



Profiles of Prosperity

How NIH-Supported Research Is Fueling Private Sector Growth and Innovation



United for Medical Research

ADVOCATES FOR NIH AND THE LIFE SCIENCES CENTURY

Introduction

The National Institutes of Health (NIH) is the center of an innovation ecosystem that demonstrates how smart federal investment can serve to fuel private sector development and economic activity. While the primary mission of NIH is to fund research to improve the health of our nation—a mission it has successfully executed for more than a century—federal support of medical research at research institutions in all 50 states has also catalyzed growth, created jobs and established the United States as a global leader in the life sciences.

This isn't merely a hypothesis; it's an economic fact. NIH-supported research added \$69 billion to our GDP and supported 7 million jobs in 2011 alone. But the economic reality is about more than just numbers—stories involving lifesaving breakthroughs and real-world products and companies can be found all over the country.

Transforming an Idea into a Thriving Industry

“The wealth of the nation comes from research and then innovation, which is the process of bringing research to market.” — Jonathan Rothberg, Founder of Ion Torrent

The biomedical innovation ecosystem is populated with dynamic partnerships between NIH, research scientists at universities and private sector companies, all working together to produce lifesaving products and fuel economic growth. The raw material for economic growth begins with a partnership between NIH and researchers blazing new trails in the life sciences, working at universities and research institutions nationwide. NIH funding provides these scientists and their labs with the support they need to seek the answers to fundamental questions. Translating those answers into practical applications that improve society’s ability to heal the injured, cure the sick and prevent health problems before they happen requires collaboration between basic scientists, clinical researchers and life sciences companies. Out of that symbiotic relationship comes new industries, job creation and economic activity.

The NIH plays a unique and essential role at the center of the biomedical innovation ecosystem. NIH-funded basic, high-risk and pre-commercial research is the foundation for medical advancements and technology development. The federal investment is amplified and enhanced by the private sector, which provides additional capital, performs further research, testing and development, links research in one area to discoveries in another, creates new research technologies and enables new methods of discovery, develops manufacturing capacity and expertise, assumes regulatory and reimbursement risks, and in many other ways shepherds NIH discoveries from the bench to the bedside.

The private sector participants in the ecosystem are diverse and interdependent. Examples include:

- The pharmaceutical and biotechnology industry, which builds on federally funded research to develop the next generation of drugs, devices and diagnostics to treat, cure and prevent disease;
- The research tools and technologies sector, which provides critical equipment and technologies used for NIH-funded research;
- Start-up and spin-off companies, resulting from university or non-profit technology transfer activities that seek to turn research into marketable applications and commercial ventures.

As Peter Abair of Massachusetts Biotechnology Council said, “We consider the NIH the very foundation for the industry. When we talk about the industry and ultimately life-saving products, it starts really with the NIH and the kind of basic research it’s supporting.”

Although it is too simplistic to say that NIH-funded discoveries leave off where private sector development begins, it is true that close examination of the roots of many successful biotechnology, pharmaceutical, research tool and startup companies leads back to NIH. Whether it is individual

scientists whose breakthrough discoveries lead to a licensable technology at a university or NIH small business research grants sought by start-up and spin-off companies or industry professionals trained via NIH-funded career development awards, federal funding of medical research underlies the U.S. life sciences industry.

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In this report, United for Medical Research examines just a few of those success stories: innovative life science companies that evolved from research discoveries made with NIH support. They range from freshly minted firms in the early stages of testing to biotech giants that produce crucial medical devices with the aid of thousands of employees.

Radiation with a Twist

How TomoTherapy is helping cancer patients and creating manufacturing jobs



Today the company, which emerged from NIH-funded discoveries, employs 1,100 people worldwide, and its fiscal year 2012 revenue exceeded \$400 million. They've produced 500 machines, 60 percent of which are sold overseas. And they still make every device in Wisconsin.



A patient undergoes a tomotherapy scan.
Photo credit: TomoTherapy

Madison, WI and Sunnyvale, CA: Tomotherapy changed how cancer is treated with radiation—permanently, everywhere—vastly reducing the number of side effects that patients suffer. And it started with NIH support.

In the early 1990s, radiation treatments for cancer meant firing large beams at tumors from several directions at once. The beams reduced the cancers, but often damaged non-cancerous organs nearby.

Thomas Mackie and his colleagues at the University of Wisconsin had been gnawing on this problem for years, largely supported by NIH grants. They'd already settled on the idea of tomotherapy, which attacked a tumor in thin slices instead of all at once, but technical problems stymied their progress. In particular, if a patient moved during treatment, the thin slices might overlap or underlap, making the treatments uneven.

Though Mackie had been a radiotherapy researcher his whole career, he didn't have his eureka moment until 1991. Mackie was sitting in his office in Madison, reading about how CT scanners rotated around the patient in a spiral. He sat up straight: rotating the beam of radiation would "blur the treatment" thus avoiding the problem of unevenness.

It was the critical breakthrough.

"We hadn't even filed patents on our ideas for tomotherapy, and we started calling it helical tomotherapy," Mackie said.

Development took another ten years, in which Mackie and his colleague Paul Reckwerdt used both NIH funding and money from General Electric to continue refining the technology. In 1997, they founded TomoTherapy Inc. to raise venture capital.

The TomoTherapy machine went through numerous changes in preparation for the market. Mackie said he learned a lot about himself, particularly that he's good at marketing and development but terrible at finance and sales.

"That's why we need the business guys," he said.

In 2002, TomoTherapy treated its first patient. As the company ramped up production, its executives realized that they weren't just in biotech—they were also in manufacturing. Wisconsin, as it happens, is one of the manufacturing capitals of the world, but due to the long decline of heavy industry in the area, a lot of skilled manufacturing workers were looking for jobs. TomoTherapy took them in and established a production base in Madison.

By 2007, TomoTherapy's machines had proved so effective they were being used widely in oncologists' practices. Competitors began producing similar products. In the face of competition and the financial meltdown a year later, TomoTherapy merged with Accuray for \$277 million.

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Behind the Scenes

How Pure Protein LLC underpins life-saving advances and a multi-billion dollar industry



HOW NIH FUNDING FEEDS THE ECOSYSTEM

The vast majority of the NIH budget—nearly 90 percent—is granted to scientists, universities and private companies through a competitive, merit-based process. Most NIH grants take the form of research project grants, given to individual scientists or teams of scientists whose ideas undergo a rigorous review by other scientists in the field. The benefits of the discoveries made by these scientists are returned to the public through the process of technology transfer. The intellectual property is protected through patents, commercialized through relationships with existing companies or through creation of a start-up or spin-off, and ultimately generates a product or industry. This process not only leads to advances in technology or medicine, but also creates jobs, local economic development and revenue to support further research and development.

NIH also directly supports small businesses, particularly start-ups and spin-offs resulting from federally funded research discoveries, through programs such as the Small Business Innovation Research (SBIR) grants. The SBIR program is designed to provide seed funding to small businesses to perform early-stage proof of concept studies. This program has been very successful in providing critical funding for small companies to test promising but early-stage discoveries in order to advance such projects to a point where venture capital and other private investments become involved. Companies compete for these grants, so only the best ideas get funded.

In addition to direct research support, NIH plays a critical role in supporting the training and career development of the biomedical research workforce. From graduate training grants to early career awards and research funding for individual scientists, NIH provides crucial support for biomedical researchers, including physician scientists, which develops the human capital driving research technology development and economic innovation.

Austin, TX and Oklahoma City, OK: University of Oklahoma researcher William Hildebrand knew he had a commercial opportunity when companies started flying him around the country to discuss his research in the late 1990s. If companies were so interested in his studies, maybe they would pay him to do the work.

Hildebrand's research, which has been supported largely by NIH, focuses on the body's "alarm system," known to be initiated as human leukocyte antigens (HLA). When the human body discovers a virus or cancer cell gone rogue, it uses these HLA cells to alert the immune system to get to work. But each person has his or her own type of alarm system, which means researchers studying particular diseases or vaccines need a wide variety of HLAs as tools to test their ideas. Hildebrand's company, Pure Protein, produces HLAs and provides technical support.

Founded in 1999, the company often partners with larger corporations—one recent partner had a \$35 billion market capitalization—to produce HLAs and provide support for their research teams. Hildebrand's company has been running for 15 years as a hybrid between his university lab and his company lab, depending on the needs of the organization and funding levels. He employs 25 people between the two labs and has found that working with for-profit companies has honed his research, refining experimental design to better address the questions raised through the process of developing medical products.

Among its projects, Pure Protein is working with a partner to improve the health of organ recipients. Unless a person gets a match from an identical twin, his or her immune system is likely to attack the new organ. Traditional therapy relies on immunosuppressants, which can severely restrict a transplant recipient's ability to go into public, for fear of illness.

With good HLA matching, however, Hildebrand thinks he can determine which antibody is attacking the organ and filter that specific antibody out of the bloodstream, while leaving the rest of the immune system intact. If successful, the patients would have a far greater ability to live normal lives, and the transplanted organs would have much longer working lives.

Sequencing Sensation

One scientist's quest to improve DNA sequencing for health and the economy

New Haven, CT, Guilford, CT, Branford, CT and San Francisco, CA: Throughout his career, Jonathan Rothberg has applied the technology of the dot-com boom to the process of gene sequencing, in order to enhance research and health. In the process, he has demonstrated how relatively small NIH-supported projects can, in the hands of a scientist-entrepreneur, prompt substantial private investments that result in major technology advances and job creation.

Rothberg started his first company in 1991, right after he completed his NIH-supported doctorate in biochemistry at Yale. He secured an NIH grant to develop a standardized gene sequencing process, using robots to save on repetitive labor and lowering the cost of an extremely pricey process. Able to demonstrate the technology, he attracted private funding and built the company CuraGen out of his basement.

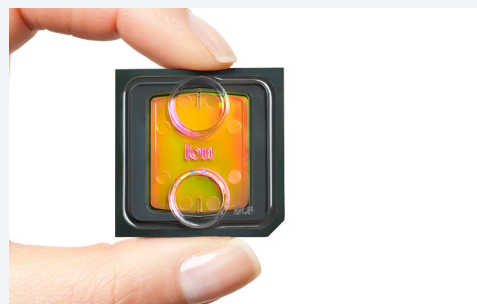
Ten years later, Rothberg had a new inspiration to improve DNA sequencing, this time using light to identify the different nucleotides along the classic double helix. He formed a new company, 454 Life Sciences, and eventually sequenced the genome of James Watson, the Nobel prize winning co-discoverer of the structure of DNA. At their combined peaks, CuraGen and 454 together employed nearly 1,000 people.

Using capital from those first two companies and the knowledge he developed in devising those technologies, Rothberg brought genetic sequencing to the digital age in 2007. He realized that he could use the chemical signals produced by a strand of DNA and link it to a silicon computer chip. The process radically accelerated gene sequencing and dramatically reduced its cost.

Rothberg sold his latest venture, Ion Torrent, to Life Technologies in 2010. The Ion division currently employs approximately 350 people.

The NIH-supported advances in sequencing that Rothberg devised and matured have profoundly changed our understanding of cancer, and the nature of cancer research and treatment today.

This modern sequencing played a critical role in rapidly identifying the source of a deadly food-borne *E. coli* outbreak that swept across Europe in 2012, saving countless lives. And today sequencing is used in clinical research to identify undiagnosed diseases and uncover new treatments pathways for patients across the U.S., giving families answers and hope.



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Above, a proton semiconductor chip on which DNA sequencing takes place. Below, Jonathan Rothberg holds a silicon wafer from which an Ion computer chip is cut. Photo Credit: Ion Torrent

Taking a Deep Breath

How Cureveda is fighting a leading killer with science



Baltimore, MD: Chronic obstructive pulmonary disorder (COPD) is the third leading cause of death in the United States, affecting more than 15 million Americans. Worldwide, that number soars to 210 million patients. Current treatments of COPD aim at relieving the symptoms of the disease, rather than trying to cure the underlying illness.

Dr. Shyam Biswal, co-founder of Cureveda, is a NIH-funded researcher at Johns Hopkins University Bloomberg School of Public Health. Dr. Biswal has been working with his scientific partners to understand how COPD works at the molecular level and identify targets for drug therapies that can treat COPD at its

root cause. These therapeutic targets may prove useful for other chronic respiratory conditions as well, including asthma and emphysema.

NIH funding advanced the initial research and development to the point of preclinical proof-of-concept studies. Now Cureveda is working to bring those ideas to fruition, recently announcing a collaboration with pharmaceutical giant GlaxoSmithKline to further the hunt for promising new therapies. Maryland Governor Martin O'Malley has highlighted the company as an example of positive economic change in the state's life science industry.

The NIH Medical Innovation Ecosystem

Over the past 30 years, the U.S. has become the world leader in biomedical research because of its unique innovation ecosystem. Read below to learn how funding for the National Institutes of Health strengthens our nation's health and economy from research laboratories to private industry to patients — the ultimate beneficiaries of medical research.

The Biotechnology and Pharmaceutical Industries

These industries build upon federally-funded scientific research to develop the next generation of drugs and devices to treat and cure disease.

The world market for the biopharmaceutical industry is greater than **\$140 billion**, with more than **1 million employees** in the U.S. alone.



Research Tools and Technologies Sector

Providers of research tools and technologies develop critical equipment used for NIH-funded research, as well as private drug and diagnostic development.

The life sciences tools industry, with an **annual revenue of over \$42 billion**, employs hundreds of thousands of workers at facilities across the country, making everything from test tubes to gene sequencers.



NIH:

The largest funder of biomedical research in the world, supporting the work of **135 Nobel Prize laureates**. The NIH community consists of more than 330,000 scientists and research personnel at over **2,500 research institutions** across all 50 states.



Research Universities

Federally funded research conducted at these universities provides the foundation for private sector development of new drugs, technologies and treatments that aid our nation's health.

56% of basic scientific research in the U.S. takes place at research universities.

Start-Ups and Spin-Offs

Universities often have offices of technology transfer that seek to turn research into **marketable applications and commercial ventures**.

These companies continue to advance discoveries in science while providing a growing sector of entrepreneurs interested in pursuing research.

Count on this Technology

How Flow Cytometry has transformed medical research and disease monitoring



A THREAT TO OUR ECONOMIC FUTURE

In 2012 alone, NIH funding supported more than 402,000 jobs and \$57.8 billion in economic output nationwide.

Yet since 2003, NIH funding has been falling as a share of GDP and in inflation-adjusted dollars. Sequestration exacerbated that decline, lopping off \$1.1 billion, or 5.1 percent, from NIH's awards budget. The net result will ultimately be the loss of 20,500 jobs and \$3 billion in economic activity.

That kind of loss doesn't appear instantly in job reports or measures of GDP. Advances in life science take years, and even decades, to bear fruit, and sometimes the breakthroughs don't stand alone.

San Diego and San Jose, CA: One of the classic examples of NIH investment helping to transform medicine is in flow cytometry, a technology used to measure specific cell types and characteristics in blood, bone marrow, body fluids and tissues in order to unravel the mysteries of cellular biology and our immune system. Many decades ago, with support from NIH, a Stanford University researcher named Len Herzenberg developed a machine to count and sort human cells at what then was the incredible speed of 1,000 per second. Early private investment from BD—the 116-year-old global medical technology company—and later investment from others, has turned flow cytometry instruments and associated reagents into an indispensable tool used by hospital and university laboratories around the world.

Long after the first NIH grant, U.S. companies continue to lead the world in this technology. BD, Beckman Coulter and other companies employ

hundreds of scientists and engineers who continue to design and manufacture flow cytometers that are better, smaller and faster. We can now count and sort cells at the incredible speed of 50,000 per second. Flow cytometry has enabled progress in fighting a range of diseases, including HIV/AIDS, leukemia and lymphoma, as well as improving life-saving treatments like bone marrow transplantation. It has become so central to medical care that more than 100,000 scientific papers have referred to its use.

One new San Diego company, NanoCellect, is building on cell sorting discoveries by an NIH-funded University of California researcher named Yuwaha Loa. With the help of an NIH Small Business Innovation Research grant, the company has devised a sorter that is using microfluidics to analyze and sort cells for research in stem cells, cancer and immunology.

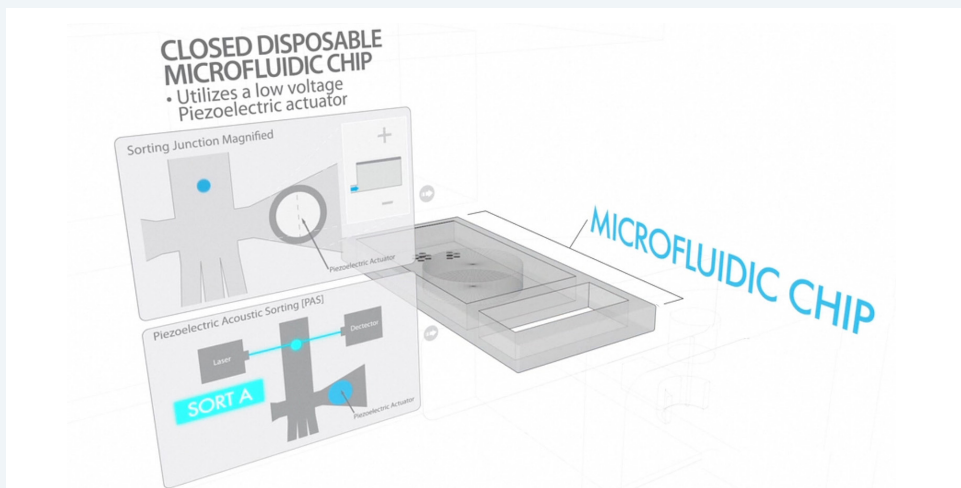


Photo Credit: BD

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Solving the Mystery of Rare Disease

How Signature Genomics is altering lives and the local economy



Spokane, WA: For the Napier and Lane families, the work of Signature Genomics was life-altering. As documented in *The New York Times*, the two families have daughters missing exactly the same part of their genetic codes, resulting in developmental problems like impaired communication and socialization skills. The disorder is so rare that it's identified only by the name of the chromosome that's missing: "16p11.2."

After years of guesswork about which therapy helped and which didn't, the two families finally found Signature Genomics. The company helped them identify the source of their daughters' struggles—the missing piece of DNA—and also connected them to each other. The Napiers and the Lanes were able to share strategies and take comfort in their daily challenges.

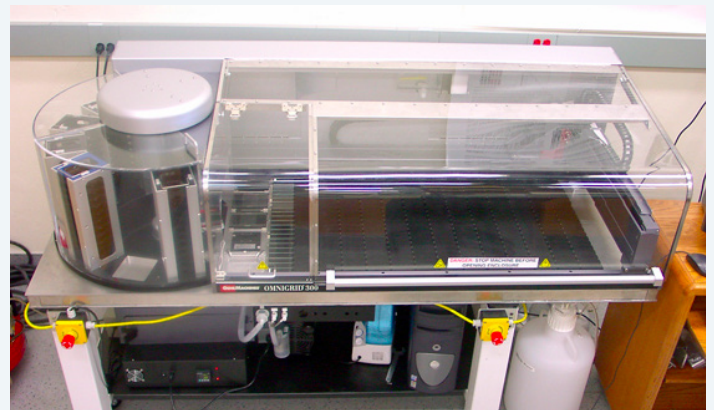
The story encapsulated how Signature Genomics changed everything for children and families coping with genetic abnormalities. Signature Genomics' core technology, called microarray comparative genomic hybridization, had been developed with NIH support by Dan Pinkel and Joe Gray at the University of California, San Francisco. The technology was licensed by Abbott Laboratories, and then sublicensed to Signature Genomics, a company founded by Washington State University-Spokane researchers, Bassem Benjamin and Lisa Shaffer and by Sacred Heart for clarity. The hospital recruited Shaffer and Benjamin to come to Washington to commercialize the technology.

Signature Genomics grew rapidly, and by 2010 it employed 120 people in highly skilled jobs. In 2010, the raw, NIH-funded discovery that Besses, Shafer and their investors had turned into a productive business was purchased by PerkinElmer for \$90 million.

Signature Genomics made two major innovations to the technology. First, they made the process much more efficient. Traditional DNA diagnostic detection could only look for one abnormality at a time, and it had to be looking for an abnormality known to exist. Using microarray CGH, Signature Genomics could compare a sample genome to a normal genome and look for any variation, whether it was a small deletion or a bit of extra genetic code. Benjamin and Shaffer and their team figured out how to digitize the process, so it could be done very quickly.

The newer, faster genome check helped thousands of families gain the elusive answers they were looking for, but it had another positive side effect. Because of market demand for their test, Signature Genomics needed a good system to track the many samples they processed. Before long, they realized their database had its own value for researchers and families. Families like the Napiers and the Lanes, long isolated by trying to care for children with special needs, could connect and share their common struggle.

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A microarray comparative genomic hybridization, used to identify genome abnormalities. Photo credit: Signature Genomics

Saving Millions in Health Care Costs

How RightCare Solutions is preventing hospital readmissions and reducing costs



NIH + PRIVATE SECTOR FUNDING = PATIENT INNOVATIONS

Without significant R&D spending by the private sector, the research investments made by NIH would not come to fruition. A 2012 Battelle study found that the U.S. life sciences industry was expected to spend over \$82 billion in R&D in 2013. While the NIH focuses mainly on basic research, the private sector invests heavily to take those discoveries to the next stage of development. A study published by the Milken Institute examined the impact of NIH funding on private R&D spending. It noted that, instead of displacing private R&D, NIH funds are complementary to private dollars. Firms respond to new information from publicly funded basic research and over time increase their own R&D investments. In the pharmaceutical industry, a \$1.00 public investment in basic research is estimated to lead to an additional \$8.38 of private R&D after eight years.

Moreover, the road from bench to bedside is long—as research moves along the R&D spectrum of incremental progress of basic science to expensive and involved clinical trials—and fraught with regulatory hurdles. All of the components of the innovation ecosystem, public and private partners alike, must continuously work together to ensure the best ideas are brought to market to improve human health. While the path is seldom linear and still in need of improvement, it has been made even more difficult as support for federally-funded basic research has diminished, weakening the landscape on which this partnership is delicately balanced.

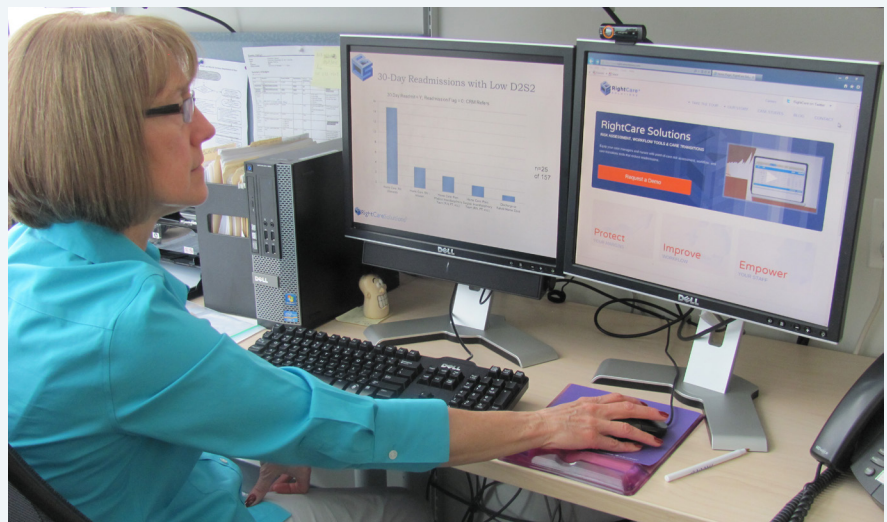
Washington, PA: RightCare Solutions' software saves hospitals money. Dr. Kathryn Bowles, a researcher who focuses on older patients, discovered that hospitals did not have complete information about whether patients could take care of themselves after a hospitalization. Many patients couldn't keep track of their medications, had cognitive impairment or were depressed. Many had to be readmitted weeks or months later, a negative result for their health and for the hospitals' costs.

Bowles found that, when she collected certain pieces of information, she could predict who was in the high-risk pool and guide hospitals to arrange for follow-up care in the form of home nursing, family help or other resources. If hospitals used the recommendations to identify and act on high-risk patients, they could dramatically reduce readmissions.

The best tool for the job turned out to be software. Nurses ask questions of patients when they're admitted, and the resulting data are packaged and sent to social workers and patient care advocates—the people best able to arrange for post-hospitalization resources.

Bowles invented the tool in 2007, relying on NIH funding to continue the development process.

She formed RightCare Solutions last year. RightCare software is in beta testing in five hospitals in Philadelphia, Baltimore and New York City. She has a staff of five who do IT support, programming and work with her at hospitals, and she has a waiting list of hospitals looking to buy in.



Dr. Kathryn Bowles works with RightCare Solutions' software. Photo credit: RightCare Solutions

Fighting Fear with Science

How Virtually Better is using virtual reality to help real people and create real jobs



Decatur, GA: Barbara Rothbaum, a psychologist at Emory University, specializes in exposure therapy for phobias and post-traumatic stress, but she was all too keenly aware of the limitations on her clinical work.

She wondered, if someone has a phobia of flying, must a therapist board a plane with him or her to overcome the fear? Must a therapist accompany someone afraid of public speaking to a large auditorium to treat his or her fear? Must a veteran of Iraq or Afghanistan return to a war zone to confront his or her lingering trauma?

Recreating real-life versions of these situations would cost thousands of dollars and possibly put both patient and therapist in danger. There had to be a better way.

So when Larry Hodges, a computer scientist at Georgia Tech, approached her in 2003 about using virtual reality to transcend those limitations, she was keen on the idea.

The pair formed Virtually Better, a company that would use NIH funding to design hardware and software to virtually simulate situations that patients find difficult to navigate.

Wearing virtual reality goggles and headphones, Virtually Better can simulate airplanes, crowded lecture halls or war zones for veterans suffering from post-traumatic stress. After patients learn the skills to deal with the virtual world, they are better able to cope in the real world.

Today, the company has its devices installed in 60 clinics around the world.

The last five years have been a period of growth for Virtually Better as the company moves to take advantage of the explosion

in inexpensive, portable computer electronics. Josh Spitalnick, a researcher and psychologist at the company, led a move toward a new software architecture to help people defeat other personal demons, from overeating to alcoholism to bullying.

The new interactive software in development simulates situations in a video environment that could be problematic for patients: a holiday dinner for an overeater, a happy hour for the alcoholic. The simulation rewards patients for their decisions to shape their behavior. Spitalnick's early research results show they can transfer these skills to the real world.

Spitalnick's work has allowed Virtually Better to increase its staff by 50 percent, and its annual revenues range between \$1.5 million and \$2 million. The company plans to hire more staff when its software hits the market next year.



Barbara Rothbaum of Virtually Better works with virtual reality software.
Photo credit: Virtually Better

Wearing virtual reality goggles and headphones, Virtually Better can simulate airplanes, crowded lecture halls or war zones for veterans suffering from post-traumatic stress. After patients learn the skills to deal with the virtual world, they are better able to cope in the real world.

A Win-Win: A Successful Start-Up and Saving Lives



How Armune Bioscience Inc. is improving early cancer detection



Jeanne Ohrnberger works with Armune's test, which improves the accuracy of prostate cancer diagnoses. Photo credit: Armune Bioscience

Kalamazoo, MI: Early cancer detection could save thousands of lives a year, if the detection catches the cancer early enough.

Technology from Armune Bioscience uses the body's own immune system as an amplifier to detect the earliest, weakest signs of a cancerous invasion. Published papers indicate these markers could pick up lung cancer five years before clinical diagnosis.

NIH-funded work by researcher Arul Chinnaiyan at the University of Michigan showed that the body's immune system starts responding to tumors in their earliest stages, long before antibodies produced by the tumor are easily detected. Increased levels of these biomarkers can reveal the presence of the cancer, and it can do it in a blood test.

In the near term, Armune is focused on improving the accuracy of prostate cancer diagnoses. Traditionally, doctors rely on the Prostate Specific Antigen test to provide an indication of cancer. If levels are high, most patients get a needle biopsy to confirm the presence of cancer. About 75 percent of the time, the biopsy comes back with no signs of a tumor. But there's the possibility of a false negative: The biopsy needle could have simply missed the tumor. Armune's test can help to identify men with the highest probability of prostate cancer and determine whether a second biopsy should be performed.

The autoantibodies Armune uses as biomarkers are more stable and more numerous than the antigens themselves, and thus can provide a better indicator of prostate cancer.

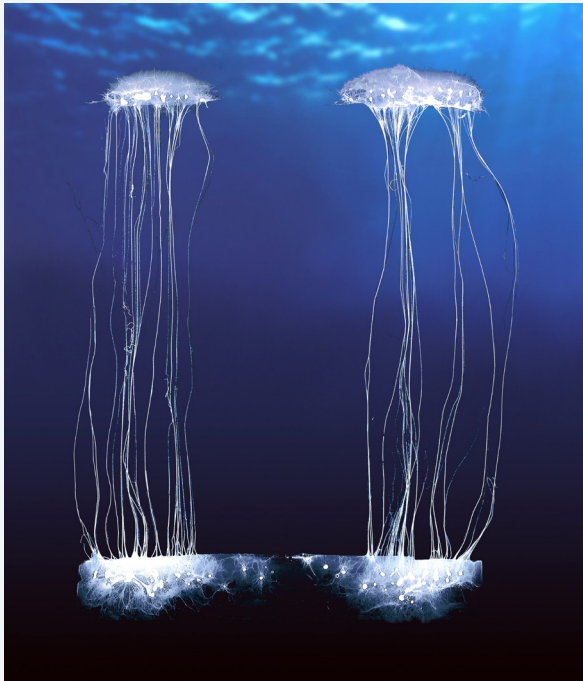
The company plans to start marketing to the country's 9,600 urologists late this year, with hopes of ramping up use of its tests next year. At the same time, the company will develop a prostate cancer prognostic test to indicate the aggressiveness of the cancer, an improved lung cancer test and possibly a breast cancer test using the same technology.

"The whole antibody technology, that has to be done through NIH funding," said Eli Thomassen, CEO for Armune. "It's high risk, and there's not going to be funding through other sources, yet there are big rewards when they hit on something."

The company has five staff now, but it plans to hire 17 people to ramp up prostate cancer testing, and they hope to recruit up to 100 employees over the next five years.

Growing the Spine to Start a Business... Literally!

How Axonia Medical is taking the cutting edge of regenerative medicine to the market



Stretch-grown axons superimposed on the ocean.
Photo credit: Axonia Medical.



Philadelphia, PA and Kalamazoo, MI: Doug Smith thinks he can fix severed spinal cords, and he has whales to thank for the insight. His company, Axonia Medical, is the most futuristic of the companies listed in our report, and its technology the least proven. But its potential is vast: to heal injuries that would have been untreatable in the past.

Basic neuroscience teaches that the axons of nerve cells in people grow out only a fraction of an inch to reach their targets. However, Smith, a University of Pennsylvania researcher who normally studies brain trauma, discovered a second phase of axon growth that can extend the axon over long distances. As animals grow, the axons become stretched, which triggers them to grow at the same rate as the stretch. This way, axons can extend up to a stunning 100 feet in the blue whale.

Copying nature, Smith and colleagues generate long axon tracts in the lab through “stretch growth,” to create transplantable nervous tissue akin to living jumper cables. Axonia is still early in its development, so the company has not quite reached the point of fixing spinal cords, but it is pretty close to repairing peripheral nerves in the shoulder, arm or leg.

Imagine someone in a car accident who suffers a severed nerve in his shoulder. This person is at risk of losing feeling and movement of his arms and hands. Smith can transplant an engineered nerve to bridge the damaged region, in turn facilitating recovery of the entire nerve. Indeed, the bridge allows the body’s axons to grow across the lesion and return function down the arm. His group is currently working on spanning nerve gaps greater than two inches, which have previously been impossible to repair.

While the core technology for Axonia was developed through NIH support, last year they raised \$2 million in venture capital. Smith is optimistic that his new results will attract more investment, which will speed advancement of the program.

And while he expects to be repairing nerves in limbs soon, he’s already begun the work on spinal cords. Paraplegics with back injuries may someday walk again.

Conclusion

Just the tip of the iceberg: NIH is a wise investment for health and the economy

Few policy alternatives have promoted growth the way public investment in science has. That means that the NIH isn't just one tool for improving patients' lives, generating economic growth and creating jobs. It's one of our best tools.

The companies profiled in this report, who trace key advances to NIH funding, have developed miracle cures: nerve repair, better ways to treat cancer, lower costs for the research process and genetic testing with speed and accuracy never imagined before. As they refined their products, they all hired skilled workers at high wages. Many of them grew to create new networks of suppliers and support companies.

NIH is the center of the innovation ecosystem and thus supports a wide-array of economic activity and employment opportunities—jobs that also improve the health of all Americans—yet we're in the process of eroding that critical focus.

The fact is that the next big medical breakthrough, and the next billion-dollar business idea, may well be sitting in the mind of a graduate student right now. With strong and continued NIH support, we have the perfect formula for another scientific, health and economic success story.

The federal research investments that fueled the real-world products, companies and scientific breakthroughs highlighted in this report took place all across the country.



ABOUT UMR

Because the scientific opportunities to improve human health have never been greater, and the economic benefits of biomedical research have never been more important, leading research institutions, patient advocates, medical professional organizations and biomedical companies have united in support of robust funding for the National Institutes of Health.

The nation's investments in NIH have helped wipe out diseases that killed our grandparents. Those investments have led us to the brink of new discoveries in deadly and debilitating illnesses such as cancer, Alzheimer's, heart disease, diabetes, rare diseases and many more.

Indeed, NIH's mapping of the human genome, and other advances in our understanding of the building blocks of life, have ushered in an exciting new era of discovery, unique in history. Scientists now have the opportunity to use new knowledge of biological structures and functions to beat back disease. They are no longer limited to describing an illness's symptoms, employing whatever tools are available, and watching to see what works.

Instead, using the knowledge gained through more than 40 years of arduous study, researchers can now zero in strategically on a disease, identifying its triggers and crucial moments of development. Through recent discoveries and new technologies developed in the

last decade alone, researchers more fully understand the molecular drivers of disease and how to affect them. This is a powerful moment in science, full of new hope for patients and new opportunities that scientists can pursue as fast as funding allows.

NIH is also an important economic engine. The large majority of NIH funding is awarded to more than 325,000 researchers in public and private research institutions across the U.S. In every state in the country, NIH-funded projects support new and experienced scientists and numerous jobs in industries that provide research facilities, supplies and equipment. Moreover, NIH-funded research is the foundation of the U.S. biotech and pharmaceutical industries and a vital tool for reducing the burden of disease and its associated health care costs.

At this critical moment in our nation's history, sustained investments in biosciences through the only federal agency specifically designed for this purpose—NIH—is more important than ever.

United for Medical Research (UMR) is dedicated to seeking the NIH funding necessary for delivering on the promise of this historic moment in biomedical science.

This report was written by United for Medical Research and Eric Wolff. To learn more, visit us at: www.unitedformedicalresearch.com

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