparation techniques with nanopore sequencing and computational data analytics. Janus-I Science will integrate and automate the entire process, which includes analysis and interpretation of sequencing data to provide clear, actionable results for use in a healthcare setting where the information is needed.

### Previous Funding

Janus-I Science does not have a profile in Pitchbook, suggesting that it has not received any funding. It does appear that they have received two federal contract awards through DoD:[13]

- In February 2018, they were awarded $1.5M for development and integration of sample preparation and tropical fever assay on the "man portable diagnostic system" (MPDS)
- In September 2017, they were awarded $2.9M for predicting influenza contagiousness prior to symptom display

### Strategic Partnerships

**Oxford Nanopore Technologies and the Naval Health Research Center in San Diego**

For their work on the BARDA DRIVe project, Janus-I Science is partnering with Oxford Nanopore Technologies in the UK and the Naval Health Research Center in San Diego to build the assay workflow and demonstrate its accuracy using real-world specimens.

[13] https://govtribe.com/award/federal-contract-award?searchId=5c62f410a1c4c50f7d4bac79

Other partners list on website include

- Natural Selection, Inc.
- ASPR
- DARPA
- Henry M. Jackson Foundation for the Advancement of Military Medicine
- NJK & Associates

## Cost share

DRIVe and Janus-I Science, Inc. are committed to a public-private partnership, with DRIVe contributing $710,619 of the total $1,015,179 estimated project cost. Janus-I Science will fund the remaining development costs.

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