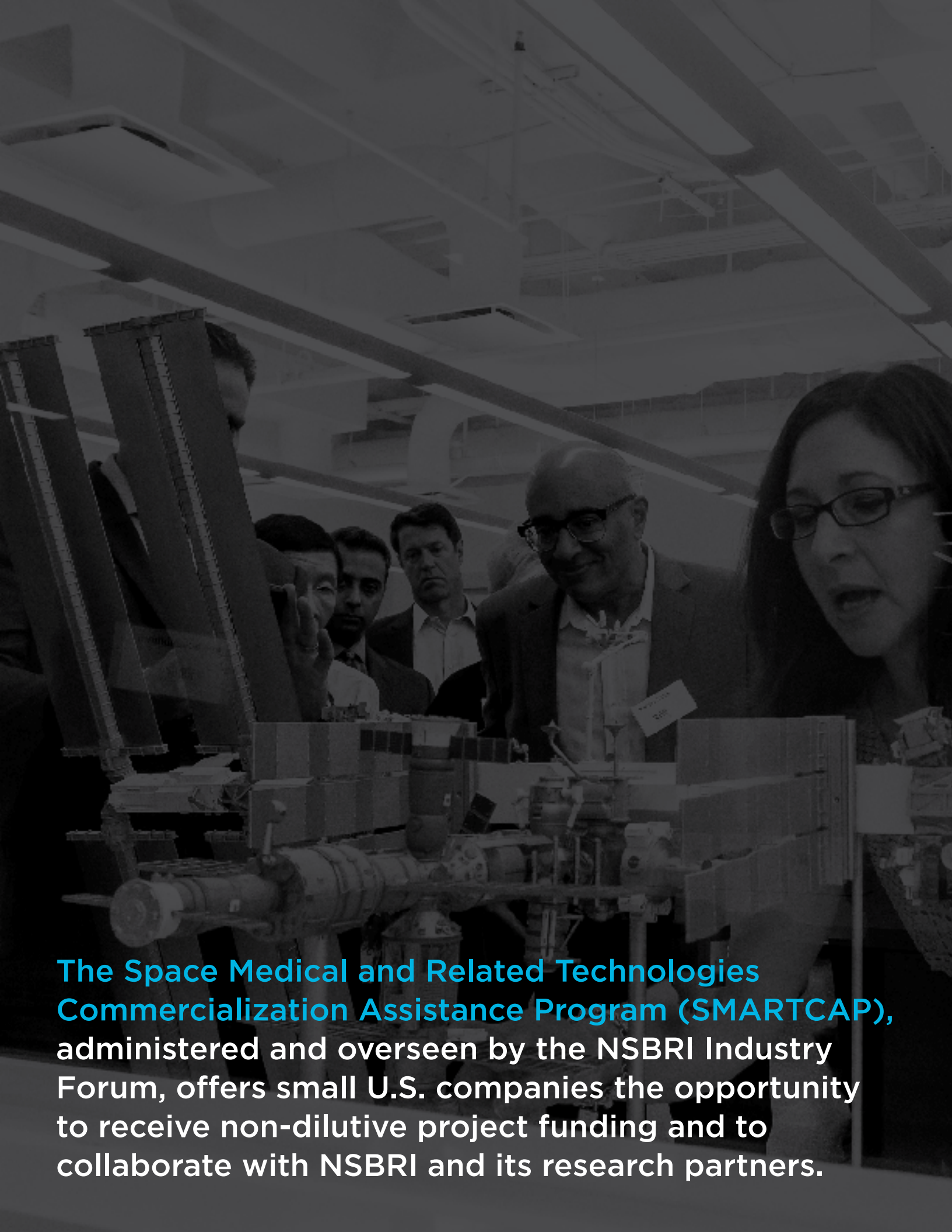
SMARTCAP

Space Medical And Related Technologies
Commercialization Assistance Program

INDUSTRY FORUM SMARTCAP PORTFOLIO

NSBRI
Industry Forum



The Space Medical and Related Technologies Commercialization Assistance Program (SMARTCAP), administered and overseen by the NSBRI Industry Forum, offers small U.S. companies the opportunity to receive non-dilutive project funding and to collaborate with NSBRI and its research partners.

NASA is in need of medical technologies that can be used in space. Meeting this need requires novel approaches to administering healthcare.

Transitioning a technology from bench to market (or space) is an expensive and complex endeavor, requiring specialized expertise in diverse areas of science, medicine, engineering, and business. As a federally funded entity, NSBRI is committed to ensuring that its investments in research have the broadest possible impact for the U.S. human space program as well as health on Earth.

To this end, the NSBRI Industry Forum partnered with the private sector to develop space-compatible healthcare solutions. Through its non-dilutive grants administered through the Space Medical and Related Technologies Commercialization Assistance Program (SMARTCAP) opportunity, federal dollars are matched at 100 percent with privately raised funding. SMARTCAP has been implemented from 2011 to 2016 with 8 solicitations, and has received close to 200 applications from small U.S.-based companies. It has funded over a dozen companies that have developed 3 software tools, seven devices, and several nutraceutical or pharmaceutical countermeasures. The funding is modest, with total programmatic expenditures equivalent to one single four-year openly-solicited NSBRI/NASA Research Announcement grant.

SMARTCAP deliverables have the potential to reduce human health risks in the areas of radiation, sleep, spaceflight- induced visual impairment and intracranial hypertension and intervertebral disc damage.

The intent of SMARTCAP was to:

- Recruit and partner with industry to solve problems for space
- Deliver refined products to NASA to address health risks
- Leverage private and other sources of funding
- Diversify the portfolio of academic projects and products
- Identify and support state-of-the-art emerging medical technologies
- Facilitate commercialization and foster economic growth of small business
- Educate the public and industry on NASA's needs
- Educate the public and industry on the constraints of spaceflight
- Fuel scientific and technological advances

This program was appealing to small businesses because the SMARTCAP application process, while rigorous, was streamlined with less than six months from application to award. In addition, the SMARTCAP project was designed to build on the company's on-going efforts and existing commercialization strategy. At the same time, the new work enabled pursuit of expanded market opportunities via projects that address both space exploration demands and terrestrial market applications. The Industry Forum worked with the successful candidates to develop a work plan that was aligned with both the terrestrial and space applications of the product.

It was my honor and pleasure to work with our dedicated Steering Council and my collaborator and consultant, Ms. Marti Fleming, to serve our nation's human spaceflight program in launching and overseeing SMARTCAP and to present this compilation of industry projects and deliverables to NASA and patients on Earth.

Dorit B. Donoviel, Ph.D.
Industry Forum Lead and
Deputy Chief Scientist, NSBRI

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BioSHIELD 4 MARS

Background

Physical or magnetic shielding from space radiation is not currently feasible, particularly protecting against high energy galactic cosmic rays (GCR) and unexpected solar particle events (SPEs). Hence, the development and validation of biological countermeasures is an important avenue to protect astronauts against the adverse effects of ionizing radiation during long-duration space travel. Countermeasures and prophylactic agents (e.g., pharmaceutical or medical foods) must be safe, clinically impactful, and have a long shelf-life in the space environment.

Ionizing radiation affects a plurality of organ systems. It is highly unlikely that one countermeasure will address all facets of radiation toxicity. Of particular interest are agents that protect the gastrointestinal tract, the brain, the lung, the heart, and the immune and hematopoietic systems from insults due to radiation and other environmental influences.

The Opportunity

Radiation is the #1 health risk facing humans in space. The NSBRI Industry Forum initiated BioShield 4 Mars to address this risk with the intent of awarding at least one $250,000 grant in 2016. Small U.S.-based companies who have developed or in-licensed agents that have demonstrated promise in protecting healthy tissues from the deleterious effects of ionizing radiation; either conventional (gamma-rays) or space-like (proton, X-ray, and heavy ion) were invited to apply.

Applicants were required to submit credible scientific peer-reviewed publications that support their claim that the proposed agent is an effective radiation countermeasure or prophylactic. All applications were reviewed by a panel of scientific experts in radiation biology.

The Industry Forum recognizes that the market for radiation protection is not large enough to attract follow-on funding from investors. Hence, applicants must propose an additional indication and provide a rationale and preliminary data to support its potential efficacy and the market opportunity. SMARTCAP funding may then be used to execute key proof-of-concept or other preclinical studies in support of the additional indication. This will de-risk investment opportunities and have the final outcome of delivering a promising product to market for clinical use that is also efficacious for protecting healthy tissues against radiation.

Two companies have been selected to advance: Entrinsic Health Solutions and Humanetics. These companies are required to present their proposals in person to the NSBRI Industry Forum Steering Council. The Steering Council evaluates the companies and their proposals and recommends the most compelling project(s) to the NSBRI Selection Official for a SMARTCAP BioShield 4 Mars grant.

Entrinsic Health Solutions, LLC

Gastrointestinal Health Proposal

Shown to be a an effective countermeasure for proton and gamma irradiation effects on the gastronintestinal tract, Entrinsic Health now proposes to conduct a randomized, double-blind, two-arm Phase II clinical trial to assess the efficacy of enterade® as a countermeasure for melphalan-induced gastrointestinal toxicity. High dose melphalan has replaced total-body irradiation as the standard of care for bone marrow depletion prior to hematopoietic stem cell transplantation. Melphalan, an alkylating agent, has effects and toxicities similar to those experienced with total body irradiation, with particularly high incidence of gastrointestinal toxicity (diarrhea, mucositis, nausea, vomiting and decreased appetite). Melphalan also decreases intestinal barrier function, facilitating translocation of bacteria and endotoxins into the bloodstream.

EHS hypothesizes that daily enterade® consumption will help maintain bowel regularity and function compared to placebo, resulting in reduced diarrhea and nausea, reduced duration of hospital stays, improved appetite and weight maintenance, reduction in systemic markers of a damaged intestinal wall and improved quality of life. Given the similarities in intestinal pathology caused by total-body irradiation and melphalan treatment, similar mitigating effects are likely to be observed for astronauts exposed to radiation during space missions.

Humanetics Corporation

Humanetics is a clinical-stage pharmaceutical company focused on radioprotectants, radiomitigators, and radiotherapeutics.

To evaluate BIO 300 as a radiation countermeasure for low dose applications, the company proposes a large animal study to monitor the incidence of DNA double strand break markers in the presence or absence of BIO 300. This study will be carried out using research animals exposed to single or multiple doses of low-dose ionizing radiation at doses similar to those received from a medical imaging CT scan. Markers of radiation-induced damage will be quantified in isolated peripheral blood lymphocytes (PBLs). Validated bioanalytical methods will determine the pharmacokinetics of BIO 300. This will establish the pharmacokinetic/pharmacodynamics relationship for BIO 300 and the resulting biological response. Using isolated PBLs, the company will determine whether BIO 300 treatment reduces DNA mutations resulting from low-dose radiation exposure. In combination with the ongoing clinical study in lung cancer patients these studies will rapidly move BIO 300 toward the market as a radiation countermeasure. A study site and population of NHP's has been identified to carry out this research plan.

LumosTech, Inc.

"Having NSBRI's backing has significantly improved the company's outlook and potential and will enable us to explore new markets."

—Vanessa Burns
CEO of LumosTech

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NSBRI User Panel members, Astronaut Commander Ken Bowersox (Ret.) and former NASA Flight Surgeon Dr. Jonathan Clark (Ret.) try out the sleep mask.

LumosTech was awarded a SMARTCAP grant in November of 2015 to continue its development of a programmable sleep mask that uses light therapy during sleep to shift an individual's circadian rhythm. In space, there may not be a normal night and day cycle. On the ISS, astronauts experience multiple sunrises over the course of 24 hours and frequently need assistance to optimize their sleep/wake cycles based upon the work plan for the week. Additionally, NASA ground crews are sometimes required to adjust to work-related sleep changes and must be fully alert during the middle of the night.

The LumosTech smart sleep mask is based upon technology discovered, developed, and clinically validated by Stanford University researchers. This research demonstrated that short pulses of light, administered while sleeping, may be effective in shifting human sleep cycles. The programmable mask under development by LumosTech will deliver millisecond pulses of light while the user sleeps, specifically designed to achieve the desired adjustment of the user's sleep cycle.

"Having NSBRI's backing has significantly improved the company's outlook and potential and will enable us to explore new markets." —Vanessa Burns, CEO of LumosTech

In a 24/7 world, this technology has the potential to benefit many people, from international business travelers who must rapidly transition into different time zones to shift workers whose schedules require them to be alert and at peak performance during normal sleep hours. By using this sleep mask, travelers can shift their sleep schedule and rapidly realign their circadian rhythm to the local environment. This technology may lessen the effects of jet lag and preserve their ability to perform. The companion smartphone app uses a mathematical model of circadian phase to deliver light pulses at the maximally effective time and collects data on the user's sleep quality.

The LumosTech SMARTCAP project is focused on refining the mask prototype for both comfort and performance. Upon completion, manufacturing will be commissioned. The company is offering early adopters the chance to reserve a smart sleep mask now for $175, with delivery anticipated in late 2016. This technology can be used by anyone with shifted sleep patterns: astronauts, frequent travelers, shift workers, athletes, and teenagers.

VISION4MARS
CHALLENGE

A unique strength of the NSBRI Industry Forum is its capacity to quickly and cost-effectively rally experts from the private and public sectors to help meet NASA's emerging medical challenges.

A number of astronauts have developed visual symptoms related to the time spent in space; some of these symptoms raise serious medical concerns. For more information, see humanresearchroadmap.nasa.gov

The NSBRI Industry Forum Lead reached out to the ophthalmology business and entrepreneur community during the Ophthalmology Innovation Summit at the 2014 American Academy of Ophthalmology meeting in Chicago. Dr. Donoviel announced the Vision 4 Mars (V4M) Challenge aimed at safeguarding the eye in space by way of a public-private partnership.

The V4M challenge leveraged SMARTCAP to identify and fund ophthalmology and vision-related technologies being developed by small U.S. based companies. To help NSBRI and NASA find space-appropriate state-of-the-art ocular technologies, the NSBRI Industry Forum Lead recruited a "Dream Team" made up of both clinical experts and business leaders. These highly-respected individuals visited the Space for Biomedicine facility in November of 2014 and heard from NASA and NSBRI experts about the clinical manifestations of the ocular syndrome in astronauts.

The V4M "Dream Team" (see roster on right) made a series of recommendations regarding appropriate ophthalmologic technologies which were subsequently incorporated into the V4M SMARTCAP solicitation. In addition, the Dream Team reached out to their contacts to tell them about the opportunity. As a result, dozens of quality applications were received and reviewed by the Industry Forum Steering Council, and in February 2015, four finalist companies with promising technologies presented in Houston to the Council and to NASA and NSBRI personnel.

Three of the four invited companies were selected to receive SMARTCAP funding. Annidis, Inc. of Grandville, MI developed a revolutionary technology (the Annidis RHA™ ophthalmoscope) for early detection of outer retinal and choroidal disorders, conditions that can potentially affect astronauts during long duration space travel. They will use the award to do a clinical study to correlate diagnostic findings with clinical outcomes. Equinox, LLC of Sioux Falls, SD also received a SMARTCAP grant to develop Balance Goggles™, a simple and comfortable pair of eye wear that will safely and gently regulate the pressure inside each eye either up or down. Web Vision Centers Group, LLC of South Jordan, UT also received a V4M-related award to customize adjustable prescription glasses for astronaut use during spaceflight, to work with select vision lens companies and the NASA flight medicine practitioners to meet operational vision assessment needs.

THE OPHTHALMOLOGY DREAM TEAM

William J. Link, Ph.D.
Managing Director
Versant Ventures

Eugene de Juan, Jr., MD
Founder & Vice Chairman
ForSight Labs

Richard L. Lindstrom, MD
Founder & Attending Surgeon
Minnesota Eye Consultants

Jane E. Rady, MS, MBA
Divisional VP, Business Development
Abbott Medical Optics

Randy McDonald
Founder and President
The Magnum Group, Inc.

Kuldev Singh, MD, MPH
Professor Of Ophthalmology
The Stanford University Medical Center

Steven Schallhorn, MD
Private Practice Physician, GWS Vision
Chief Medical Director, Optical Express

Paul Hallen, MS
Head, Global Retina
Alcon, a Novartis Company

John Berdahl, M.D.
Private Practice Physician
Vance Thompson Vision

Bob Main, ABOM
President
Web Vision Centers Group, LLC

eVision Smart Optics, Inc.

"The announcement of eVision's selection by NSBRI to receive a SMARTCAP grant really elevated people's awareness of the potential uses of our electronic optics. We received many inquiries from people interested in our platform because of their scientific curiosity about NASA's needs, which led to a greatly enhanced understanding of our technology's use in Earth applications."

—Joel Zychick
President & CEO

E-VISION SMART OPTICS
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NSBRI Astronaut User Panel Chair Dr. Leroy Chiao (Commander, Ret.), tries a pair of glasses with electronically adjustable lenses.

The company received a SMARTCAP grant in November 2015, to develop electronically adjustable prescription glasses that will address the vision changes astronauts experience during spaceflight. These glasses need to be adjustable in real-time to maximize an astronaut's visual acuity for each task.

"Liquid crystal lenses can be re-programmed electronically to adapt to an astronaut's changing vision. Our goal is to develop a lens that can be programmed with far, near & mid-range sections, or with all sections of the lens at a single focal length," —Tony Van Heugten, Chief Technology Officer of eVision Smart Optics.

"The announcement of eVision's selection by NSBRI to receive a SMARTCAP grant really elevated people's awareness of the potential uses of our electronic optics. We received many inquiries from people interested in our platform because of their scientific curiosity about NASA's needs, which led to a greatly enhanced understanding of our technology's use in Earth applications." —Joel Zychick, President & CEO

Long-duration exposure to the micro-gravity environment in space often results in unpredictable vision changes for astronauts. On Earth, we lose our ability to change focus as we age (presbyopia). Creating eyeglasses that can not only be reprogrammed but can dynamically and instantly change focus will allow astronauts to change their prescription if needed during a long mission while on Earth people will once again be able to focus upon objects at many varying distances. Four months post award, the company has made good progress in creating first generation prototypes with a larger tunable lens than is currently available. e-Vision continues to develop its platform technology, Smart Focus Optics™, which relies on electrically modulating optics and lenses to refract, diffract, or diffuse light. The company protects its technology with a well-honed intellectual property strategy, having almost 400 patents and patent applications issued or in process.

The company's current active development projects are accommodating contact lenses, on/off optical power changing eye glasses, dynamic adjustable eye glasses for space and earth, virtual and augmented display optics that compensate for accommodation (or a lack of it in some cases) and certain military optics. Each of these projects has either a government or commercial partner helping fund the effort. For example, the on/off eyeglasses are in the commercial scale-up phase by their licensee Mitsui Chemical of Japan. In all of these cases, technical overlap exists between projects resulting in added value for each partner. The company anticipates that working, demonstration prototypes will be completed for contact lenses, dynamic adjustable eyeglasses, and the augmented and virtual reality optics in the last quarter of 2016.

Adaptica Srl, the company's Italian partner, employed technology licensed from eVision to develop VisionFit™, an electronic phoropter. It received a CE Mark in 2015 and is now available in Europe. The compact size of this wearable and mobile system requires less office space and reduces examination time.

E-Vision recently closed a round of financing within its existing shareholder base to fund its accommodating contact lens development program.

Equinox, LLC

"The SMARTCAP grant provided early validation of the Equinox technology and enabled the company to raise private investment that exceeded its required 100% match by fivefold. Additionally, our collaboration with NSBRI and NASA scientists raised awareness of the potential to treat glaucoma by lowering intraocular pressure with our Balance Goggles."

—John Berdahl, MD
Founder and CEO of Equinox, LLC

EQUINOX

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Ophthalmologist John Berdahl, MD demonstrates a very early prototype of the Balance Goggles.

Equinox received a SMARTCAP Vision 4 Mars grant in March 2015, to advance the development of a novel approach to moderating intraocular pressure (IOP) for the treatment of glaucoma. John Berdahl, MD, Founder and CEO of Equinox, conceived the approach based upon his insight that relative pressure rather than absolute pressure within the eye contributes to the problems experienced by glaucoma patients. Equinox is developing Balance Goggles™ eyewear that incorporates a micro-pump capable of adding or removing pressure on the eye externally and thus moderating IOP.

In space, astronauts experience Vision Impairment and Intracranial Pressure (VIIP) Syndrome, believed to result, at least in part, from increased intracranial pressure. It frequently manifests as alterations in visual acuity. An increase in intracranial pressure while in space will alter the pressure gradient between the ocular nerve and IOP. The Balance Goggles may be an effective countermeasure to return IOP and ICP to a normal relative pressure thus ameliorating some of the visual effects that have been observed.

The SMARTCAP grant was employed by Equinox to develop prototypes of the Balance Goggles™ and undertake safety testing in a non-significant risk, IRB-approved study here in the U.S. The study is evaluating the impact of the goggles on several measures of eye health: OCT, keratotomy and dryness. At presstime, this study was at a halfway point and Dr. Berdahl expects results to be available by Q2 2016. According to Dr. Berdahl, the company's early development efforts focused on the pump that controls pressure within the goggles. While off-the-shelf goggles have been used with the company's early prototypes, Equinox is now working on a purpose-designed goggle that will emphasize comfort, breathability and "sealability", i.e. the goggle's ability to maintain pressure over time. "The SMARTCAP grant provided early validation of the Equinox technology and enabled the company to raise private investment that exceeded its required 100% match by fivefold. Additionally, our collaboration with NSBRI and NASA scientists raised awareness of the potential to treat glaucoma by lowering intraocular pressure with our Balance Goggles." —John Berdahl, MD, Founder and CEO of Equinox, LLC

This technology also has the potential to benefit millions of glaucoma patients around the world who do not respond to, or cannot take, currently approved medications. By using these goggles to decrease the pressure within the eye, patients may avoid surgery or the side effects of medication. As of early 2016, Equinox has one full time employee and four part-time employees, having grown from a single part-time employee at the time of the award in 2015. The company's goals for 2016 include completing the development of a qualified, commercial quality device and initiation of a clinical study to demonstrate both safety and efficacy in a patient population which may share common features with the eye condition experienced by astronauts.

Another important question that must be answered is how long must a patient wear the goggles to achieve the desired effect. Dr. Berdahl and his advisors have undertaken a review of literature to help determine the range that will be tested. The company also expects to finalize the regulatory pathway for the device during 2016.

Annidis, Inc.

"Engaging with NSBRI through SMARTCAP expanded our perspective on utilizing the RHA for earlier detection of a wider variety of anomalies in human retinas and potential applications of the device in neurology and neuro-ophthalmology."

—Rick Clayton
Director of Product Development

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The Annidis RHA™, a multispectral ophthalmoscope with multi-image software processing. This device can be miniaturized for spaceflight.

VISION 4 MARS CHALLENGE

In March of 2015, **Annidis** was awarded a SMARTCAP Vision 4 Mars grant to evaluate the company's proprietary multispectral imaging technology and determine if it offers insights into the VIIP Syndrome not achievable with technologies currently deployed on the International Space Station. The Annidis RHA™ is a multispectral ophthalmoscope with multi-image software processing that quickly and non-invasively generates detailed, multi-layer retinal images heretofore unachievable even from more complicated and invasive procedures.

"Annidis' Multi-Spectral Imaging is a revolutionary technology for early detection of outer retinal and choroidal disorders, which can potentially affect astronauts during long duration space travel." —Dr. Gene de Juan, the Jean Kelly Stock Distinguished Professor of Ophthalmology at University of California, San Francisco, and a member of the Vision 4 Mars Advisory Team.

"Engaging with NSBRI through SMARTCAP expanded our perspective on utilizing the RHA for earlier detection of a wider variety of anomalies in human retinas and potential applications of the device in neurology and neuro-ophthalmology. Scientists at NSBRI connected us to NASA's Jet Propulsion Laboratory team which leads the field in the advanced application of multi-spectral image acquisition technology and analysis. A less tangible benefit is the excitement within the company at being involved in contributing to human space exploration."— Rick Clayton, Director of Product Development

Given that the VIIP syndrome is one of the top priorities for NASA related to long-duration spaceflight missions, there is an urgent need to identify technologies that are easy to use, safe, and provide insight into pathological targets of interest. Multispectral imaging provides a high resolution view of the retinal and choroid tissues, and gives a unique view compared to other technologies such as optical coherence tomography (OCT), fundoscopic photography, and manual eye exam. The SMARTCAP project will compare the RHA's images of posterior eye tissues to those generated by technologies currently in use on the ISS. The project will assess whether the device provides additional insights into the eye pathology of idiopathic intracranial hypertension (IIH) patients, a condition on Earth analogous to VIIP. The Annidis technology may allow early detection of a variety of ophthalmological conditions including diseases that affect the retina, choroid, and optic nerve structures such as glaucoma, retinopathy, and disorders of elevated ICP such as IIH.

As a biomedical engineering company with core expertise in photonics, optical systems, software, and eye disease, Annidis has produced what many consider the best device for rapid screening of overall eye health. The Annidis RHA is particularly effective at capturing images for the detection and monitoring of Age-related Macular Degeneration (AMD) and Diabetic Retinopathy (DR) through best-in-class images of the Retinal Pigment Epithelium (RPE) layer and the high differential visibility of retinal and sub-retinal features.

The company's target market is optometric and ophthalmic professionals in North America and China who consider themselves the primary care practitioners for eye health. Annidis has an installed base of approximately 100 units and a foundation of satisfied customers from which to expand. The Annidis mission is to enable clinicians to detect pathologies in eyes as early as possible so patients receive the treatment needed to maintain optimal eyesight.

Web Vision Centers

"SMARTCAP funding enabled Web Vision Centers to identify and evaluate more than 30 companies/technologies and led to the funding of eVision Smart Optics in 2015."

—Bob Main
Founder and President of Web Vision Centers

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Various optical technologies were evaluated by Web Vision Centers on behalf of the space program.

VISION4MARS CHALLENGE

Web Vision Centers received a SMARTCAP-related grant in March 2015, to identify and qualify companies that could meet NASA's need for adjustable power eyeglasses and miniaturized vision testing equipment.

"I was able to fully investigate a significant number of companies whose technologies may help NASA solve several vision related issues. In many cases, I was able to see the technology in action and meet with their technology team and executives to fully evaluate the company's technology and capabilities." —Bob Main, Founder and President of Web Vision Centers

The search for Adjustable Power Eyeglasses led to 12 companies/technologies of which eight were investigated in person. Two companies are now undergoing further testing by NASA's vision experts. A total of 19 companies/technologies with miniaturized vision testing equipment were evaluated. Four of these companies provided a device for evaluation of which three were recommended to Dr. C. Robert Gibson, NASA/JSC Flight Medicine Vision Consultant for further evaluation.

The technologies currently under further investigation by NASA are:

SVOne (Smart Vision Labs)—Technology is a hand-held autorefractor. An evaluation unit has been delivered to Dr. Gibson. A clinical study will begin in the first half of 2016 at NASA's Flight Medicine Optometry Clinic. If successful in the study, the unit will be evaluated for flight certification. It has the potential to solve an important need for better and more frequent vision testing inflight.

SwitchVision (SWITCH)—Technology is quick-change eyeglass lenses for specially designed eyeglass frames. Initial reaction from Dr. Gibson and the astronaut User Panel was extremely positive. Several pairs of the SwitchVision glasses were made for Dr. Gibson and astronauts for evaluation. Dr. Gibson reported that these will be used in-flight in 2016.

Focuss Manual Adjustable Power Eyeglasses (Adlens)—A pair of demo glasses were made for Dr. Gibson. Initial reaction was very positive. NASA engineers are now evaluating the glasses. Materials have been forwarded to NASA for flight certification. If all checks out, this appears to be the solution for having adjustable power glasses to remedy the hyperopic shift issue.

Because this field is evolving rapidly, the existing technology is constantly changing and new companies are developing novel approaches. It will be essential to continue evaluating options to ensure that the best solution for adjustable power eyeglasses and miniaturized vision testing technology is delivered to NASA for the ISS.

For example – manual adjustable power glasses from Adlens Focuss are undergoing evaluation by NASA and it looks very promising. However, company executives anticipate several improvements to the technology that may provide many additional benefits for NASA. These improvements will be rolled out between late 2016 and mid 2018.

ZetrOZ Systems, LLC

"NSBRI's support enabled ZetrOZ to further develop its bio-electronic sustained acoustic medicine delivery platform and to build additional clinical evidence supporting the utilization of sam® for chronic pain management." The company believes that by supporting the development of the next generation system, NSBRI has helped open new market opportunities. ZetrOZ looks forward to future tests of the device to alleviate the back pain experienced by astronauts.

—Dr. George Lewis, Jr.
Founder and President of ZetrOZ

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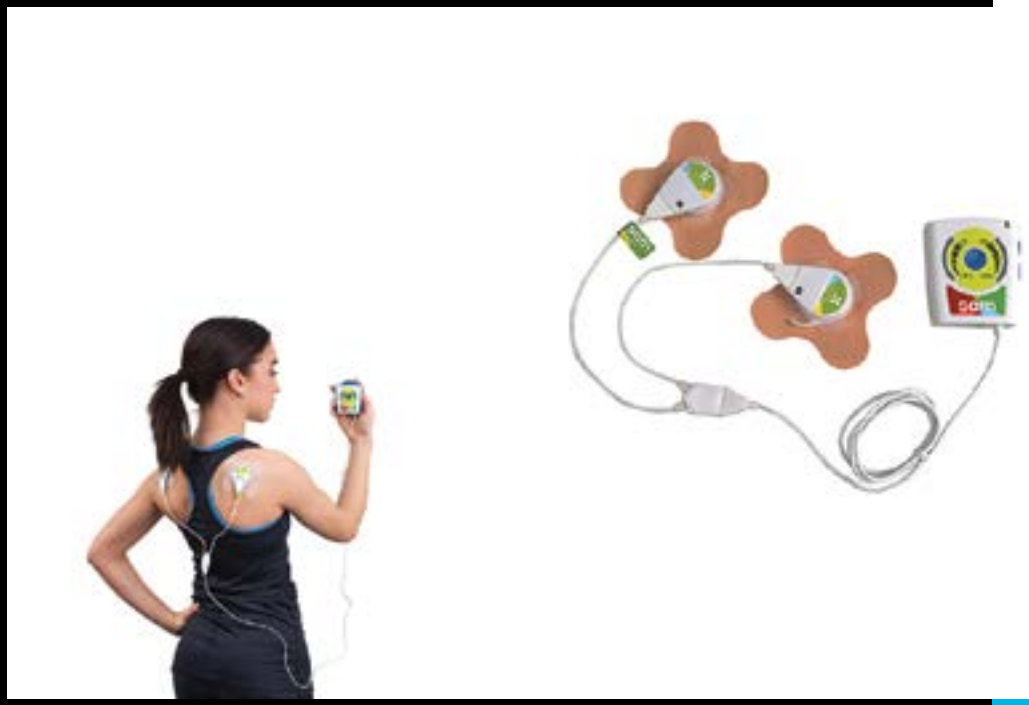

sam® Sport, the only FDA-cleared wearable device for multi-hour continuous therapeutic ultrasound.

Astronauts experience back pain in space and after flight and it has been shown that they exhibit a significant risk of herniated nucleus pulposes.

In August 2014, **ZetrOZ** was awarded a SMARTCAP grant to investigate the potential utility of its sustained acoustic medicine device, sam®, to address the back pain experienced by astronauts both while in space and upon returning to Earth. This bio-regenerative pain management and healing product has been approved by the FDA and is available by prescription to reduce the pain associated with tendon, ligament, or muscle injuries.

ZetrOZ is undergoing two clinical trials one of which is focused on back pain and is supported by the SMARTCAP grant. The prototype for those trials is complete and regulatory testing will be completed in the first half of 2016. Studies will take place at three different sites and data collection is expected to be complete by year end 2016. Phase one of a second trial which focused on arthritis and was supported by National Institutes of Health (NIH), has been completed. The company intends to continue working with the NIH on the second phase of the trial.

"NSBRI's support enabled ZetrOZ to further develop its bio-electronic sustained acoustic medicine delivery platform and to build additional clinical evidence supporting the utilization of sam® for chronic pain management." The company believes that by supporting the development of the next generation system, NSBRI has helped open new market opportunities. ZetrOZ looks forward to future tests of the device to alleviate the back pain experienced by astronauts. —Dr. George Lewis, Jr., Founder and President of ZetrOZ

Since receiving the grant, ZetrOZ and the sam® have been featured on CBS and Fox newscasts and in Triathlete Magazine. sam® also landed the number two spot on Medical Design Technology Magazine's Top Ten list of intriguing new products following the Compamed trade fair in Dusseldorf. Additionally, sam® was awarded the 2015 Medical Device Excellence Award. The company has received several awards from the state of Connecticut as well as gubernatorial support.

According to Dr. Lewis, the company is working to promote the FDA-cleared sam® device for chronic and acute tendonopathy as the product gains traction with professional athletes. Multiple sport teams are using the product to promote recovery including the New England Patriots and the Pittsburgh Penguins. Maggie Steffens, a member of the World Champion U.S. Women's water polo team, recently tweeted about her use of sam® to promote recovery following matches. For professional athletes in the United States, sam® is covered by insurance.

ZetrOZ has made excellent progress integrating sam® for workman's comp insurance and auto insurance recovery strategies and has increased traction with groups that manage care in New York, New Jersey, and Connecticut. Care managers are recommending the ultrasound therapy to speed employee recovery and return to work. Insurance companies have begun to run analytics that will document improvements. ZetrOZ recently held a seminar for key players in the industry at Chelsea Piers in NYC to help educate this segment.

Currently, the company has twelve patents in various stages of prosecution, primarily focused on its ultra-low impedance ultrasound miniaturization technology. The ZetrOZ patent strategy calls for obtaining broader patents in the U.S. and abroad in the future.

Oculogica, Inc.

"Engaging with NSBRI was extremely beneficial for Oculogica" ... "The SMARTCAP grant supported a clinical trial to demonstrate that EyeBox can identify changes in intracranial pressure (ICP) non-invasively. This capability could prove very valuable in space where elevated ICP in astronauts is believed to result in vision impairment."

—Uzma Samadani, M.D., Ph.D.
Co-founder of Oculogica

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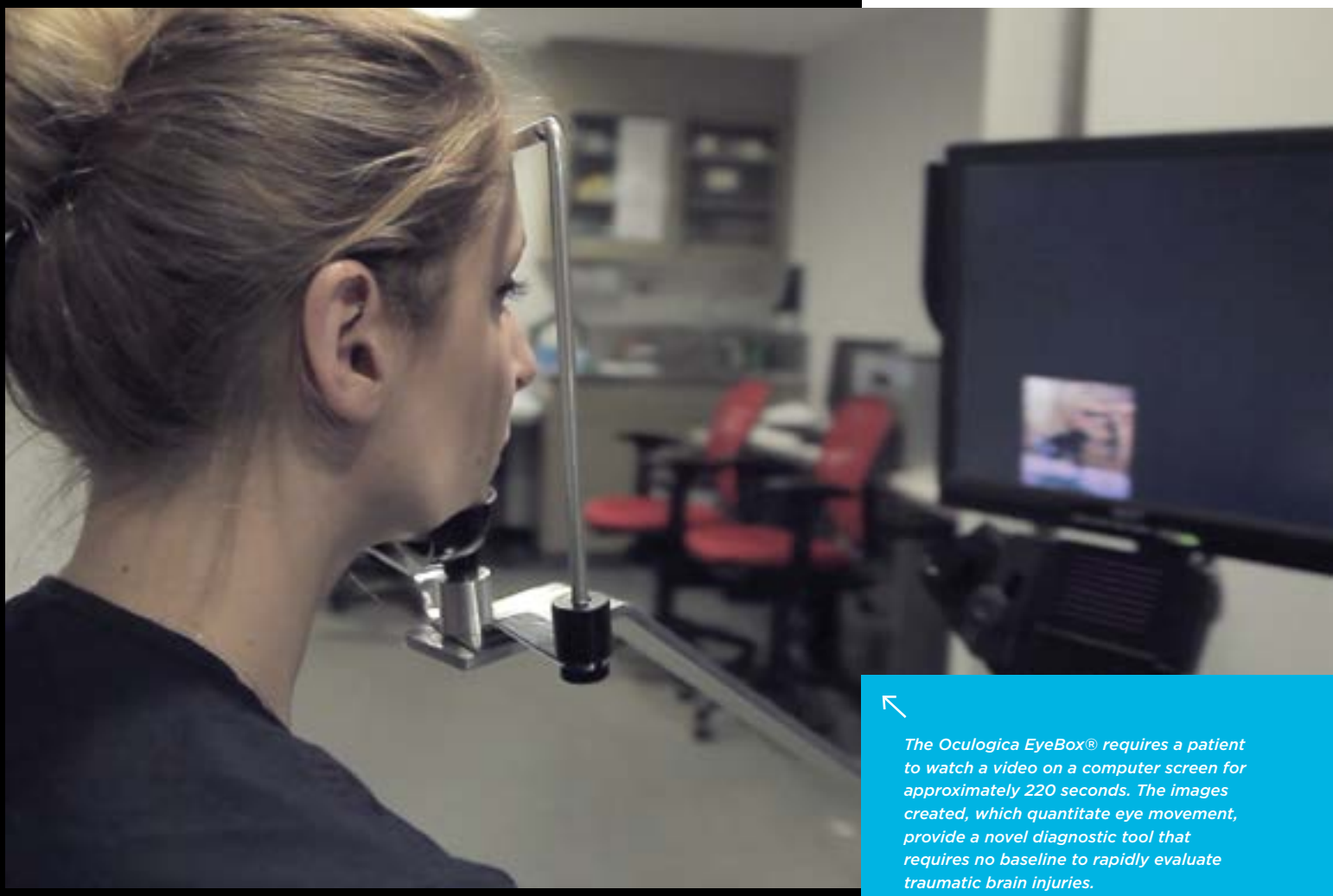

The Oculogica EyeBox® requires a patient to watch a video on a computer screen for approximately 220 seconds. The images created, which quantitate eye movement, provide a novel diagnostic tool that requires no baseline to rapidly evaluate traumatic brain injuries.

Oculogica, Inc., an early stage neurodiagnostic company, received a SMARTCAP grant in April of 2014. The company was founded to capitalize on the discovery that eye tracking might provide a window to brain injuries heretofore invisible to medicine's most sophisticated imaging devices. The eye movements of healthy individuals are tightly coordinated; the eyes of those with a brain injury often do not move in concert. Oculogica's EyeBox™, an eye tracking system that is both simple and elegant, can map and quantify the divergence. The patent pending system can detect abnormalities and identify possible causes in less than four minutes. All patients who are conscious can be evaluated with this system. It is age agnostic, language and literacy agnostic, and, if the test is used on multiple occasions, "learning" does not impact the results.

Dr. Uzma Samadani, M.D., Ph.D., is a co-founder of Oculogica and the Rockswold Kaplan Endowed Chair at Hennepin County Medical Center, the largest trauma center in the Midwest.

"Engaging with NSBRI was extremely beneficial for Oculogica" … "The SMARTCAP grant supported a clinical trial to demonstrate that EyeBox can identify changes in intracranial pressure (ICP) non-invasively. This capability could prove very valuable in space where elevated ICP in astronauts is believed to result in vision impairment." —Uzma Samadani, M.D., Ph.D., Co-founder of Oculogica

The SMARTCAP grant enabled Oculogica to undertake a proof-of-concept trial to determine the correlation between results obtained using traditional, invasive measures of intracranial pressure (ICP) and results from the EyeBox. This trial was completed and the results have been submitted to a peer-reviewed scientific journal. The company expects that the article will be published in 2016. Oculogica has published additional papers that have garnered widespread attention for the potential application of EyeBox to diagnose traumatic brain injury in sports, particularly football.

The grant also enabled Oculogica to purchase another EyeBox to send to researchers at Ft. Campbell in Kentucky, where it was used to evaluate 1,000 soldiers over three weeks. A follow-on, multi-center study, sponsored by the Steven and Alexandra Cohen Veterans Center, is utilizing the device to determine how to improve diagnosis of traumatic brain injuries in soldiers and veterans.

Oculogica intends to develop a cloud-based analytics platform to support a SAAS business model in addition to device sales. The company's initial product is available to the research market now. It anticipates launch of the clinical product in 2017. The company has made significant progress since the grant was awarded and recently signed a term sheet with investors for a series B round that will support the company's regulatory filing in the U.S. and market launch activities.

Oculogica's EyeBox has potential utility on board the International Space Station to non-invasively monitor changes in ICP. On Earth, it may allow physicians to diagnose brain injuries quickly and with far greater certainty and to determine when a patient has sufficiently recovered to return to normal activities, benefiting millions of athletes, trauma victims and soldiers who experience head trauma each year.

Pear Therapeutics, Inc.

"The SMARTCAP grant from NSBRI enabled Pear to undertake the development of its eFormulation product for insomnia well in advance of its initial timeline. Through NSBRI, we have met a number of experts in the insomnia field whose insights aided in development of the product."

—Dr. Corey McCann
Pear Therapeutics CEO

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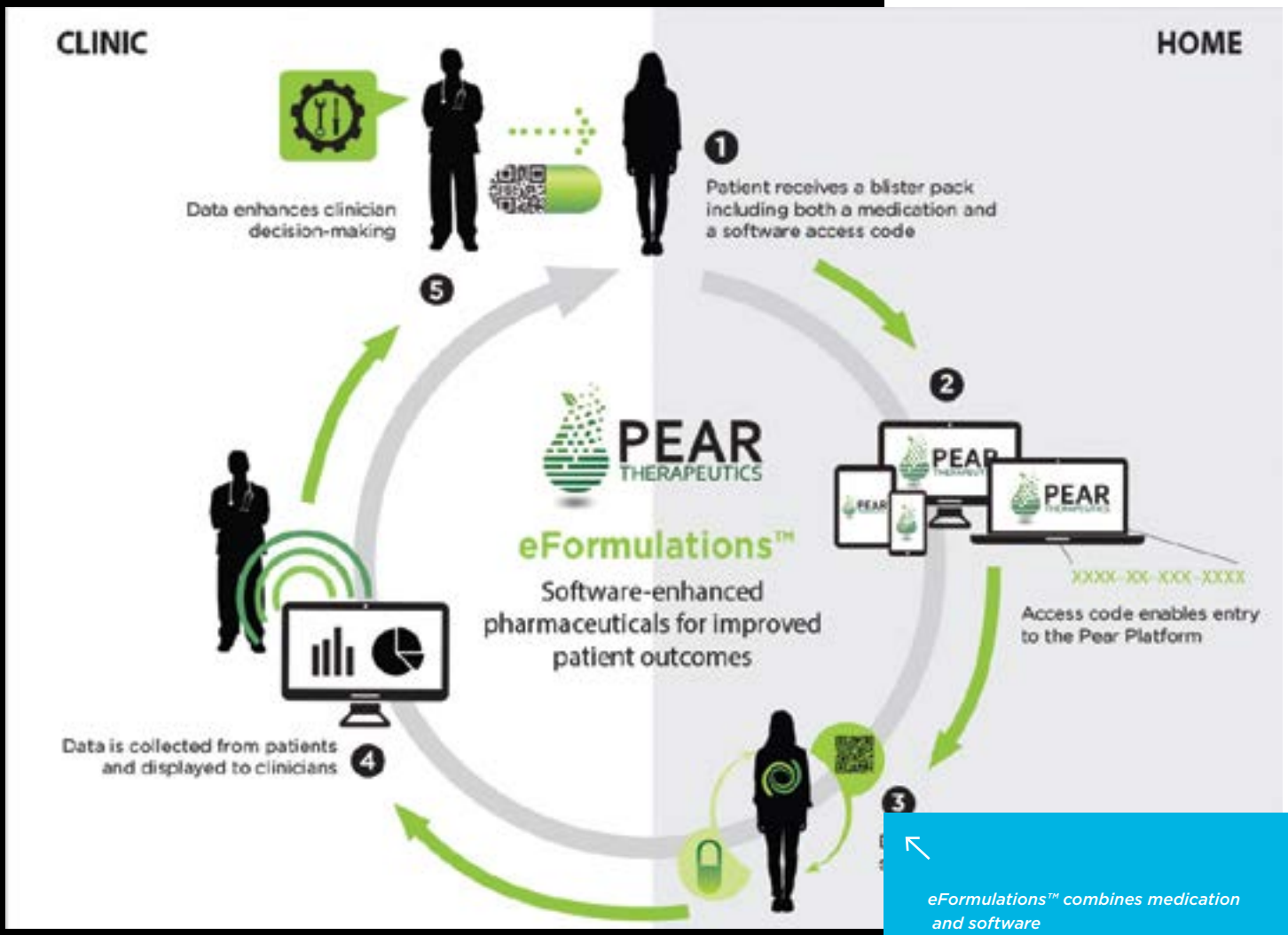

eFormulations™ combines medication and software

In April of 2014, **Pear Therapeutics** was awarded a SMARTCAP grant. Pear's novel platform, eFormulations™, involves pairing a medication of proven efficacy with a digital therapy to yield enhanced therapeutic benefits. These benefits may include reducing the amount of medication needed, enhanced efficacy on approvable endpoints, and enhanced physician efficiency through analysis of the data collected by the digital therapy. Pear's SMARTCAP grant was awarded to develop an eForumulation to help astronauts whose sleep is impacted by multiple day/night cycles in each 24-hour period while in space.

Pear continues its work to perfect the software component which will be combined with zolpidem to address insomnia. The software is drawn from a form of cognitive behavior therapy for insomnia (CBTi) and will incorporate stress reduction techniques, sleep education, and medication dosing guidance.

"The SMARTCAP grant from NSBRI enabled Pear to undertake the development of its eFormulation product for insomnia well in advance of its initial timeline. Through NSBRI, we have met a number of experts in the insomnia field whose insights aided in development of the product." —Dr. Corey McCann, Pear Therapeutics CEO

The grant, in combination with the required matching funding, will allow Pear to go all the way from concept to launch for this product.

In addition to combining pharmaceuticals with digital therapy, Pear developed and recently launched a consumer-targeted platform which pairs supplements with software. This platform, described at www.peartx.com, is the company's first-to-market product. The games and apps have been designed to address sleep, mood, stress, memory, attention, and vision training. They are available at no charge on iTunes and Google Play.

Pear's first clinical use product, reSET™, a proprietary digital therapy for the treatment of substance use disorder, combines a patient-facing smartphone application and a clinician-facing web interface. reSET will be prescribed and packaged with a code unlocking a digital therapy-based software component. The physician/therapist will receive the data generated when a patient uses the software. This data will offer a more complete picture of the patient's status and progress enhancing the physician's ability to refine the treatment algorithm. Pear anticipates filing with the FDA for approval of reSET in the first half of 2016. In addition to insomnia and addiction, Pear's pipeline includes digital therapies for schizophrenia, post-traumatic stress disorder (PTSD), and general anxiety.

In the first quarter of 2016, Pear announced that it closed a round of financing led by 5AM Ventures, Arboretum Ventures, and JAZZ Venture Partners. This round of investment is expected to support the launch of the company's first FDA-approved digital therapy, reSET.

The company operates two facilities, one in Boston with pharmaceutical experts and one in San Francisco with software and technology experts. The company has a team of 20 between the two locations and expects to add employees as it expands its clinical and regulatory efforts for the pharmaceutical combination products.

Cerebrotech Medical Systems, Inc.

"Cerebrotech's Intracranial Fluids Monitor will improve outcomes for both acute stroke and TBI patients by enabling physicians to intervene earlier, before the edema results in secondary brain injury."

—Mitch Levinson

Cerebrotech Medical Systems Co-founder and CEO

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Wireless, battery operated device communicates with the laptop by Bluetooth. The devise was used in a seminal study in Germany that simulated the headward fluid shifts in space with head-down tilt.

Cerebrotech was awarded a SMARTCAP grant in March of 2013 to support development of its Intracranial Fluids Monitor (ICF), a device for non-invasively monitoring changes in the volume of intracranial fluids. Intracranial hypertension is a condition of concern both to NASA and neurologists / neurosurgeons here on Earth. The ICF provides early detection of cerebral events that can result in severe adverse effects in patients suffering from acute stroke or traumatic brain injury (TBI). Outcomes are significantly improved by early intervention. In space, some astronauts experience VIIP (Vision Impairment Intracranial Pressure) Syndrome. A non-invasive method for monitoring intracranial fluids is essential in enhancing NASA's understanding of the syndrome.

Cerebrotech utilized the grant to execute a clinical trial correlating intracranial pressure with intracranial fluid changes in patients in intensive care. NSBRI introduced the company to two neurology and vascular critical care specialists at BCM: Eric Bershad, M.D. and Chethan Venkatasubba Rao, M.B.B.S., who proposed testing the device in a patient population undergoing dialysis. Cerebrotech has developed and used the resulting algorithms in a clinical trial to monitor cerebral edema.

"Cerebrotech's Intracranial Fluids Monitor will improve outcomes for both acute stroke and TBI patients by enabling physicians to intervene earlier, before the edema results in secondary brain injury." —Mitch Levinson, Cerebrotech Medical Systems Co-founder and CEO

Since receiving the grant, Cerebrotech successfully completed four clinical studies, developed three succeeding generations of its Intracranial Fluids Monitor (ICF), doubled its patent portfolio, raised additional funds and grew the team from one full-time employee to twelve. The device has evolved into a battery-powered, wireless platform and will be miniaturized for continuous wear. The device received a CE Mark in August of 2015, and falls under an FDA Class II 510(k) Exemption in the U.S. market. Development of the fifth generation prototype was nearing completion as of February 2016.

The device utilizes Volumetric Integral Phase-shift Spectroscopy (VIPS), a technology invented at University of California, Berkeley, and in-licensed by Cerebrotech. Changes in the electrical properties of brain tissue result from small shifts in fluid volume and can be detected by measuring the frequency response of the phase angle between a transmitter and receiver antenna. It is sufficiently sensitive to differentiate between types of fluids, i.e., blood and cerebrospinal fluid.

NSBRI also introduced the company to Jose Ignacio Suarez, M.D., Section Head—Vascular Neurology and Neurocritical Care at Baylor College of Medicine. Dr. Suarez subsequently joined Cerebrotech's Scientific Advisory Board. According to Levinson, his input has been extremely valuable in the evaluation of clinical models for the device.

Although the SMARTCAP grant work was completed in 2014, Cerebrotech continues its interest in the visual impairment and intracranial pressure (VIIP) syndrome experienced by astronauts and participated in a NSBRI-sponsored VIIP study conducted by the Institute of Aerospace Medicine at the German Aerospace Center in Cologne, Germany in June of 2015. This study explored intracranial fluid shifts that can occur in a zero-gravity environment, and in the harsh atmospheric environment onboard the International Space Station. The ICF Monitor can eventually be used to better understand intracranial fluid control during space travel.

ACell, Inc.

"The SMARTCAP grant enabled our scientific team to fast track the development of the gel formulation and to develop a novel wound healing model in which to test the gel. We are confident that the gel formulation developed in partnership with NSBRI will one day be a powerful tool for treating torturous wounds."

—Thomas Gilbert
Chief Science Officer

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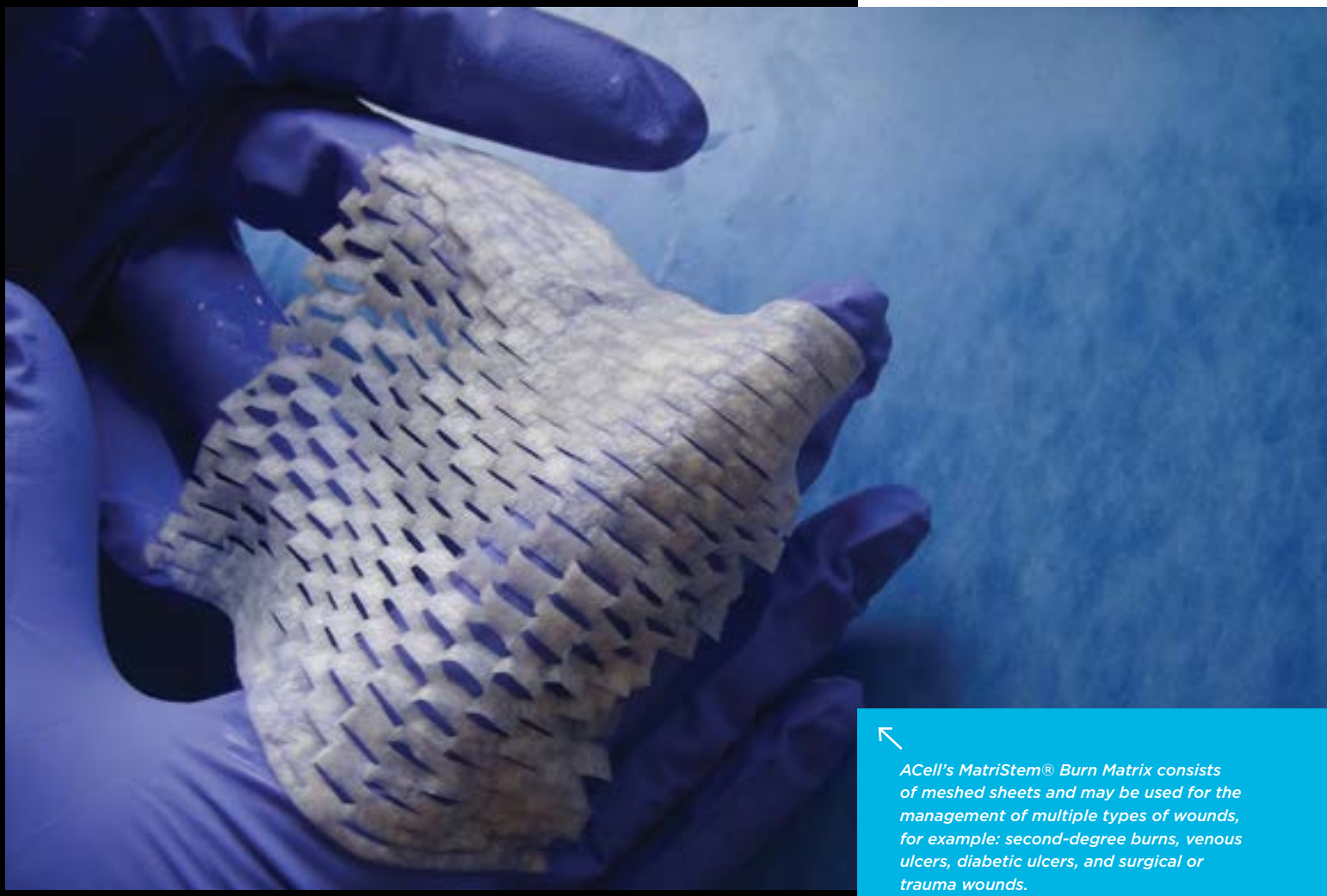

ACell's MatriStem® Burn Matrix consists of meshed sheets and may be used for the management of multiple types of wounds, for example: second-degree burns, venous ulcers, diabetic ulcers, and surgical or trauma wounds.

ACell, a leading regenerative medicine company, received a SMARTCAP grant in May 2012. ACell develops and manufactures products designed to facilitate the body's ability to repair and remodel tissue.

Astronauts experience abrasions and skin lacerations that do not heal as quickly in space where the body's immune system is somewhat compromised. In addition, exposure to radiation may cause skin damage. Products that can enhance wound and skin healing would be very useful in spaceflight.

ACell used the SMARTCAP grant to develop a gel-based formulation of its MatriStem® line of wound dressings. The gel formulation will be more appropriate for use in the microgravity environment than existing powder and sheet formulations. On Earth, a gel product will allow doctors to address a number of difficult-to-treat wounds and open up new market opportunities for the company.

"The SMARTCAP grant enabled our scientific team to fast track the development of the gel formulation and to develop a novel wound healing model in which to test the gel. We are confident that the gel formulation developed in partnership with NSBRI will one day be a powerful tool for treating torturous wounds." —Thomas Gilbert, Chief Science Officer

In August 2014, United States Patent 8802436 titled "Methods of manufacturing bioactive gels from extracellular matrix material" was issued to ACell. The work which led to the patent was funded in part by the SMARTCAP grant and focused on evolving ACell's marketed wound dressings (MatriStem®) into a gel-based formulation.

ACell's proprietary urinary bladder matrix (UBM) technology platform is based on an extracellular matrix, or ECM, derived from porcine urinary bladder. The UBM includes an intact epithelial basement membrane surface and lamina propria opposing surface. ACell maintains a proprietary method of processing this raw material. The resulting products, named MatriStem, possess characteristics that facilitate the body's own regenerative capabilities and help restore normal site-appropriate tissue. Three clinical studies are currently underway including a post-market randomized controlled trial comparing MatriStem to Dermagraft® for treatment of diabetic foot ulcers (DFU) that failed to adequately heal following initial standard of care therapy.

The company also was issued U.S. Patent number 8,975,075 in March 2015. The patent title is "Hemostatic Device" and describes a hemostatic device, method of making, and method of using for internal and external applications to wounds in the body of a patient to induce hemostasis at an anatomical site. The gel formulation is covered within the patent for its hemostatic properties.

Entrinsic Health Solutions, LLC

"Our company would never have been able to complete the necessary and critical first steps in assessing the importance of Dr. Vidyasagar's work and its translation from space travel to supportive care therapy for cancer patients around the world"...."The NSBRI-supported work laid the foundation for what we believe will be a groundbreaking therapy to address many of today's gastrointestinal health issues."

—Stephen Gatto

Entrinsic Health Solutions, LLC Chairman & CEO

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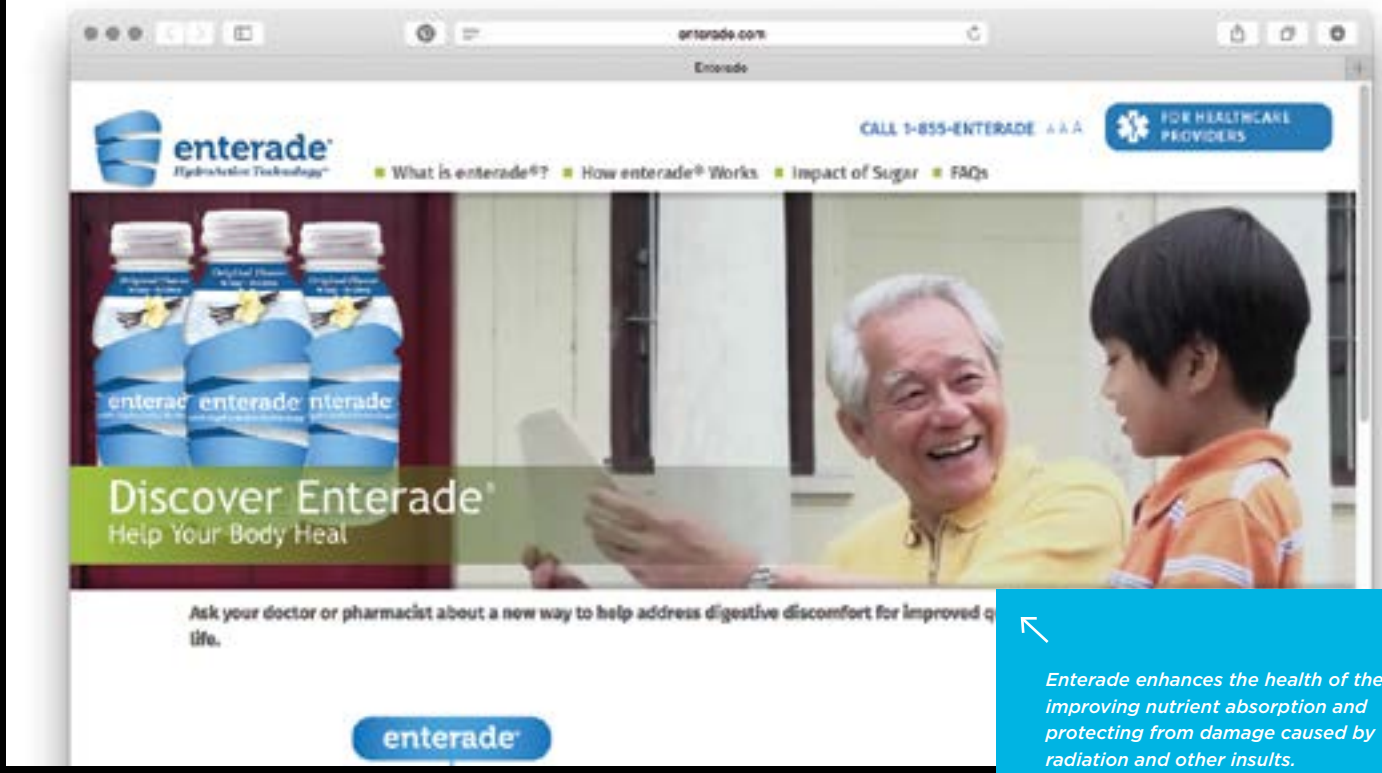

Enterade enhances the health of the gut, improving nutrient absorption and protecting from damage caused by radiation and other insults.

In 2012, **Entrinsic Health Solutions LLC, (EHS)** received a SMARTCAP grant to study the performance of its novel, patented, glucose-free rehydration and gastrointestinal health solution, enterade®, a medical food that may help mitigate radiation-induced enteritis in astronauts and cancer patients. The grant funded a study of mice exposed to proton irradiation and treated with enterade or odansetron, the current standard of care. The team of scientists in the Radiation Oncology Department at the University of Florida, led by Dr. Sadasivan Vidyasagar, found that enterade-treated mice experienced less nausea, less weight loss, had enhanced fluid uptake and improved survival when compared to mice treated with odansetron.

Dr. Vidyasagar validated that traditional glucose-enabled hydration mechanisms break down under these conditions. This breakdown can diminish the body's ability to remain hydrated, resulting in increasingly negative health outcomes. His ongoing research uncovered radically more effective transporters for hydrating and nourishing the body—a select group of amino acids. The result of this research is a patented technology platform, Amino Acid Coupled Technology™ (A2CT). A2CT uses a select subset of amino acids to facilitate the active transport of electrolytes to achieve whole-body hydration and superior nutrient absorption.

This work served as a principal validation of enterade's effects in the gut and has served as a foundation for future research.

"Enterade would never have been able to complete the necessary and critical first steps in assessing the importance of Dr. Vidyasagar's work and its translation from space travel to supportive care therapy for cancer patients around the world"…."The NSBRI-supported work laid the foundation for what we believe will be a groundbreaking therapy to address many of today's gastrointestinal health issues." —Stephen Gatto, Entrinsic Health Solutions, LLC Chairman & CEO

Over the past year, EHS has undertaken clinical trials in partnership with:

- 21st Century Oncology: a randomized open-label trial to evaluate enterade's ability to maintain bowel regularity in 50 patients experiencing gastrointestinal toxicity due to radiation therapy and/or chemotherapy.
- 21st Century Oncology: a 100 patient sample study assessing the efficacy of enterade for mucositis, dehydration, nausea, and diarrhea, expected to conclude in the third quarter of 2016.
- The U.S. Army: randomized study on 44 participants comparing enterade with a commercial oral rehydration solution and a sports drink containing carbohydrates. The study will evaluate three endpoints: rate of hydration, volume of fluid retained, and electrolyte shifts into the various fluid compartments. The pilot phase is complete. Enterade (at 50% and 100%) provided faster fluid uptake and improved fluid retention. This study is expected to conclude by Q2 of 2016.

In addition to ameliorating the GI impact of radiation and chemotherapy, EHS believes the company's underlying Amino Acid Coupled Technology™ (A2CT) may be effective in addressing conditions such as IBD (Crohn's and colitis), IBS, celiac, and diarrhea caused by disease.

The company is commercializing enterade as a medical food product to address unwanted side effects associated with chemo and radiation therapy treatment. Enterade is available through the company website: www.enterade.com. Medical foods should be used under the supervision of a health professional.

Pulsar Informatics, Inc.

"The SMARTCAP grant from NSBRI was a critical catalyst for translating the PVT we developed for the ISS to the Earth market. The SleepFit app opened new market opportunities for Pulsar with its speed and ease of use."

—Daniel Mollicone, Ph.D.
Pulsar Informatics President

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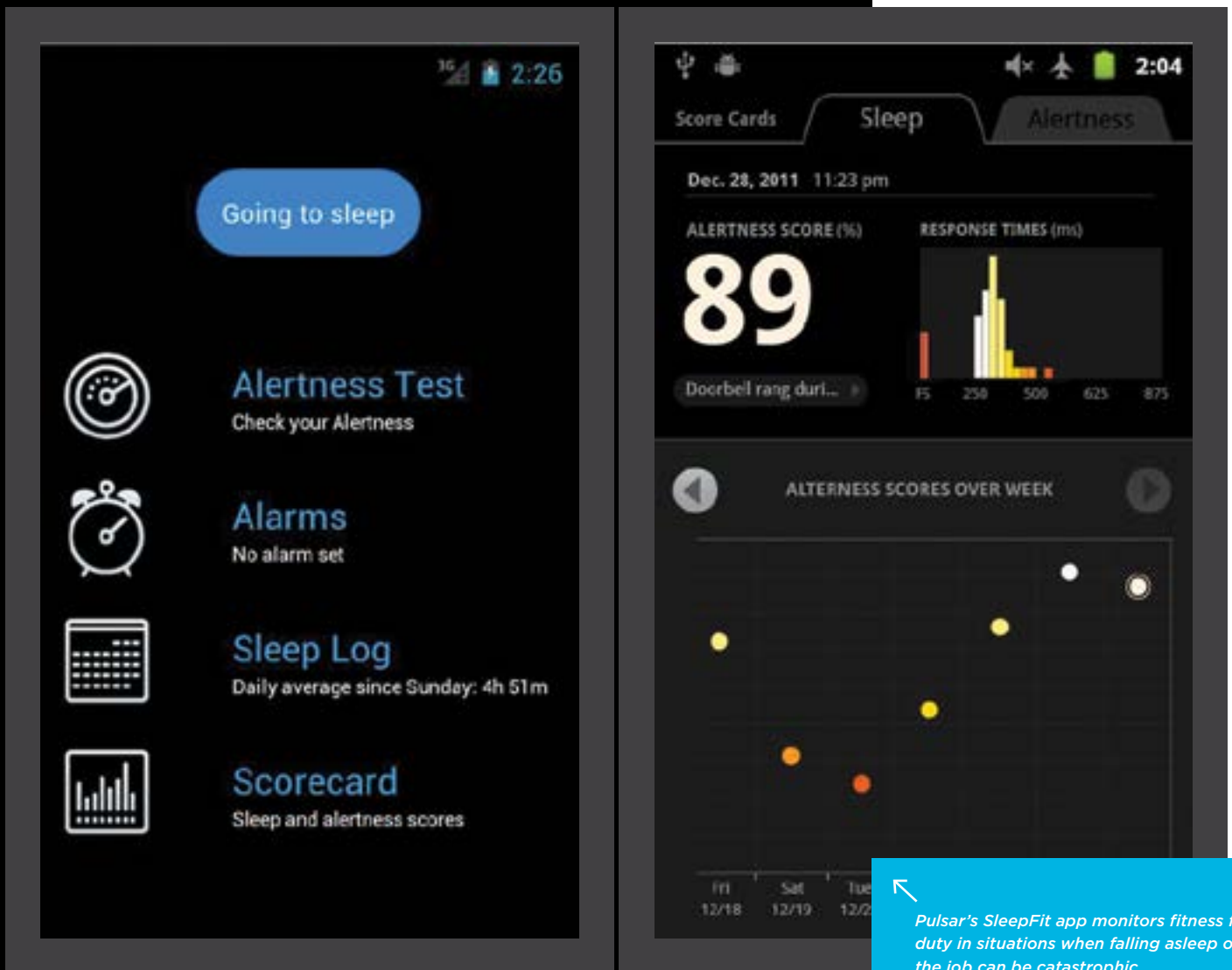

Pulsar's SleepFit app monitors fitness for duty in situations when falling asleep on the job can be catastrophic.

Pulsar Informatics, Inc. received the first ever SMARTCAP grant in the fall of 2011. It used the grant to develop SleepFit, a smartphone-based, three-minute Psychomotor Vigilance Test (PVT). The PVT has been in use on the International Space Station (ISS) for more than five years to help assess an astronaut's level of fatigue prior to mission-critical assignments.

SleepFit was used in a field study sponsored by the Federal Motor Carrier Safety Administration (FMCSA) to evaluate Hours of Service (HOS) regulations for commercial truck drivers. Pulsar contributed to the study, which assessed fatigue in long haul truck drivers. The results were reported in January 2014, in the FMCSA Hours of Service Study.

"The SMARTCAP grant from NSBRI was a critical catalyst for translating the PVT we developed for the ISS to the Earth market. The SleepFit app opened new market opportunities for Pulsar with its speed and ease of use." —Daniel Mollicone, Ph.D. Pulsar Informatics President

This study brought into focus the importance of fatigue planning and a gap in products for the commercial motor vehicle market related to tracking and mitigating driver fatigue. There is a need for route planning software that helps drivers and dispatchers track fatigue and plan drives in a way that optimizes constraints related to load assignments, hours-of-service regulations, fatigue, traffic, and rest stop availability. Pulsar's technology combines fatigue assessment and mathematical models, providing the perfect platform to address this need. The product, called Trucking Fatigue Meter, will be available for purchase as an add-on to route planning and electronic log solutions through industry leading route-planning products.

Pulsar executed a contract with the Department of Defense Health Program to develop a tool that will be used as part of the Performance Triad health initiative led by the Surgeon General of the Army. The performance triad focuses on three elements of health: nutrition, exercise, and sleep. Pulsar will evolve SleepFit to serve as a personalized sleep health coach for participants, enabling them to monitor and improve their sleep hygiene.

Since receiving the inaugural SMARTCAP grant, Pulsar has expanded its Fatigue Risk Management technology offerings to provide a comprehensive suite of products and services to mitigate fatigue risk. Pulsar now serves many Fortune 500 companies including some of the most recognized brands in the petroleum, manufacturing, finance, and retail industries.

As it looks to the future, which may include its first capital raise with outside investors, Pulsar is evaluating the strategic and tactical options available to drive growth for the company.

Finally, astronauts and ground control personnel may track their own fitness for duty through the use of this app on their personal devices.

NSBRI DEPUTY CHIEF SCIENTIST AND INDUSTRY FORUM LEAD:

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As Deputy Chief Scientist, Dr. Donoviel oversees the diverse portfolio of science and technology research and development projects at NSBRI that address the challenges faced by humans in space. She leads the NSBRI Industry Forum and the SMARTCAP grant program that funds and mentors small startup companies. Dr. Donoviel is Director of the Laboratory for Biomedical Innovations where she evaluates new technologies and countermeasures that have the potential to transform medical care in space and on Earth.

A published scientist herself, Dr. Donoviel interfaces with NASA at many levels ensuring programmatic alignment with the highest risks to human space flight while safeguarding scientific excellence. She is the recipient of several NASA Human Research Program awards, and serves on advisory and review boards in the space life sciences both nationally and internationally.

Dr. Donoviel is an Assistant Professor in the Department of Pharmacology and a member of the Center for Space Medicine at Baylor College of Medicine, lecturing and mentoring medical students in space biomedical research.

Before joining NSBRI, Dr. Donoviel was engaged in pharmaceutical drug discovery at Lexicon Pharmaceuticals, a biotechnology company based in The Woodlands, Texas. For eight years, she managed a metabolism research group that identified and validated targets for drug discovery by using in-vivo functional genomics technology, and developed small molecule compounds, antibody, and protein therapeutics against these validated targets.

Dr. Donoviel received her Bachelor of Science from the University of California, San Diego and her Doctorate in Biochemistry from the University of Washington. She was awarded a Human Frontiers Fellowship to carry out postdoctoral work at the Samuel Lunenfeld Research Institute in Toronto, Ontario, Canada where she developed genetically-modified mouse models for Alzheimer's Disease.

NSBRI INDUSTRY FORUM CONSULTANT AND SMARTCAP CO-ADMINISTRATOR:

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Since 2005, Ms. Fleming has been an independent consultant, working with multiple companies across many facets of the biopharmaceutical industry. She began serving as a consultant to the National Space Biomedical Research Institute (NSBRI) in 2010, preparing reports on the commercialization potential of multiple technologies funded by the institute. In 2011, she worked closely with Dr. Dorit Donoviel on the design, initiation, and operation of the Space Medical and Related Technologies Commercialization Assistance Program (SMARTCAP). Since inception, this program has awarded grants to 12 small companies developing products that have the potential to reduce risks to human health during space exploration.

Ms. Fleming has worked in the biopharmaceutical industry for more than 25 years in a variety of roles, focused primarily in business development, strategy, and new product development. She has worked for both large and small companies and enjoys the unique challenges presented by early stage companies.

Ms. Fleming has served as an advisor to several early stage companies and as acting Chief Operating Officer for QD-Quality and Training Solutions, Inc. and Alchemy Ionics, Inc. She also serves as a mentor to the Houston Technology Center's Life Sciences Acceleration Committee. Ms. Fleming worked with several colleagues to found Angels in The Woods, a nascent angel investment network. Ms. Fleming holds a Bachelor of Science degree from the University of Florida and a Master in Business Administration from Harvard University.

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Photo courtesy of NASA

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